PICO™ incision closure in oncoplastic breast surgery: a case series

Single-use negative pressure wound therapy (PICO™) has been used on high-risk surgically incised wounds with encouraging results, but there is no evidence for its use in oncoplastic breast surgery. This article reports a case series with closed incisions in oncoplastic breast procedures following the introduction of PICO™.

Following the widespread introduction of oncoplastic breast techniques, the number and variety of surgical procedures available to patients with breast cancer has increased significantly over the last decade or so (McCulley and Macmillan, 2005; Dietz et al, 2012). With the development of newer techniques aimed at improving long-term aesthetic outcome, the onus falls on the surgeon to ensure that, most importantly, these techniques do not compromise oncological safety, and are audited to identify potential complications, particularly those that could lead to a delay in adjuvant therapies.

Breast-conserving surgery in the form of wide local excision followed by radiotherapy is a well-recognized, common practice with long-term oncological safety (Hamdi et al, 2007). However, the long-term aesthetic results can be unpredictable and may be associated with significant long-term deformity of the affected breast, which can be very difficult – if not impossible – to adequately correct (Slavin and Halperin, 2004; Munhoz et al, 2008).

Therapeutic mammoplasty exploits the resection patterns of conventional breast reshaping and reduction in order to resect the tumour. McCulley and Macmillan (2005) described two differing scenarios:

1. The tumour is located in the breast tissue to be removed and the nipple is moved on a standard pedicle
2. The tumour is located in tissue that would normally be conserved as part of a breast reduction and therefore requires either a longer pedicle to fill the defect or two pedicles – one for the nipple and a secondary pedicle to fill the defect left by the tumour resection.

The reported benefits include not only the long-term cosmesis but also the ability to resect tumours with a wider margin than conventional breast-conserving surgery. This, in turn, greatly reduces the likelihood of margin involvement, reduces the amount of remaining breast tissue receiving radiotherapy and increases the potential to resect larger tumours in larger breasts. The trade-off associated with therapeutic mammoplasty is a more complex surgical intervention involving reshaping and moving the non-involved breast parenchyma, which can result in a longer wound healing time and greater potential for wound breakdown when compared with simple excision and closure. A review article (McIntosh and O'Donoghue, 2012) examined the results of 1619 patients who had undergone therapeutic mammoplasty in twenty-three trials and found a large variation (10–90%) in reported complication rates. Complications reported commonly included skin necrosis, delayed wound healing, wound infection, abscess formation, nipple–areolar complex necrosis, fat necrosis, and haematoma and seroma formation. Although only a few of the studies examined reported delays in adjuvant therapy, in those that did, the rates of delay ranged from 1.9 to 6%.

Another technique that exploits the traditional Wise pattern skin incision is the inferior dermal flap coverage of implant-based reconstruction post-mastectomy. The inferior dermal flap covers the lower pole of implants in skin-preserving mastectomy avoiding the cost associated with acellular dermal matrices while giving the patient with breast ptosis an aesthetically superior result when compared to traditional immediate implant-based techniques. Complication rates range from 6.98% to 31.6% in the literature of which wound healing complications are commonly reported (Dietz et al, 2012; King et al, 2014).

The common site for delayed wound healing and breakdown in both therapeutic mammoplasty and inferior dermal flap techniques is the T-junction of the Wise pattern skin excision. This is the point under maximum tension and at the periphery of the skin flaps. Delay in wound healing can lead to wound complications such as infection and associated sequelae, and necessitate repeated dressings and specialist wound care intervention which may be distressing for the patient. More importantly delays beyond 12 weeks in delivery of adjuvant chemotherapy are detrimental to outcome (Lohrisch et al, 2006). Most complications from this type of procedure are managed in the outpatient setting. In a previous study from this unit there was one readmission for haematoma in 40 patients undergoing therapeutic mammoplasty. The patient required a return to theatre (Harvey et al, 2014).

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Topical negative pressure dressings

Negative pressure wound therapy has been introduced over the last decade as an additional intervention for surgically closed wounds. PICO™ is a canister-free, single-use negative pressure wound therapy system. The device delivers -80 mmHg of pressure and is simply activated by one button. The dressing is composed of four layers including a top film with high moisture vapour transmission rate to transpire exudate, an absorbent layer, an innovative airlock layer which maintains 80 mmHg negative pressure across the wound bed and a silicone adhesive wound contact layer.

