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Smile - Secure my intravenous line effectively: A pilot randomised controlled trial of peripheral intravenous catheter securement in paediatrics

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ABSTRACT

Aim: Evaluate the feasibility of an efficacy randomised control trial (RCT) of paediatric peripheral intravenous catheter (PIVC) securement to prevent failure without resultant skin damage.

Methods: A 3-arm, pilot RCT in an Australian paediatric hospital. Random assignment of 330 children to receive (i) bordered polyurethane dressing (BPU) + non-sterile foam (NSF), (ii) integrated securement dressing (ISD) + sterile foam (SF), or (iii) tissue adhesive (TA)+ NSF. Primary outcomes were feasibility and PIVC failure. Secondary outcomes included: skin/bloodstream infection; occlusion; infiltration; dislodgement; phlebitis; dwell; serious adverse events; acceptability and microbial colonisation of catheter tips, wound site, and foam.

Results: Most feasibility outcomes were confirmed; 98% of eligible patients consented, 96% received their allocated dressing and no patients were lost to follow up. Eligilbility feasibility (58%) was not met. 11 randomised patients did not require a PIVC. Of 319 patients receiving a PIVC (20,716 PIVC-hours), a significant reduction in PIVC failure was demonstrated with ISD, 31/107 (29%, p = 0.017) compared to BPU, 47/105 (45%). Although not statistically significant, compared to BPU, TA 34/107 (32%, p = 0.052) was associated with less PIVC failure. On Cox regression, no securement intervention significantly reduced PIVC failure. Older age (HR 0.92; 95% confidence interval [CI] 0.88–0.96; p = < 0.01), no infection at baseline (HR 0.51; 95% CI 0.34–0.78) and insertion by vascular access specialist (HR 0.40; 95% CI 0.26–0.64) were significantly associated with reduced failure (p < 0.05).

Conclusion: ISD and TA had reduced PIVC failure compared to BPU. A large efficacy trial to test statistical differences is feasible and needed.

1. Introduction

Insertion of peripheral intravenous catheters (PIVCs) is the most common invasive medical procedure performed in paediatric inpatients [1]. Approximately two billion PIVCs are sold globally each year [2–5]. Despite its ubiquity, insertion of PIVC is not benign, complication and failure is high [6,7] affecting approximately 1 in 2 PIVCs [5,8–11]. Insertion of PIVC has been associated with medical device related skin damage; both through insertion of PIVC which creates a wound in the skin, enabling a portal for micro-organisms to enter the bloodstream, and through the adhesive properties of dressings used to secure these devices [12,13]. Failure of PIVC is costly due to additional financial

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Abbreviations

BPU	Bordered polyurethane dressing
CI	Confidence interval
h	Hours
HR	Hazard Ratio
ICU	Intensive care unit
IQR	Interquartile range
IR	Incidence rate
ISD	Integrated securement and dressing
ITT	Intention to Treat
IV	Intravenous
NSF	Non-sterile foam
PIVC	Peripheral intravenous catheter
ReN	Research nurse
RR	Risk rate
SD	Standard deviation
SF	Sterile foam
TA	Tissue adhesive
VAS	Vascular access specialist

implications associated with extra product use, treatment delays, procedural anxiety and tissue damage associated with repeat insertion (skin puncture) and delayed treatment [6,8,14,15].

The etiology of PIVC failure is multi-factorial, with inadequate securement an important contributor [1,4–6,11]. Approximately 10% of PIVCs dislodge, despite having a dressing *in situ* [6,16]. Inadequate securement allows catheter micro-motion within the vein, contributing to vessel irritation, infection, and extravasation [1,4,6,17]. Traditional polyurethane (PU) film dressings provide a sealed environment and clear view of the insertion site, however, do not fully stabilise and secure the PIVC [18]. Consequently, international guidelines recommend dedicated securement devices [19,20]. Traditionally these have additional attachment points and adhesive base pads to anchor the PIVC, however, can be bulky, and reduce dressing adhesion [7].

