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Research paper

A pilot randomised controlled trial of dressing and securement methods to prevent arterial catheter failure in intensive care

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ABSTRACT

Background: Critically ill patients in an intensive care setting often require arterial catheters for blood pressure monitoring and arterial blood collection. Arterial catheter failure, which manifests in both mechanical and infective forms, remains common. Dressing and securement inadequacies may impact this failure; however, the best method for dressing and securing arterial catheters is yet to be determined.

Objectives: The objective of this study was to establish the feasibility of a definitive randomised controlled trial comparing methods for dressing and securing arterial catheters and to prevent device failure in an adult intensive care setting.

Methods: A pilot, parallel-group, randomised controlled trial was conducted between April 2017 and June 2018. Patients receiving treatment in two adult intensive care units (Queensland, Australia) were eligible for inclusion and were allocated to receive either (i) an integrated securement dressing or (ii) a simple polyurethane dressing (with gauze/foam), applied to their newly inserted arterial catheters.

Main outcome measures: Primary outcomes were (i) feasibility (defined by pre-established criteria: patient eligibility, consent, protocol adherence, retention, and staff acceptability) and (ii) all-cause arterial

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catheter failure (a composite of local and bloodstream infection, occlusion, dislodgement, infiltration/extravasation, arterial inflammation, thrombosis, and/or inaccurate trace). Secondary outcomes included: failure type, dwell time, dressing adhesion, adverse event profiles, and staff acceptability.

Results: In total, 109 patients were studied (n = 53 integrated securement dressing; n = 56 simple polyurethane). The feasibility criterion was met by most patients (including rates of consent [86%], protocol adherence [93%], and retention [100%]); however, the criteria for patient eligibility were not met (73%). All-cause device failure did not differ significantly between the integrated securement device group (n = 12/53, 23%) and the simple polyurethane group (n = 6/56, 11%) (hazard ratio = 2.39, 95% confidence interval = 0.89–6.37, p = 0.083).

Conclusions: Findings indicate a larger study is feasible, with minor alterations to recruitment methods required. Arterial catheter failure remains unacceptably common; further research to determine optimal dressing/securement practices is urgently needed.

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1. Introduction

Patients requiring treatment within intensive (or critical) care units (ICUs) are highly dependent on the successful function of medical devices and associated technology to ensure optimal health outcomes.¹ Arterial catheters (ACs) are vascular access devices commonly used in ICU patients for blood pressure monitoring and repeated collection of arterial blood for blood gas analysis.² It is estimated that in the United States alone, approximately 2 million ACs are inserted each year.³

Regrettably, AC failure related to malfunction, including poor waveform monitoring, occlusion, dislodgement, uncontrolled bleeding, limb ischaemia, local infection, and catheter-related infections, remains common, with up to 60% of ACs requiring replacement after complications.^{4–7} AC failure can result in adverse outcomes including patient discomfort, delayed patient assessment affecting treatment timeliness, and, in rare cases, morbidity (limb loss) and mortality resulting from excessive bleeding or systemic infection.⁴

International guidelines recommend the use of both (i) a primary dressing, to minimise site contamination risk, and (ii) a secondary (additional) securement dressing to reduce AC micromotion and resulting complications such as infiltration or occlusion.^{8,9} While there is a paucity of research on secondary dressing use in adults,¹⁰ a recent paediatric audit demonstrated 61% of patients had simple primary dressings without an additional (secondary) securement method.¹¹ Suboptimal AC dressing and securement has been identified as a potential contributing factor for AC failure.¹⁰ Further supporting this argument, two pilot randomised controlled trials (RCTs) found 20–21% of ACs dressed with a simple polyurethane (SPU) (standard) dressing failed, while advanced (bordered) dressings used in conjunction with secondary securement technologies (such as glue) demonstrated failure rates as low as 4–6%.^{12,13} Despite this observed benefit, there are insufficient rigorous RCTs to definitively recommend any one product (or method) over another.^{10,11} Recent advancements in product development, such as integrated securement dressings (ISDs), have not been tested for ACs. These products incorporate the function of both a secondary securement device and a gauze border dressing⁸ and have been successfully pilot tested for peripheral venous catheters.^{14,15}

The aim of this pilot RCT was to establish the protocol safety and feasibility of conducting a large RCT comparing SPU dressing and gauze/foam with an ISD for AC securement in the adult ICU cohort.

2. Methods

2.1. Aim/objectives

We aimed to assess the feasibility of conducting a large, parallel-group, efficacy RCT of ISD versus SPU dressing with additional gauze/foam secondary securement, applied to ACs for adult ICU patients, by assessing pre-established feasibility outcome measures (including patient safety), and incidence of AC failure.

2.2. Setting

This trial was conducted within adult ICUs at two Australian hospitals (Brisbane, Queensland) between 28 April, 2017, and 28 June, 2018. Participants were screened/enrolled in the intensive care unit and operating suites (pretheatre). Sites were large referral and teaching hospitals (26-bed ICU [site 1]; 21-bed ICU [site 2]) primarily caring for patients admitted for trauma and neurosurgery (site 1), elective cardiothoracic surgical patients (site 2), and other general medical/surgical intensive care patients (site 1, site 2).