One complete PICO™ kit enables 7 days of therapy and includes two dressings, handling up to 300 ml of fluid across both dressings (*Figure 1*).

A number of theories exist as to how topical negative pressure works to improve wound healing (*Figure 2*). These include improved perfusion, removal of excess fluid and oedema leading to less tension on the wound. Morykwas et al (1997) and Timmers et al (2005) both used laser Doppler to examine the perfusion of the wound with negative pressure wound therapy applied and found increased perfusion although they found differing cut-off pressures for the effect. Conversely Kairinos et al (2013) used thermography to analyse the perfusion of skin in healthy volunteers treated with negative pressure wound therapy and found no evidence of increased perfusion at pressures of -75, -125 or -400 mmHg. The exact mechanism of action still has to be unequivocally proved.

Figure 1. Components of the PICO™ kit.

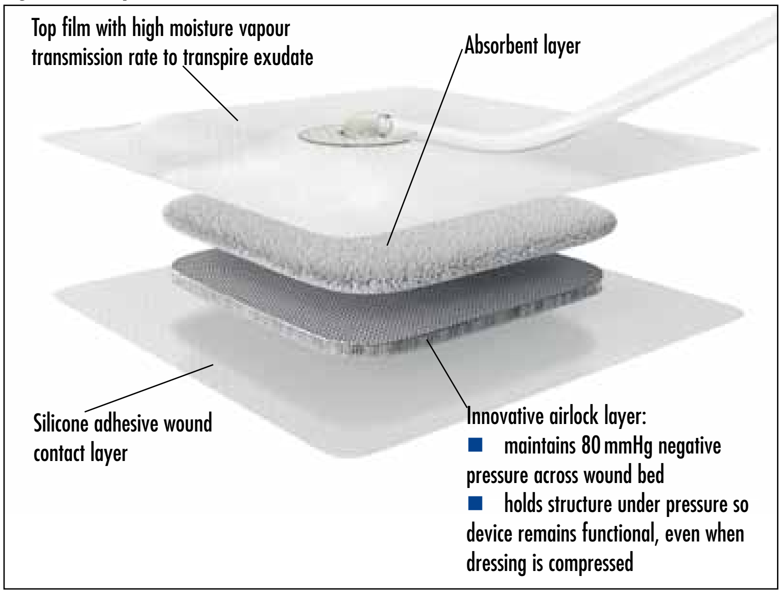
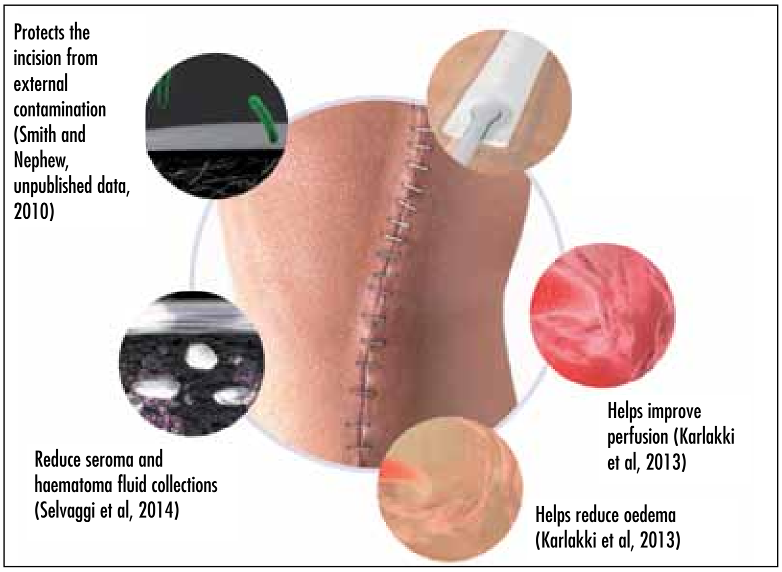


Figure 2. Proposed mechanisms of action of negative pressure wound therapy.