New, low-profile, dressing and securement products might provide a solution for paediatric patients. Integrated securement devices (ISDs) combine dressing and securement functions in one product, minimising bulk. Medical-grade tissue adhesive (TA), in addition to the dressing, can temporarily bond the catheter to the skin at the point of insertion and under the catheter hub [21]. Within paediatrics, ISD and TA have been demonstrated as safe and acceptable for peripherally inserted central catheters [22] and central venous catheters [23,24]. Their effectiveness for securing PIVCs in paediatric patients has not been evaluated, although an *in vitro* study [21] reported TA to have 4 x higher pull out force compared to standard PIVC dressing ($P < 0.01$), as well as anti-microbial benefits which demonstrate reduced migration of micro-organism through the wound created to insert the catheter, down the catheter track. The efficacy, acceptability and cost-effectiveness of these products needs to be evaluated prior to health service adoption. Therefore, the aim of this study was to assess the feasibility of conducting an efficacy randomised controlled trial (RCT) in paediatric PIVCs, to reduce failure without resultant skin damage. We hypothesised that these new generation dressing and securement products will reduce PIVC failure.

2. Methods

2.1. Study design

A three-arm, superiority, pilot, RCT was undertaken in the medical and surgical wards of a Queensland Children's Hospital, a tertiary referral paediatric hospital in Australia. Hospital and university ethics and governance were obtained (HREC/16/QRCH/75;2016/487), prior to commencement. The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616001073493).

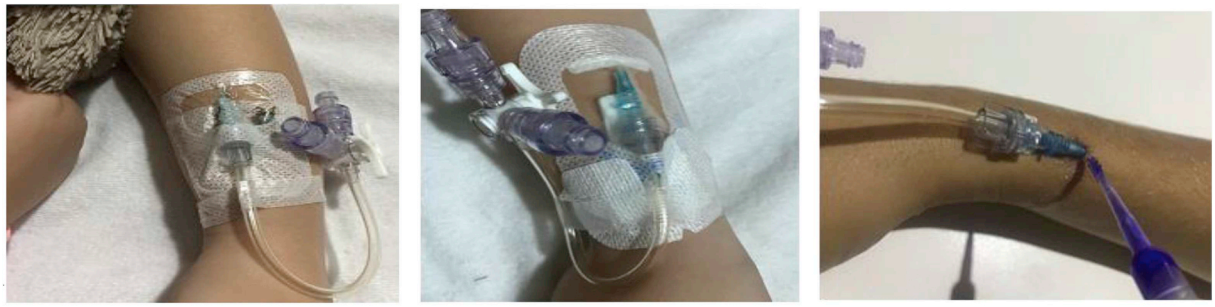
2.2. Participants and sample size

Children were eligible if: aged < 18 years and requiring a PIVC expected to dwell > 24 h. Patients were excluded for: bloodstream infection (positive blood cultures within previous 48 h prior to recruitment); non-English speaking without interpreter; PIVC inserted through diseased, burned or scarred skin; another PIVC already *in situ*; known allergy to any study product; or previously enrolled in the study. Monday to Friday, the research nurse (ReN) screened medical and surgical inpatients; and only one PIVC per patient was studied. Written informed consent was prospectively obtained by substitute decision-maker prior to PIVC insertion. The target sample size was 330 participants, as per feasibility and pilot trial sample size recommendations [25] (100 participants per group plus 10% for potential attrition).

2.3. Interventions

Patients were randomly assigned to receive PIVC dressing and securement (illustrated in Fig. 1):

1. *Standard care*: Bordered Polyurethane (BPU) dressing (Tegaderm™ 1682W (5 cm × 5.7 cm) or 1683W (6.5 cm × 7 cm) [dependent on patient size]; 3M, St Paul, Minnesota) and non-sterile Microfoam™ (NSF) (3M, St Paul, Minnesota)



Arm 1: Standard Care- Bordered Polyurethane Dressing (BPU) + Non-Sterile Foam (NSF)

Arm 2: Integrated Securement Device (ISD) (Sorbaview Shield™) + Sterile Foam (SF)

Arm 3: Tissue Adhesive (TA) (Histoacryl™) + BPU + Non-Sterile Foam (NSF)

Fig. 1. PIVC securement methods.