2.3. Ethical approval

Human Research Ethics Committee study approval was provided by the Children's Health Queensland Hospital and Health Service (EC00175) (HREC/16/QRCH/75) and Griffith University (EC00162) (Ref No. 2016/487). The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616001074482).

2.4. Participants

Participants were eligible for inclusion if they required an AC for treatment and were (i) able to provide informed consent; (ii) expected to require the AC for ≥ 24 h; (iii) aged ≥ 16 years (no upper age limit); and (iv) receiving treatment in the ICU. Participants were excluded if (i) they had a known current bloodstream infection (positive within 48 h); (ii) they were non-English-speaking in the absence of an interpreter; (iii) the AC was inserted through diseased, burned, or scarred skin; (iv) they were at high risk of a skin tear; (v) they had a known allergy to any of the study products; (vi) the AC was inserted into the femoral artery; or (vii) they had been previously enrolled in the trial. Femoral AC exclusion was related to a disproportionate risk of bloodstream infection resulting from this site, compared with more common sites (e.g., radial

artery);¹⁶ patients previously enrolled were excluded to ensure larger generalisability of the sample.

The research nurse (ReN) screened ICU/theatre lists daily to assess for patients scheduled to receive a new or replacement AC. Eligible participants, or their responsible patient representative, were approached by the ReN who provided them with a detailed participant information sheet and consent form; informed written consent was provided by the patient or their representative before study enrolment and AC insertion. The required sample size was 110 (50 per group, plus 10% attrition), as per recommendations for pilot (feasibility) trials.¹⁷

2.5. Intervention and control

This pilot, parallel-group, RCT compared the use of the following:

- Control: an SPU dressing, IV3000[◇] Standard, 10 cm × 14 cm (Smith & Nephew, Hull, UK) with gauze/foam applied as per hospital policy: a single piece of Hypafix[®] (BSN Medical, Charlotte, USA) (applied externally, 8 cm × 2.5 cm) (site 1) or an Easlv[™] IV (ConvaTec, Skillman, USA) (applied under the IV3000[◇]) (5.8 cm × 7.6 cm) (site 2). The primary difference between site 1 and site 2 control dressings was the additional securement attached (site 1, a single piece of gauze tape applied external to the dressing; site 2, an additional supportive foam border under the dressing). Site-specific (control) dressings were designated based on standard care for each participating ICU, in accordance with the feasibility design of the RCT.
- Intervention: an ISD (Sorbaview SHIELD[™], Centurion Medial Products, Williamston, USA): size Contour SV430 (9.5 cm × 11.8 cm) (site 1); or Small SV254 (6.4 cm × 10.2 cm) (site 2) (Fig. 1). These intervention dressings (minor differences in size between site 1 and site 2) incorporated a primary gauze border dressing with a transparent window, with incorporated blue tensile strips to add additional support, and a secondary gauze border to attach under the catheter extension but above the primary gauze dressing.

Randomisation was masked until allocation via a centralised web-based program (Griffith University Randomisation Service,

<https://randomisation.griffith.edu.au/>), generated in a 1:1 ratio using varying block sizes of 2 and 4 and stratified by hospital site. The ReN responsible for consent and enrolment provided the correct dressing allocation to the inserting clinician, who then applied the dressing (with supervision/support as required).

Catheter type (Vygon Leader Cath[™] 20 g [Vygon, Swindon, UK]; Arrow[®] 20 g [Teleflex, Wayne, USA]; or BD Insyte[™] Autoguard[™] 20 g [Becton Dickinson, Sandy, USA]) was selected by the inserting clinician. Local resources and hospital guidelines informed device insertion processes including site preparation (2% chlorhexidine gluconate in 70% alcohol) and use of sterile gloves. Transducer kits (Edwards Lifesciences[™], Irvine, USA) and pressure bag were prepared/primed before device insertion. Local anaesthetic (1% lignocaine, subcutaneous) was injected before AC insertion, if indicated. After allocated dressing application, AC care and maintenance (e.g., blood sampling; connection changes) was as per the treating clinicians (and informed by local guidelines and policies), including the decision to change AC dressing and securement (prepacks of dressing allocation supplied at the bedside). Microbiological specimens (e.g., blood cultures, catheter tips) were collected by clinical staff upon the suspicion of infection, as per usual clinical practice. The decision to remove the AC or send microbiological specimens was as per standard clinical practice and not influenced by study procedure or research staff.