Despite this, the experience of using negative pressure wound dressings on surgically incised wounds has a growing body of evidence (Gomoll et al, 2006; Reddix et al, 2009; Stannard et al, 2012). Studies report a decrease in wound complications, surgical site infections, wound drainage, seromas, length of stay and readmission rates (Karlakki et al, 2013; Selvaggi et al, 2014). Furthermore other studies assessing the use of negative pressure wound therapy have suggested an advantage for their use in breast surgery (Pellino et al, 2014) although a review article looking at this specific indication suggested that more evidence was needed to confirm the hypotheses (Kostaras et al, 2014).

A study from Harvey et al (2014) suggested that while therapeutic mammoplasty did not delay adjuvant treatment, the rate of wound complications in this cohort was relatively high (37%). Having reviewed the evidence for this product in other specialties the authors' department introduced PICO™ negative wound pressure therapy dressings for high risk breast incisions in an attempt to improve wound healing times and reduce problematic wound breakdowns. There are no previously published data that reports the use of PICO™ in this cohort of patients, i.e. patients undergoing oncoplastic breast surgical resection.

The following case series reports the results of a prospective departmental audit designed to assess whether this change in practice influenced patient outcomes. The authors wanted to assess if the described advantages of this product are transferable to oncoplastic breast patients and if the application of negative pressure wound therapy dressings (PICO™) on closed incisions in patients undergoing therapeutic resection promotes superior wound healing. The first twenty four consecutive cases following the introduction of PICO™ into the department were reviewed. The PICO™ dressing was used on the therapeutic side while standard care dressings were used to dress the contralateral symmetrising reduction side so that a direct comparison could be made, eliminating many biases such as patient age, comorbidities and other influencing factors.

Methods

This audit was approved by the Clinical Audit department at University Hospital of South Manchester (ethical approval not required as the study compared one wound dressing against another dressing already in use).

Twenty four consecutive patients had either therapeutic mammoplasty or skin-sparing mastectomy and immediate reconstruction with inferior dermal flap and implant performed by the senior author over a 20-month period. The patients had elected to have the oncoplastic procedures following discussion in clinic on at least two occasions, in which a variety of procedures were offered. Standard therapeutic mammoplasty was performed using Wise pattern skin incisions and either one or two pedicles. Where patients were undergoing implant-based reconstruction using the inferior dermal flap technique, a Wise pattern skin excision was marked and the inferior part of this skin pattern was de-epithelialized and used to achieve lower pole coverage of the implant. The dermal flap was sutured to the elevated pectoralis major to achieve full implant coverage. All patients had a simultaneous symmetrising breast reduction at the same sitting. The therapeutic breast had PICO™ applied at the time of surgery while the symmetrising reduction was dressed with conventional dressings.

Patient demographics, comorbidities, procedures performed and resection weights were recorded (*Table 1*). Wounds were assessed in the dressings clinic on days 6 and 12 postoperatively. The PICO™ was removed at the first appointment on day 6 in all cases. Outcome measures that were recorded were delayed healing, wound breakdown, fat necrosis and delays to adjuvant therapy.

Results

Twenty-four patients were included in this study. Of these patients 21 underwent therapeutic mammoplasty and three had Wise pattern skin-sparing mastectomies and immediate implant or inferior dermal flap technique. The average age of the patients was 55.8 years (range 42–70 years) and the average body mass index was 31.1 kg/m^2 (range 23–53 kg/m^2). One patient was a smoker and one was an ex-smoker (*Table 1*).

The tumour resected was ductal carcinoma in situ in seven cases and invasive ductal carcinoma in the rest. Of the invasive ductal carcinomas, one case was grade 1, 10 cases were grade 2, and the remaining six cases were grade 3. The average resection weight of the therapeutic mammoplasty resections was 237.2 g (51–617 g) while the average mastectomy weight was 858.3 g (730–926 g). The nipple was preserved in twenty out of the twenty one therapeutic mammoplasty cases, reconstructed immediately in one of the dermal flap procedures, free nipple grafted in a second and removed in the other.