2. *Integrated securement and dressing (ISD)*: SorbaView® SHIELD Micro SV226UDT (5.7 cm × 6.7 cm) or Small SV254UDT (6.25 cm × 10 cm) [dependent on patient size]; Centurion Medical Products, Williamston, Michigan) and sterile Hubguard® (SF) HGL8 (Centurion Medical Products, Williamston, Michigan)
3. *Tissue Adhesive (TA)*: TA (Histoacryl®; B. Braun Melsungen AG, Melsungen, Germany) BPU (Tegaderm™ 1682W or 1683W [dependent on patient size]), and non-sterile Microfoam™ (NSF) (3M, St Paul, Minnesota). The BPU was applied after the TA dried (i.e. once the PIVC was held in place for 10 s).

The application of additional securement such as an arm-board or tubular elastic bandage (Tubigrip®; Molnlycke Health Care, Gothenburg, Sweden) was at the discretion of the clinician inserting the PIVC, patient preference or personnel assisting. Non-sterile foam was placed under the BPU dressing, consistent with standard practice to reduce pressure injury risk. Sterile foam was placed under the PIVC hub in the ISD group to enable comparison of colonisation between the two foam types.

2.4. Outcome measurements

The first primary outcome was feasibility of a full-efficacy trial established by composite analysis of the elements of eligibility; recruitment; protocol adherence; retention and missing data. The second primary outcome was all-cause PIVC failure: a composite of infection (laboratory confirmed skin or bloodstream infection), occlusion, infiltration, dislodgement, phlebitis, thrombosis (suspected or confirmed).

Secondary outcomes included PIVC complications; individual elements of PIVC failure due to infection (BSI and skin site infection), occlusion (when the PIVC will not infuse), infiltration (movement of fluids into the surrounding tissues), dislodgement (complete or partial dislodgement of catheter), phlebitis (presence of pain, redness, swelling and/or a palpable cord); PIVC dwell (from insertion until removal); safety, (including skin complications such as pressure area, itchiness, skin tear and blisters); adverse events (unplanned admission to intensive care unit); staff and patient satisfaction and acceptability of the intervention (assessed on a 0–10 numeric scale of increasing acceptability and dressing performance - maintains skin adhesion without resultant skin damage).

2.5. Microbial sub-study

The incidence of colonisation associated with the study products was determined by a blinded microbiologist through a microbiological sub-study of PIVC tips, wound site swabs and cultures of NSF and SF. Convenience sampling was used (i.e. samples were taken when research nurses were available at the time of PIVC removal) and samples were cultured within 72 h.

Catheter tips were cultured using Roll-Plate Method [26]. The catheter was removed aseptically from the specimen container and, using a spreader bar the catheter tip was rolled around a 5% Horse Blood Columbia Agar plate (HBA). The Microfoam™ (3M) or Hubguard® (Centurion Medical Products) was removed from the specimen container, gently pressed onto the HBA plate, turned over and pressed again. The swab from the wound site was removed from the specimen container, streaked across the entire HBA plate whilst rolling the swab tip. All plates were incubated at 37 °C for 24 h, and then bacterial colony counts were recorded. The HBA plates were re-incubated for 72 h for slow-growing organisms. Isolates were identified by traditional cultural methods and reported as Colony Forming Units (CFU).

2.6. Randomisation and masking

The ReN accessed a computer-generated random assignment for patients (1:1:1) from a centralised web-based service (www151.griffith.edu.au) using varied block sizes (3 or 6) ensuring allocation concealment. Due to the nature of the intervention clinicians and researchers were not blinded to study group, however, the data analyst was blinded, and all infection [27] and microbiological end points were assessed by blinded infectious disease physicians or laboratory scientists. A project manager ensured randomisation compliance and ReN maintained protocol fidelity by providing the allocated study product at insertion.

2.7. PIVC insertion and maintenance

PIVCs were inserted by trained medical officers or vascular access specialists (VAS). Prior to insertion the skin was disinfected with SoluPrep™ sticks (2% chlorhexidine gluconate in 70% alcohol; 3M). The PIVC site, catheter gauge, add-on devices, and ultrasound guidance were chosen by the clinician inserting the PIVC, based on clinical judgement and assessment of the patient needs. All PIVCs were non-winged Insyte™ Autoguard™ BC (BD Medical, Sandy, UT, USA) with active needle safety. Tuta N-Pulse (Medical Australia Limited, Lidcombe, New South Wales, Australia) needle free neutral displacement valves were applied directly to the PIVC or via a 10 cm extension set with bonded 3-way Connecta™ (BD Medical).