2.5. Outcomes

2.5.1. Primary feasibility outcome

Feasibility: a composite measure of feasibility (threshold) criteria, established *a priori*,¹⁸ included the following:

- Patient eligibility: More than 80% of patients screened would be eligible
- Consent: More than 80% of eligible patients would agree to be enrolled
- Protocol adherence: More than 90% of randomised patients would receive the allocated intervention
- Retention: Less than 5% of patients enrolled would be lost to follow-up
- Staff acceptability: (i) Ease of dressing application and (ii) removal (both on 0 [worst] to 10 [best] numerical rating scales)

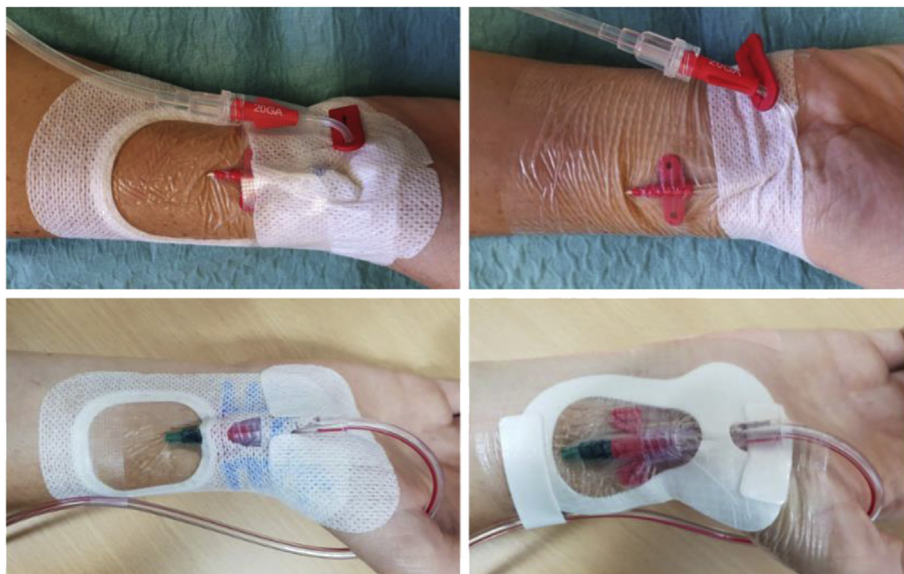


Fig. 1. Intervention (left) and control (right) dressings: Site 1 (above) and site 2 (below).

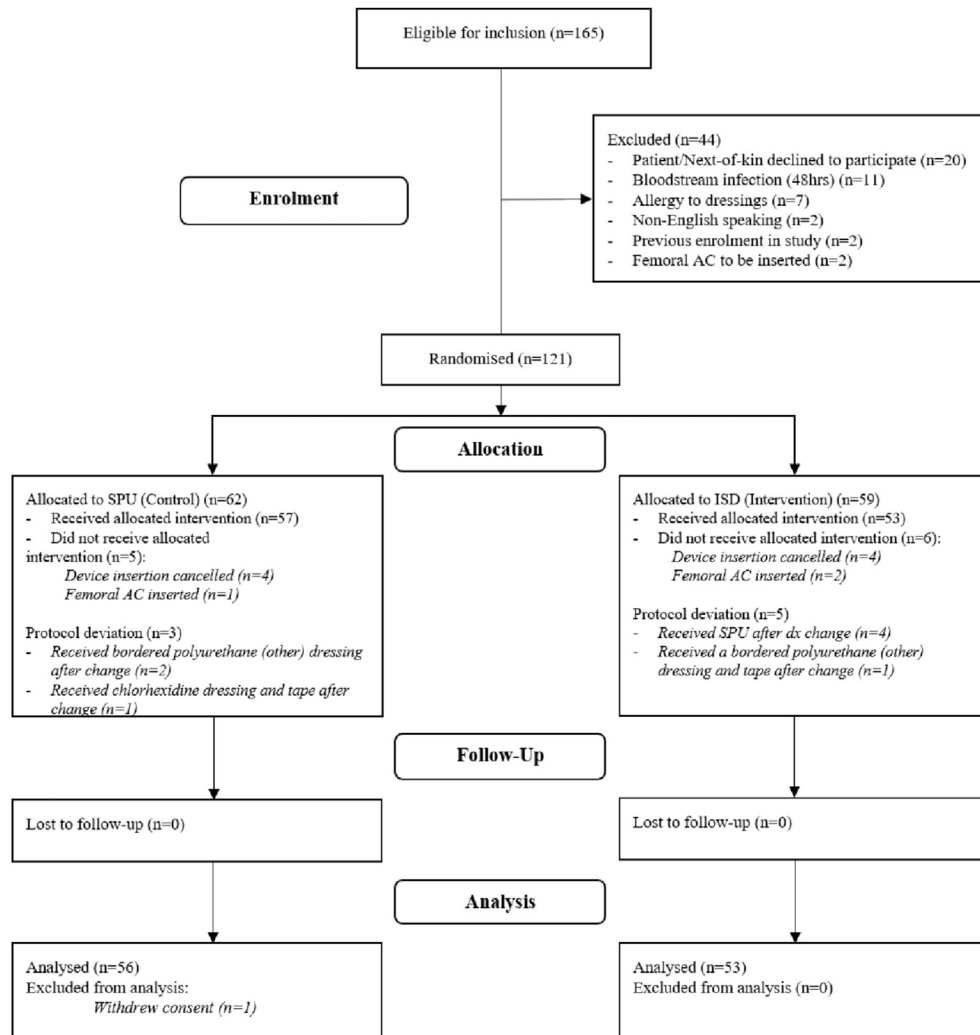


Fig. 2. Consolidated Standards of Reporting Trials (CONSORT) flow diagram. AC, arterial catheter; SPU, simple polyurethane; ISD, integrated securement dressing.