In the 21 patients who had therapeutic mammoplasty 10 were scenario 1 patients with the tumour resected as part of a reduction mammoplasty pattern while the other 11 were scenario 2 patients who required a second dermoglandular pedicle to aid reshaping of the breast. The contralateral reduction was performed with a supero-medial pedicle in 14 cases, a supero-lateral pedicle in one case, a lateral pedicle in one case and an inferior pedicle in the remaining eight cases (*Figure 3*).

In the therapeutic mammoplasty group no patients (0%) had wound breakdown on the therapeutic side whereas three patients (14.3%) had T-junction breakdown on the contralateral side at day 12. One mastectomy patient had delayed wound healing at the T-junction on both sides at day 12. This was managed by reapplication of PICO™ on the therapeutic side which had healed by the next visit (day 18); however, the symmetrising reduction side took an additional 28 days to fully heal. This did not cause any delay to adjuvant therapy as chemotherapy or radiotherapy was not required for that patient. The overall rate of wound breakdown in the 24 patients was 4.2% (one patient) on the therapeutic side compared with 16.7% (four patients) on the reduction side (*Figures 4* and *5*).

One patient (4.2%) had an 8-week delay to starting chemotherapy because of a complication of fat necrosis following a complex two-pedicle therapeutic mammaplasty and axillary node clearance. At re-operation there was an area of discharging fat necrosis distant from the wound edges (from the second dermoglandular pedicle). This was a complication of interruption of blood supply to part of the breast parenchyma rather than a wound complication.

Excluding this patient, the mean time to healing was 10.7 days in the therapeutic side treated with PICO™ compared with 16.1 days on the symmetrising side. The re-operated breast took 26 days to heal.

Subjective assessment at days 6 and 12 by nursing staff in the dressing clinic found an improvement in wound appearance on the treated side compared with the contralateral side in the majority of patients – but this is very difficult to quantify at this stage.

There was no correlation of age, body mass index, smoking status, mass resected, tumour size or nodal status with the propensity to have complications. The number of patients were too small to allow meaningful testing for statistical significance.

Discussion

A previous study from this unit (Harvey et al, 2014) demonstrated that in 40 patients there was no significant delay to adjuvant chemotherapy in therapeutic mammoplasty patients when compared with those undergoing traditional breast conserving surgery. However, there was an overall complication rate of 37% per breast. Furthermore, Harvey et al (2014) demonstrated nine episodes of wound breakdown in 41 breasts, equivalent to 22%. The current study demonstrated a 16.7% rate of wound breakdown in the contralateral symmetrising reduction side while only 4.2% of breasts dressed with PICO™ had a wound breakdown. While 16.7% is only slightly lower than 22% seen previously and could be explained by a learning curve effect, the authors believe this is not the case for a number of reasons. First, the surgery was performed by the senior author. Second, the 22% seen in the previous study was on therapeutic