To maximise intervention fidelity, education was delivered to staff before and during the trial regarding the application of allocated products and post insertion care/maintenance. The randomised dressing intervention was applied by the clinician inserting the PIVC. The ReN reviewed the patient Mondays to Fridays, and collected relevant data. Post insertion maintenance (including dressing reinforcement), the decision to take a swab of the wound site, blood cultures or examine PIVC tip on suspicion of PIVC-associated infection, and the decision to remove the PIVC, was managed by treating clinicians.

2.8. Data collection

Data were collected using the REDCap® database (Research Electronic Data CAPture, Vanderbilt) by the ReN [28]. Baseline patient demographic (e.g. age, sex, diagnosis, co-morbidities) and device insertion (e.g. catheter gauge, site of insertion, inserter information) characteristics were verified with bedside nurse and recorded by research nurse. After device insertion, the number of attempts, difficulty of insertion, and the successful inserting clinician were recorded. The ReNs inspected study patients' PIVC site daily (Monday to Friday) until failure or removal. During the PIVC dwell, dressing integrity, the use of additional dressing and immobilising equipment, device usage, signs and symptoms of complications (including skin reaction), were collected. When the PIVC was removed, date and time of removal, dressing condition, reason for device removal, and patient/parent/staff acceptability were collected by the ReNs from patient medical record and/or conversation with patient/parent/staff respectively. Satisfaction and acceptability of the intervention were assessed at PIVC removal, on a 0–10 numeric scale of acceptability. After 48 h of PIVC removal the ReN reviewed the microbiology results for positive catheter tip or blood culture. Feasibility outcomes (e.g. eligibility, recruitment, retention and attrition) were collected from enrolment screening logs and REDCap®.

2.9. Statistical analysis

De-identified data was transferred from REDCap to Stata 15 for analysis. Data cleaning involved checks of missing and improbable data values. Missing values were not imputed. Feasibility outcomes were reported descriptively, and analysed against predetermined criteria. All outcomes were analysed on an intention-to-treat basis. The patient was used as the unit of measurement with one PIVC per patient analysed. Hypothesis tests were completed using the chi-squared, Fisher's exact, Kruskal-Wallis and log-rank tests as appropriate. Incidence rates (IR)

and rate ratios (RR) were calculated per 1000 PIVC-hours with 95% confidence intervals (CIs) to summarise the impact of each dressing regimen. Kaplan-Meier survival curves compared failure over time by groups. Univariable (crude) and multivariable (adjusted) Hazard Ratios (HRs) were calculated with Cox regression to test the effects of group allocation and patient/device characteristics on device failure. Some of the variables were re-categorised or otherwise adjusted to suit the regression analysis. Pairwise correlations were checked before using both variables together in the same model. Covariates were deemed eligible for multivariable analysis at a univariable significance of $p < 0.20$ (likelihood ratio test); group allocation was kept in the multivariable model regardless of p-values. Variable selection for the final multivariable model was performed using the manual stepwise removal/addition method guided by $p < 0.05$ (Wald test). The proportional hazards assumption was tested.

3. Results

3.1. Participant characteristics

A total of 319 participants were recruited over the 15-month study period. Most participants were < 5 years old, with good skin integrity and no co-morbidities. Patient demographics and PIVC characteristics were typically similar between groups at baseline. Despite randomisation some imbalance (> 10% absolute difference between groups) existed including; patients with infection at baseline, insertion by VAS, and use of ultrasound guided insertion (Table 1), this can be expected in a pilot trial. Most PIVCs were inserted to infuse medications and/or fluids (Table 1).

3.2. Feasibility outcomes

Between February 2017 and May 2018, 571 patients were screened, 330 (58%) were eligible for study inclusion, 232 (42%) were ineligible due to PIVC required for < 24 h (medical day infusion) or PIVC inserted outside usual business hours (Fig. 2). Therefore, the feasibility criteria of eligibility (80%) was not met. Remaining feasibility criteria were achieved including a high rate of eligible patients agreeing to participate; only 9 (3%) patients declined and none withdrew consent, thereby meeting the recruitment and retention criteria. The allocated dressing was applied to 305/319 (96%) patients meeting the protocol adherence criteria. Of 330 randomised patients, 11 (3%) had a cancelled PIVC insertion and thus were excluded from the primary analysis. No (0%) outcome data was missed and there were no patients lost to follow up; thus the attrition feasibility criteria was met.