2.5.2. Primary intervention outcome

All-cause AC failure: a composite measure of any device failure (secondary outcomes: i-vii).

2.5.3. Secondary outcomes

Modes of AC failure:

- Local infection:** defined as meeting criteria for the arterial or vascular infection criteria; or *bloodstream infection:* defined as a laboratory-confirmed bloodstream infection – unrelated to another source of infection which either meets (AC-related BSI) or does not meet (primary BSI) the vascular-arterial infection criteria, as per the Centres for Disease Control/National Health and Safety Network Surveillance Definitions (2018).¹⁹
- Occlusion** – the AC will not aspirate or infuse, or leakage (outside tissue) occurs when fluid is infused.²⁰
- Dislodgement** – partial (change in AC external length) or complete (completely leaves the artery).⁴
- Local inflammation** – two or more of pain, erythema, swelling, and a palpable cord.^{21,22}
- Infiltration/extravasation** – infusate leaking into the subcutaneous tissue with/without surrounding tissue damage.²²

- Thrombosis** – suspected (too painful to tolerate) or confirmed (radiological evidence).⁵
- Inaccurate pressure trace** – defined as failure of or recurrent interruption of arterial pressure waveform monitoring.⁴

Secondary outcomes also included (viii) uncontrolled bleeding (continuous blood loss resulting in device removal/replacement);^{4,5} (ix) AC dwell time; (x) first dressing duration; (xi) nonroutine dressing change frequency; (xii) dressing adhesion; and (xiii) skin safety (e.g., tear, dermatitis).

Mortality and bloodstream infections (any) were reported as serious adverse events to the approving HRECs, as per the conditions of approval.

2.6. Data collection

Data were collected and entered by ReNs using Research Electronic Data Capture (REDCap) tools,²³ with a purpose-built data collection template. Owing to the nature of the trial, the patient, ReNs, and treating clinical staff members were not blinded to study allocation; however, the data analyst and infectious diseases physician (who assessed infection outcomes) were blinded.

At study entry, participant details collected included age, sex, dominant hand, skin type (Fitzpatrick scale²⁴), skin integrity (good,

Table 1
Patient characteristics.

	SPU (control) n = 56	ISD (intervention) n = 53	Total N = 109
Hospital			
- Site 1	17 (30)	16 (30)	33 (30)
- Site 2	39 (70)	37 (70)	76 (70)
Male	42 (75)	33 (62)	75 (69)
Age [years, median (IQR)]	64 (16)	60 (22)	62 (18)
Skin type			
- Very fair	1 (2)	2 (4)	3 (3)
- Fair	25 (45)	21 (40)	46 (42)
- Medium	25 (45)	26 (49)	51 (47)
- Olive	1 (2)	1 (2)	2 (2)
- Brown	4 (7)	3 (7)	7 (6)
Skin integrity			
- Good	19 (34)	17 (32)	36 (33)
- Fair	30 (54)	34 (64)	64 (59)
- Poor	7 (12)	2 (4)	9 (8)
Reason for admission^a			
Surgical elective	23 (41)	28 (53)	51 (47)
Medical	24 (43)	15 (28)	39 (36)
Surgical emergent	8 (14)	6 (11)	14 (13)
Trauma	1 (2)	4 (8)	5 (5)
Oncology/haematology	1 (2)	0 (0)	1 (1)
Other	2 (4)	0 (0)	2 (2)
APACHE II , median (IQR)	17 (7)	16 (9)	17 (8)
Infection (during study)	21 (38)	19 (36)	40 (37)
Comorbidities			
- Nil	4 (7)	7 (13)	11 (10)
- One	6 (11)	5 (9)	11 (10)
- Two	8 (14)	6 (11)	14 (13)
- Three	5 (9)	6 (11)	11 (10)
- Four or more	33 (59)	29 (55)	62 (57)
BMI , median (IQR)	28 (5.6)	28 (7.8)	28 (6.4)
Wound (at recruitment)	9 (16)	14 (26)	23 (21)
IVABs (during study)	47 (84)	53 (100)	100 (92)
Diaphoretic (ever, during study)	14 (29)	13 (29)	27 (29)
Unconscious/sedate (ever, during study)	24 (50)	17 (38)	41 (44)

Frequencies (column percentages) shown unless otherwise noted.

IQR = interquartile range; IVAB = intravenous antibiotic treatment;

^a multiple answers allowed.

fair, poor), body mass index, comorbidities, admission type (e.g., planned, emergent), duration of current hospital admission, primary reason for initial admission (e.g., medical, surgical), current infection(s), and presence of wounds. Device details collected included AC type, insertion side, location of patient at insertion, artery accessed, difficulty of insertion, and/or multiple attempts at AC insertion (as per the inserting clinician).