Table 1. Patient demographics, resection details and operative techniques

Patient no	Age at operation	BMI	Smoking/ day	Tumour type	Grade	Size (mm)	Node status	Resection weight (g)	Therapeutic mammaplasty pedicle	Symmetrising reduction pedicle	Time to healing treated side	Time to healing reduction	Reason for delay
1	52	31	0	IDC and high grade DCIS	3	7 + 5	1/13	217	SM with secondary	SM	12	12	
2	48	30.5	0	DCIS	High	9	0/2	926	Inferior dermal sling	SM	12	12	
3	60	36	0	IDC and DCIS	2	17+20	1 of 3	919	Inferior dermal sling	Inferior	12	12	
4	66	24	5–10	IDC and high grade DCIS	3	14.5 + 4	0/2	450	SM	SM	12	12	
5	57	34.5	0	IDC and DCIS	3	38 + 20	6/18	262	SM with secondary	SM	67	12	Fat necrosis
6	52	34	0	IDC and high grade DCIS	2	16 + 12	0/5	152	SM and central	SM and central	12	12	
7	42	29	0	IDC and high grade DCIS	3	40 + 2	1/2	225	SM	SM	12	12	
8	54	38	0	IDC and intermediate DCIS	2	9	0/1	617	Inferior	Inferior	12	12	
9	50	23	0	IDC and high grade DCIS	2	28 + 13	0/1	137	Inferior	SM	12	12	
10	64	53	0	Lobular/ductal IC and low grade DCIS	2	12	0/10	325	Long lateral	Long lateral	12	12	
11	64	28	0	DCIS	High	30	NA	308	Inferior	Inferior	12	12	
12	52	29.4	0	IDC	3	37	0/3	108	Inferior	Inferior	12	12	
13	52	25	0	IDC and intermed DCIS	2	25	0/1	128	SM	SM	12	12	
14	59	27.2	0	DCIS	High	28	NA	730	Inferior dermal sling	Inferior	18	70	Wound breakdown
15	67	26	0	DCIS		14	NA	353	SM	SM	12	12	
16	70	30	0	IDC and DCIS	2	9.5 + 30.5	0/2	215	SM and 2nd Inferior	SM	12	29	Wound breakdown
17	46	27.5	0	DCIS	Inter	6	NA	306	SM	SM	7	7	
18	49	28	0	IDC and DCIS	1	17	0/3	218	SM and 2nd lateral	SM	8	46	Wound breakdown
19	44	30	0	IDC	3	13.5	0/1	99	SM and 2nd inferior lateral	Inferior	7	7	
20	69	53	Ex	IDC and DCIS	2	7 + 12	0/6	51	Inferior and 2nd medial	Inferior	6	18	Wound breakdown
21	66	29	0	IDC and inter DCIS	2	11	0/1	143	Superolateral and 2nd inferior	SL	12	12	
22	59	24	0	IDC with DCIS	2	11+67	0/1	507	2 pedicle	SM	7	7	
23	47	33	0	DCIS			NA	100	SM and 2nd inferior	SM	12	12	
24	51	23.2	0	IDC	2	8	0/3	61	Extended inferior	Mastopexy	7	7	

BMI = body mass index; DCIS = ductal carcinoma in situ; IC = invasive carcinoma; IDC = invasive ductal carcinoma; SM = superomedial.

breasts only. In this study the 16.7% rate of wound breakdown in the side treated with conventional dressings was seen on the contralateral reduction side. Although to some degree these act as a control this was not strictly true as the control breasts had a simple reduction technique used rather than a therapeutic excision: the therapeutic side has usually undergone more extensive surgery where the priority is uncompromising cancer excision and therefore it would be expected that surgical site events would be more frequent.

The therapeutic side treated with PICO™ in the current study had a much lower rate of wound breakdown (4.2%) than both the contralateral side and previous reports. This represents a reduction by over one third in the number of wound breakdowns compared with the contralateral side. This result was statistically not significant, but this is likely to be because there were too few numbers in the study at this stage. In a prospective randomized controlled trial by Stannard et al (2012) 263 fractures were randomized to conventional dressings or negative pressure wound therapy on incised wounds following open reduction of lower limb fractures. They found a significant reduction in both the rate of wound infection and the rate of wound breakdown in patients treated with negative pressure wound therapy. The rate of wound breakdown was just under half in the negative pressure wound therapy group compared with the control group. Condé-Green et al (2013) reported a similar reduction in the rate of wound dehiscence in a group of

Figure 3. Typical wound healing in complex closed breast incisions. A 49-year-old woman presented with a 41 mm breast carcinoma in the upper inner quadrant of the right breast (core biopsy marks visible). She underwent a complex (two pedicle) therapeutic mammoplasty with sentinel lymph node biopsy and simultaneous breast reduction. Wounds are completely healed at day six postoperatively (PICO™ dressing applied to the right breast).