3.3. PIVC failure and complications

Overall 112/319 (35%) PIVCs failed prior to completion of treatment (Table 2). The ISD group had the lowest incidence and IR of failure (31/107, 29%, p = 0.017; IR 4.4 per 1000 catheter-hours, [95% CI, 3.09–6.25]), followed by TA group (34/107, 32%, p = 0.052; IR = 5.15 [3.68–7.21]) then the BPU group (47/105, 45%; IR = 6.65 [4.99–8.85]). There was no statistically significant difference in IRs between groups. Survival curves (Fig. 3) demonstrated longer survival of the ISD group, with separation between groups after 24 h of dwell. The median times to failure were similar between groups (approximately 50 h). Infiltration was the most common reason for device failure, with highest occurrence in the BPU group (24/105; 23%), and similar in the other two groups (ISD, 18/107; 17%) and TA (19/107; 18%).

Significant risk factors for PIVC failure in the univariable analysis (Table 3) were; younger age (HR 0.95; 95% CI, 0.91–0.99), infection on admission (HR 1.58; 95% CI, 1.09–2.30), and 24G PIVC (HR 2.25; 95% CI, 0.93–3.71) (Table 3). Device size was dropped from the multivariable model due to its association with patient age. In the final

Table 1
Patient, insertion, device and treatment characteristics.

	N	BPU	ISD	TA + BPU
Group size[a]	319	105 (33)	107 (34)	107 (34)
Age group:	319			
up to 12 months		17 (16)	23 (22)	26 (24)
1 to < 5 years		30 (29)	26 (24)	36 (34)
5 to < 10 years		34 (32)	21 (20)	24 (22)
10 to < 15 years		15 (14)	26 (24)	16 (15)
≥15 years		9 (9)	11 (10)	5 (5)
Males	319	53 (50)	55 (51)	54 (50)
Weight appearance:	319			
minimal		62 (59)	64 (60)	62 (58)
moderate		35 (33)	33 (31)	35 (33)
excessive		8 (8)	10 (9)	10 (9)
Inserted on dominant side	224	34 (40)	29 (39)	25 (38)
Skin type (Fitzpatrick scale):	319			
pale white		11 (10)	15 (14)	14 (13)
white		54 (51)	52 (49)	53 (50)
light brown		15 (14)	18 (17)	15 (14)
moderate brown		11 (10)	13 (12)	14 (13)
dark brown/deeply pigmented		14 (13)	9 (8)	11 (10)
Skin integrity:	319			
good		81 (77)	79 (74)	69 (64)
fair or poor		24 (23)	28 (26)	38 (36)
Reason for admission (multiple answers)				
medical	319	43 (41)	39 (36)	42 (39)
surgical elective	319	37 (35)	39 (36)	40 (37)
surgical emergent	319	30 (29)	32 (30)	27 (25)
Infection at baseline	319	34 (32)	27 (25)	43 (40)
Number of comorbidities:	319			
zero		56 (53)	57 (53)	62 (58)
one		26 (25)	38 (36)	25 (23)
two		12 (11)	7 (7)	10 (9)
three or more		11 (10)	5 (5)	10 (9)
Wound at baseline	319	21 (20)	22 (21)	27 (25)
History of CVAD (this admission)	319	2 (2)	2 (2)	6 (6)
Device number: subsequent	319	44 (42)	64 (60)	59 (55)
Inserted by:	316			
vascular access specialist		35 (34)	45 (43)	49 (46)
anaesthetist doctor		38 (37)	36 (34)	30 (28)
resident medical officer		14 (13)	15 (14)	9 (8)
registrar doctor		15 (14)	8 (8)	14 (13)
other		2 (2)	1 (1)	5 (5)
Inserting department:	319			
ward		44 (42)	36 (34)	41 (38)
operating theatre		34 (32)	37 (35)	27 (25)
procedure room		24 (23)	33 (31)	33 (31)
other		3 (3)	1 (1)	6 (6)
Device size:	318			
20 g		11 (11)	18 (17)	13 (12)
22 g		79 (76)	81 (76)	77 (72)
24 g		11 (11)	7 (7)	14 (13)
other		3 (3)	1 (1)	3 (3)
Placement:	315			
cephalic		39 (38)	53 (50)	57 (54)
dorsal venous arch		33 (32)	23 (22)	25 (24)
median cubital		15 (15)	13 (12)	11 (10)
greater saphenous system		4 (4)	8 (8)	2 (2)
other		12 (12)	10 (9)	10 (10)
Location:	317			
posterior lower forearm		36 (35)	35 (33)	39 (37)
hand		32 (31)	26 (24)	26 (25)
cubital fossa		15 (14)	12 (11)	12 (11)
upper anterior forearm		6 (6)	8 (7)	10 (9)
wrist		6 (6)	11 (10)	7 (7)
foot		7 (7)	9 (8)	4 (4)
other		2 (2)	6 (6)	8 (8)
Ultrasound guided insertion	319	36 (34)	47 (44)	52 (49)
Difficult insertion	318	23 (22)	35 (33)	36 (34)
Multiple attempts at insertion	288	29 (30)	38 (41)	40 (41)
Immobilising devices (multiple answers)				
tubular bandage	319	9%	10%	11%
thick elasticated tape	319	11%	9%	8%
gauze	319	9%	6%	6%
brown tape	319	7%	4%	4%
Armboard	319	4%	4%	4%