ACs were monitored daily by the ReN to assess (visual inspection) and record protocol adherence, additional dressings and securement applied, dressing adherence to skin (intact)/contamination (clean, dry), dressing changes and reasons (as per the treating nurse, documented on a bedside data collection tool), current indications for use (cardiovascular and respiratory monitoring; blood sampling) (as per treating nurse and medical records), insertion site (pain, tenderness, erythema, swelling, purulence) and skin (itch, rash, bruising) complications, device (e.g., occlusion) complications, troubleshooting methods required (if AC fails to transduce or aspirate blood), and relevant patient characteristics (diaphoresis, agitation, consciousness).

On AC removal, the ReN recorded the primary reason for removal, including any complications, dwell time, ease of dressing removal according to clinical staff, insertion site, and skin complications. Infection outcomes (from device insertion to 48 h after removal) were collected after AC removal; delivery of intravenous antibiotics during AC dwell (via a concurrently placed intravascular device) was also collected. Infection outcome data (including positive blood cultures and tip/swab cultures) were then provided

(deidentified, blinded to allocation) to a qualified infectious diseases physician, who allocated infection outcomes.

2.7. Data analysis

Before analysis, the data were cleaned for implausible and/or outlying figures, and missing data were located where possible. Intention-to-treat analysis was conducted, with the patient as the unit of analysis. Data were exported into Stata, version 15 (College Station, TX: StatCorp LLC).²⁵ Relative incidence of device failure per 100 devices, incidence rates per 1000 device-days, and hazard ratio (HR) with 95% confidence intervals (CIs; with unadjusted Cox regression) were calculated to test differences between groups; two-tailed p-values <0.05 were considered statistically significant. Individual site results were compared to assess for heterogeneity. Kaplan–Meier survival curves compared (i) device and (ii) first dressing failure, between study groups and over time. Site results were compared to assess for heterogeneity. Feasibility criteria were presented using descriptive statistics.

3. Results

Patients were screened for inclusion between 28th April, 2017, and the 21st June, 2018. Overall, 44 of 165 patients who were screened for eligibility met exclusion criteria (73% eligible); therefore, the feasibility criterion for >80% eligibility was not met (Fig. 2). The feasibility criterion for consent (>80%) was met; 14% (n = 20/

Table 2
Device and treatment characteristics.

	SPU (control) n = 56	ISD (intervention) n = 53	Total N = 109
Device sequence			
- Initial	36 (64)	39 (74)	75 (69)
- Subsequent	20 (36)	14 (26)	34 (31)
AC type			
- Vygon	36 (64)	33 (62)	69 (63)
- Arrow	10 (18)	11 (21)	21 (19)
- BD Insyte (PVC)	10 (18)	8 (15)	18 (17)
- Unknown	0 (0)	1 (2)	1 (1)
On dominant side (N = 65)	24 (77)	24 (71)	48 (74)
Inserted at			
- ICU	31 (55)	26 (49)	57 (52)
- Theatre	25 (45)	27 (51)	52 (48)
Artery			
- Radial	49 (88)	45 (85)	94 (86)
- Brachial	6 (11)	6 (11)	12 (11)
- Ulna	0 (0)	1 (2)	1 (1)
- Dorsalis pedis	1 (2)	1 (2)	2 (2)
Difficulty/multiple attempts at insertion (N = 108)	25 (45)	26 (49)	51 (47)
Additional dressing/securing^a			
Any type	28 (50)	29 (55)	57 (52)
Nonsterile tape	25 (45)	25 (47)	50 (46)
Tubular/gauze bandage	5 (9)	1 (2)	6 (6)
IV3000	4 (7)	2 (4)	6 (6)
Other simple transparent dressing	2 (4)	1 (2)	3 (3)
Bordered transparent dressing	2 (4)	1 (2)	3 (3)
SorbaViewSHIELD	0 (0)	1 (2)	1 (1)
CHG bordered transparent dressing	1 (2)	0 (0)	1 (1)
Suturing	0 (0)	1 (2)	1 (1)
Splint board	1 (2)	0 (0)	1 (1)
Other	6 (11)	6 (11)	12 (11)
AC used for^a (ever during study, N = 93)			
Cardiovascular monitoring	47 (98)	45 (100)	92 (99)
Respiratory monitoring	47 (98)	44 (98)	91 (98)
Reason for dressing change (if any, N = 46)			
Lifting	13 (52)	12 (57)	25 (54)
Sweating	1 (4)	4 (19)	5 (11)
Poor trace	6 (24)	6 (29)	12 (26)
Presence of blood	3 (12)	3 (14)	6 (13)
Leakage	1 (4)	3 (14)	4 (9)
Not aspirating	3 (12)	0 (0)	3 (7)
Routine 7-day replacement	1 (4)	2 (10)	3 (7)
Bleeding	1 (4)	1 (5)	2 (4)
Oozing	1 (4)	1 (5)	2 (4)
Skin reaction	1 (4)	0 (0)	1 (2)
Other	7 (28)	5 (24)	12 (26)
Unknown reason	5 (20)	4 (19)	9 (20)
Troubleshooting (ever, N = 93)	9 (19)	17 (38)	26 (28)
Itchiness (ever, N = 103)	1 (2)	1 (2)	2 (2)

Frequencies (column percentages) shown unless otherwise noted.