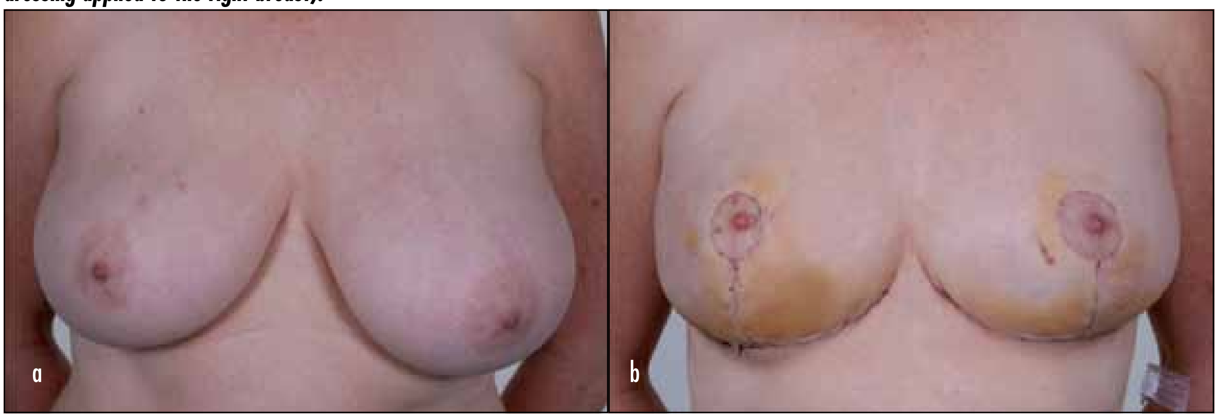
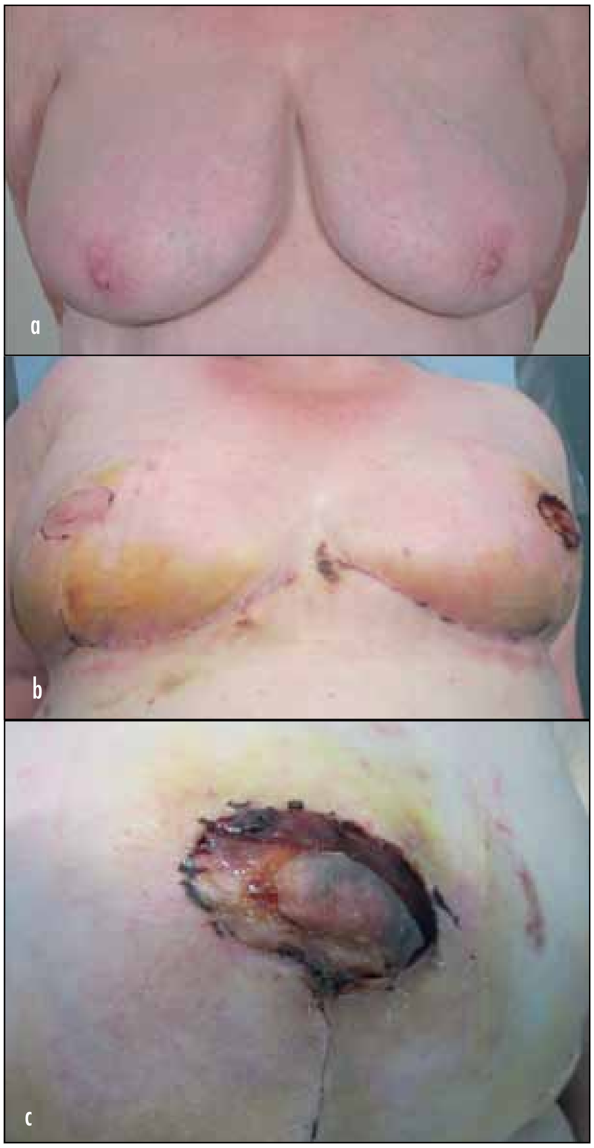


Figure 4. Slower wound healing with conventional dressings vs PICO™. a Minor wound breakdown in a breast reduction. b. The therapeutic mammoplasty had the PICO™ applied with wound healing at day 6 postoperatively. c. Patient preoperation. d. T-junction wound breakdown on breast reduction side.

patients treated with either negative pressure wound therapy dressings or conventional dressings following abdominal wall reconstruction. Their retrospective review included 56 patients and found a 9% rate of wound breakdown in patients treated with negative pressure wound therapy *vs* a rate of 39% in patients treated with conventional dressings. There was no significant difference in body mass index, number of previous surgeries or age between the two groups. In contrast a report by Masden et al (2012) found no statistically significant difference in infection or wound breakdown rates in a prospective randomized controlled trial of negative pressure wound therapy *vs* dry dressings in patients with multiple comorbidities with at-risk surgical closures. Despite this the rates of each complication were lower in the negative pressure wound therapy group. Additionally the dry dressings used were silver-containing antibacterial dressings which would not be a conventional wound dressing in most surgical practices and therefore is a possible weakness of this control group.