AC = arterial catheter; CHG = chlorhexidine gluconate; ICU = intensive care unit; ISD = integrated securement dressing; SPU = simple polyurethane.

^a multiple answers allowed.

141) of eligible patients (or representatives) declined to participate. Protocol fidelity (criterion >90%) was well maintained with 100% (n = 109) of participants receiving the correct dressing application upon AC insertion; however, 7% (n = 8/109) subsequently deviated from the study allocation (n = 3, SPU; n = 5, ISD). No patients were lost to follow-up, meeting the retention feasibility criterion (<5%).²⁶ Staff acceptability of dressing application scored highly in both groups with 9.0 (median, interquartile range [IQR] = 3.0) and 8.0 (IQR = 2.0) out of the maximum 10 in the SPU and ISD groups, respectively. Dressing removal was also rated similarly in both groups at 9.0 (median, IQR = 3.0) and 9.0 (IQR = 4.0) out of 10 in the SPU and ISD groups, respectively.

In total, 109 patients were included in the analysis (SPU, 211 catheter-days; ISD, 173 catheter-days). Demographics and device characteristics were largely balanced between the two groups. Participants were generally male (69%), older than 60 years. Most participants were admitted for elective surgery (47%) with a high

proportion of chronic disease sufferers (57% ≥ four comorbidities) (Table 1). The majority of ACs were Vygon 20 g (63%), inserted into the radial artery (86%), with 52% inserted in the ICU and 48% in theatre settings (Table 2).

AC failure (composite measure) was higher in the ISD group (23%) than in the SPU group (11%) (Table 3) (crude HR = 2.39 [95% CI = 0.89–6.37], p = 0.083). The incidence rates (IRs) per 1000 device-days were 28.4 (95% CI = 12.8–63.2) and 69.5 (95% CI = 39.5–122) for the SPU and ISD groups, respectively (Table 3) (Fig. 3). The most commonly reported complications were occlusion (4%, SPU; 12%, ISD) and inaccurate pressure trace monitoring (4%, SPU; 10%, ISD). Failure rates were similar at site 1 and site 2 (1.98 [95% CI = 0.99–3.96] and 1.93 [95% CI = 1.04–3.59], respectively); therefore, it was considered suitable to combine these site results based on homogeneity.

Dressing changes occurred more frequently in the ISD group (average, 2.48) than in the SPU group (1.76); median initial dressing

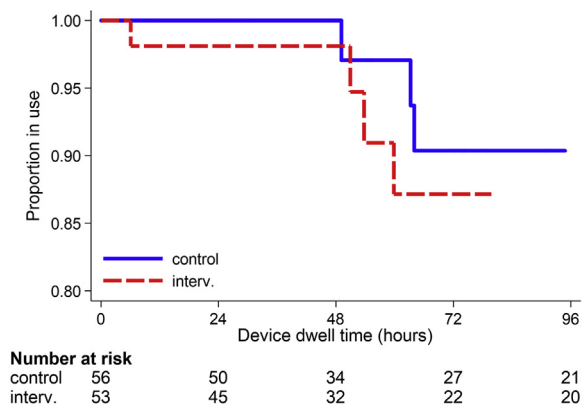
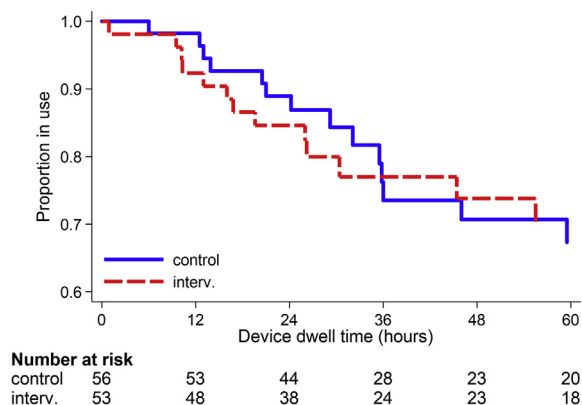
Table 3

Device and patient outcomes.

	SPU (control) n = 56	ISD (intervention) n = 53	Total N = 109
Failure (primary outcome)	6 (11)	12 (23)	18 (17)
Device-days (total)	211	173	384
Dwell time [§] (days)	2.65 (1.19–4.96)	2.14 (1.12–4.94)	2.29 (1.15–4.94)
Incidence rate (per 1000 catheter-days)*	28.4 (12.8–63.2)	69.5 (39.5–122)	46.9 (29.5–74.4)
Hazard ratio [§]	Reference	2.39 (0.89–6.37)	<i>p</i> = 0.083
Occlusion [~] (N = 107 [^])	2 (4)	6 (12)	8 (7)
Inaccurate pressure trace (N = 107 [^])	2 (4)	5 (10)	7 (7)
Deceased	5 (9)	1 (2)	6 (6)
Dislodgement (N = 107 [^])	3 (5)	1 (2)	4 (4)
Local infection (confirmed; N = 107 [^])	0 (0)	2 (4)	2 (2)
Arterial inflammation	0 (0)	1 (2)	1 (1)
AC-related BSI (confirmed)	0 (0)	0 (0)	0 (0)
Infiltration/extravasation (N = 107 [^])	0 (0)	0 (0)	0 (0)
Thrombosis	0 (0)	0 (0)	0 (0)
Ease of dressing application [§] (10 = best; N = 90)	9.0 (3.0)	8.0 (2.0)	8.0 (3.0)
Ease of dressing removal [§] (10 = best; N = 48)	9.0 (3.0)	9.0 (4.0)	9.0 (4.0)
Dressing dirty/wet/damaged (ever, N = 93)	19 (40)	18 (40)	37 (40)
Dressing required change (ever)	25 (45)	21 (40)	46 (42)
Dressing life (hours, initial dressing) [§]	35.9 (67.6)	30.4 (57.2)	35.0 (66.8)
Dressing changes (average, if any, N = 46)	1.76	2.48	2.09