Figure 5. Superficial nipple necrosis in breast reduction. a. A 69-year-old underwent (b) right therapeutic mammoplasty (PICO™) and left breast reduction. c. Note the superficial nipple necrosis – likely to be related to venous congestion. There was no delay to adjuvant treatment as only the therapeutic mammoplasty (right) required radiotherapy.



There is conflicting evidence for the use of negative pressure wound therapy on incised wounds across a range of surgical specialties and a review by Ingargiola et al (2013) concluded that while there is possible evidence to suggest decreased complications further evidence is required to make proper recommendations. While an earlier Cochrane review (Webster et al, 2012) found only five studies suitable for inclusion, and a later update (Webster et al, 2014) included another four studies, they recommended that additional high-powered studies need to be instituted to answer these important questions.

There are no previous studies that have specifically examined the use of portable negative pressure wound therapy on closed breast incisions in therapeutic mammoplasty patients. A systematic review of the literature by Kostaras et al (2014) identified twenty studies for review. Of these four were cohort studies, one a case series and 15 were case reports. None of these studies used negative pressure wound therapy primarily on closed breast incisions. For many of the cases reviewed the negative pressure wound therapy was used to manage patients with established open wounds, acute infections or postoperative wound complications. In one cohort study negative pressure wound therapy was used to treat radionecrosis of the chest wall following past radiotherapy for breast cancer. Having also searched the literature the authors believe that this is the first study that has examined the results of negative pressure wound therapy on closed breast incisions in high-risk cases.

Wounds were assessed on day 6 and day 12 in the dressing clinic. Subjective assessment by nursing staff provided reports that the side treated with PICO™ showed improved wound healing at these stages compared with the contralateral side (*Figure 4*). One limitation of this study is that wounds were only assessed at these intervals and that a greater or lesser difference may have been seen if the wound were assessed more frequently. The average time to healing in this study was 10 days in the negative pressure wound therapy group and 16 days in the conventional dressing group. This represents an average of one additional dressing clinic appointment for these patients.

One of the main arguments against the use of oncoplastic breast techniques is the potential for delay to adjuvant therapy and a possible risk of systemic recurrence (Murthy et al, 2007). Current National Institute for Health and Clinical Excellence (2009) guidelines state that adjuvant therapy should be commenced as soon as possible within 31 days of completion of surgery. Meta-analyses of observational studies suggest that a delay of greater than 8 weeks to radiotherapy is associated with an increased likelihood of loco-regional recurrence but not with distant metastases. Lohrisch et al (2006) reported that disease-free and overall survival were adversely affected when the start of chemotherapy was delayed by at least 3 months after surgery. In the current study there was one delay to adjuvant therapy resulting from an area of fat necrosis. This required re-operation but adjuvant radiotherapy was not delayed beyond 8 weeks.

Conclusions

Although this was not a randomized controlled trial, there was a contralateral breast with which to compare, providing case-matched controls to allow analysis. The authors believe that this is the first study that has examined the use of PICO™ on closed incised breast wounds in breast cancer patients. The PICO™ system was tolerated well by the patients and there were no early returns to clinic in this study as a result of malfunction of the PICO™ device or discomfort. The authors feel that this evidence further supports the use of negative pressure wound therapy on incised wounds and more importantly contributes to the argument for their use in oncoplastic breast surgery where the desire to maintain aesthetic outcomes can, unintentionally, conflict with the need to heal in a timely fashion to allow commencement of adjuvant therapy. **BJHM**

Smith & Nephew, the manufacturers of PICO, contributed to the costs of publishing this article but no funding or products were provided for this study and the article was entirely the authors' own work.

Asset number: 57949.

Conflict of interest: neither of the authors has a financial interest in any of the products or devices mentioned in this article.

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KEY POINTS

- Portable negative wound pressure therapy dressings such as PICO™ are being increasingly used to manage high risk closed surgical incisions.
- There is a growing body of evidence to support their use; however, there are no studies that have explored the use of PICO™ in oncoplastic breast incisions.
- This case series reports the use of PICO™ in closed oncoplastic breast incisions with encouraging results.