Frequencies (column percentages) shown unless otherwise noted.

BSI = bloodstream infection; AC = arterial catheter; ISD = integrated securement dressing; SPU = simple polyurethane.

~ will not aspirate or infuse, incl leakage; * 95% confidence interval also shown; [§] unadjusted Cox regression; [§] = median and interquartile range shown; [^] n = 2 AC failures missing complication type; dressing change times assumed to have occurred at half way between the previous and the next daily checks; dressing change frequency was recoded (“>2” was changed to “3” and “unknown” to “1”).**Fig. 3.** Kaplan–Meier (device failure).**Fig. 4.** Kaplan–Meier (dressing failure).

dwell times were similar (SPU, 35.9 h; ISD, 30.4 h) (Fig. 4). The most common reason for dressing changes was adhesive failure (i.e., dressing lifting) (52%, SPU; 57%, ISD), and there was frequent use of

additional dressings and securements; nonsterile tape was applied to 46% of ACs (45%, SPU; 47%, ISD). Skin safety profiles were assessed. Itch was reported in two cases (n = 1, SPU; n = 1, ISD). A single (stage 1, nonblanching) pressure area (under AC hub; SPU) occurred; a strip of Hypafix® was applied under the hub for skin protection, and no further action was required.

Three bloodstream infections occurred: two were vascular access device-related (n = 1, central venous catheter, SPU; n = 1, temporary apheresis catheter, SPU), and one was secondary to gastrointestinal infection (ISD). Two local infections occurred (n = 2, ISD), each with evidence of erythema and purulence (with and without pain/tenderness). No microbiological samples were collected by the treating clinical team to confirm organism species.

4. Discussion

This study was the first multisite pilot RCT to assess the effect of AC dressing and securement upon device failure; findings have reaffirmed the unacceptably high AC failure rates affecting patients receiving treatment in the ICU.^{5,6} Overall, feasibility outcome measures were largely met, with a low rate of loss to follow-up and excellent initial protocol fidelity. However, the most common reason for patient exclusion was refusal of consent (14%). A larger RCT, comparing AC dressings and securement methods, using a waiver or extended consent may be appropriate; this method is often used in an ICU setting where consent may be impractical and where benefits outweigh risk.²⁷

AC failure was higher in the ISD group (23%) than in the SPU group (11%); although clinically significant, it was not statistically significant. Furthermore, consideration should be given to the pilot design of this RCT; because it was not designed to detect differences in clinical outcomes (small sample size only), results should be interpreted with caution. Overall, the ISD group demonstrated similar AC failure (23%) to simple transparent dressings tested in two recent pilot RCTs (20%, n = 30¹³; 21%, n = 47¹²), suggesting that the integrated securement function may not have performed as expected. The SPU group results similarly contrasted to findings of a

recent pilot trial of AC dressing and securement, which found AC failure was lower (4%) when dressed/secured with two dressings (an SPU and BPU).¹² However, these differences may have been introduced by chance, as high-level evidence of the performance of each of these dressings is lacking. Furthermore, evidence to date has demonstrated large margins in reported AC failure rates, with one RCT (n = 300) reporting failure between 40% (SPU) and 60% (SPU with additional securement).⁷ This demonstrates a great need for a large multicentre superiority RCT, and while these piloted dressings (ISD, SPU) may be appropriate for testing, other dressing/securement methods which have shown promise, such as simple dressing with medical-grade tissue adhesive (glue) (AC failure, 6%),¹³ should be included as a comparator.

The most frequently recorded AC complication in this study related to malfunction (i.e., occlusion, inaccurate trace). This was similarly found in a recent RCT comparing dressings for AC (and other vascular access devices), reporting a malfunction rate of 12.9/1000 catheter-days.²⁸ However, it is difficult to determine if this complication is a consequence of dressing and securement alone or other device attributes such as AC material/design or connection characteristics, which have thus far only been assessed for impact on AC-related BSI.^{29,30} To date, RCTs exploring AC have primarily focussed on insertion-related topics (e.g., technology guidance and techniques, flushing solutions), with a lesser focus on postinsertion care,³¹ further demonstrating a need for increased quality research in this area.

We found no cases of AC-related BSI. We postulate this may be due to the small sample size or the exclusion of patients with femoral site AC from the trial; a recent systematic review found a significant increased risk of AC-related BSI associated with catheterisation of this site.¹⁶ There were, however, two cases of confirmed local infection (1.9%; 5.2/1000 days). A clinical review of 78 studies (>25,000 ACs) conducted in 2002 found a local infection incidence rate of 0.72%. Furthermore, Maki et al.³² reported a local infection incidence of 1.7/1000 catheter-days. While our results contrast with these findings, they are likely to have been influenced by chance (due to the small sample size and this pilot trial being underpowered to detect differences in clinical outcomes) or varying definitions used for local infection, which vary from site purulence (alone)¹⁹ to matching tip/blood microbiological specimens.³² It does, however, highlight the potential need for dressings which incorporate an antimicrobial such as 2% chlorhexidine gluconate, which recently demonstrated encouraging results in reducing AC-related BSI (HR = 0.4, 95% CI = 0.19–0.87, p = 0.02).³³

Finally, while a cost–benefit analysis was not undertaken in this pilot trial, a large superiority RCT would benefit from one which incorporated the costs of dressings and frequency of dressing changes (resources), incidence of failure, and patient-reported outcome measures (where appropriate) to determine cost-efficiency as well as superiority of interventions.³⁴

5. Limitations

The methods, and subsequent findings, of this study have limitations. First, as this was a pilot RCT, the sample size was selected to assess feasibility measures, rather than the sample required to determine intervention efficacy. Second, the trial was conducted in two ICU/theatre settings within a Queensland, Australia setting, with similar guidelines and protocols for AC care; findings may not be generalisable to an international context. Third, owing to the nature of the intervention, participants/representatives, clinical staff, and research staff could not be blinded. However, both the infectious diseases physician (classifying infection outcomes) and the data analyst were blinded. Finally, owing to funding limitations,

research staff hours were restricted; as a result, after-hours dressing change details and timely staff satisfaction scores often could not be collected (responses achieved for application n = 90, 83%; and removal n = 48, 44%). This pilot RCT, however, otherwise maintained a high level of protocol fidelity and met the established aims and objectives.

6. Conclusion

ACs are an essential device required for a population with complex needs, and the high incidence of AC failure demonstrates a failure in healthcare provision. Performance of dressing and securements to prevent AC failure has shown variability in small pilot RCTs, suggesting higher quality evidence is needed. This pilot RCT has confirmed a large multicentre RCT to determine best dressing and securement methods for AC is both feasible and necessary for the future. Intervention options may include (i) SPU (with secondary foam or gauze such as EasI-V™ IV or Veni-Gard®), (ii) ISD, and (iii) tissue adhesive to prevent mechanical or infectious AC failure.

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Conflict of Interest

E.N.L.'s employer has received a consultancy payment for an educational lecture from 3M, an investigator-initiated research grant from Cardinal Health (Medtronic), and a conference scholarship attendance supported by Angiodynamics on her behalf. A.J.U.'s employer has received investigator-initiated research grants and unrestricted educational grants from 3M, Becton Dickinson, Cardinal Health, and Centurion Medical Products on her behalf. N.M.'s previous employer Griffith University has received investigator-initiated research grants and unrestricted educational grants from Becton Dickinson and Cardinal Health and a consultancy payment provided to Griffith University from Becton Dickinson for clinical feedback related to vascular access device placement and maintenance (unrelated to the current project) on her behalf. T.M.K.'s employer has received investigator-initiated research grants and unrestricted educational grants from 3M, Adhezion, Angiodynamics, Becton Dickinson, and Centurion Medical Products and consultancy payments for educational lectures/expert advice from 3M, Baxter, Becton Dickinson, Cook, Medical Specialties Australia, Smiths Medical, and Vygon on her behalf. C.M.R.'s employer has received investigator-initiated research or educational grants from 3M, Angiodynamics; BD-Bard, Baxter; BBraun, Cardinal Health (formerly Medtronic), and Smiths Medical and consultancy payments for educational lectures/expert advice from 3M, Bard, BBraun, BD, ResQDevices, and Smiths Medical on her behalf. The remaining authors declare no conflicts of interest.

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editing. **India Lye:** Data curation, Investigation, Methodology, Project administration, Writing - original draft, Writing - review & editing. **Madeleine Powell:** Data curation, Writing - original draft, Writing - review & editing. **Sheena Tom:** Data curation, Writing - original draft, Writing - review & editing. **Gabor Mihala:** Formal analysis, Writing - original draft, Writing - review & editing. **Amanda J. Ullman:** Conceptualization, Funding acquisition, Investigation, Methodology, Writing - original draft, Writing - review & editing. **Victoria Gibson:** Project administration, Writing - original draft, Writing - review & editing. **Nicole Marsh:** Conceptualization, Funding acquisition, Writing - original draft, Writing - review & editing. **Tricia M. Kleidon:** Conceptualization, Funding acquisition, Writing - original draft, Writing - review & editing. **Ivan L. Rapchuk:** Data curation, Investigation, Methodology, Writing - original draft, Writing - review & editing. **Claire M. Rickard:** Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Writing - original draft, Writing - review & editing.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.aucc.2020.05.004>.

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