(continued on next page)

Table 1 (*continued*)

	N	BPU	ISD	TA + BPU
thin elasticated tape	319	2%	2%	2%
bandage	319	1%	1%	1%
non-sterile tape	319	1%	1%	1%
Device used for (multiple answers)				
medications and/or fluids	237	84%	72%	80%
nothing obvious	237	8%	15%	15%
future procedures	237	5%	6%	4%
Emergencies	237	7%	8%	1%
Other	237	0%	0%	1%
Medication received (multiple answers)				
low risk	319	67%	63%	53%
medium risk	319	24%	26%	21%
high risk	319	3%	1%	3%
Dressing dirty/wet/damaged (ever)	237	19%	19%	13%
Phlebitis sign/symptoms (any level, ever, multiple answers)				
Tenderness	277	18%	10%	16%
Pain	276	18%	10%	10%
Leaking	237	9%	14%	9%
Swelling	312	6%	5%	8%
Erythema	312	7%	3%	4%
Hardness	312	2%	0%	3%
vein streak	312	0%	2%	0%
Purulence	310	0%	1%	0%

Frequencies and column proportions (%) shown unless otherwise noted; average proportion of non-missing observations shown unless otherwise noted; g = gauge; CVAD = central venous access device; TA = tissue adhesive; IV = intravenous; [a]frequencies and row proportions (%) shown; [b]median (25th-75th percentiles) shown N = number of non-missing observations.

multivariate model, for every 1-year increase in age (HR 0.92, 95% CI, 0.88–0.96), and insertion by VAS compared to medical officer (HR 0.40, 95% CI, 0.26–0.64), PIVC failure was significantly reduced ($p < 0.05$). PIVCs inserted in patients with infection at baseline had significantly increased risk of PIVC failure (HR 1.95, 95% CI, 1.28–2.98). The observed effect sizes, if confirmed in a larger clinical trial would be beneficial (ISD, HR 0.72; 95% CI, 0.45–1.14; TA, HR 0.74; 95% CI, 0.47–1.18).

3.4. Staff and parental feedback

As in Table 2, staff reported PIVC insertion difficulty was higher in the ISD (n = 35; 33%) and TA (n = 36; 34%) compared to BPU (n = 23; 22%). Overall acceptability with study product was obtained from half of the study participants' or parents (or caregivers) and were comparable across groups (Table 2). Staff acceptability scores with dressing and securement products were not able to be obtained as planned due to resourcing and irregular shift patterns.

3.5. Dressing and securement outcomes

Dressing integrity and performance is reported in Table 2. The life of the first dressing was similar across groups with median time to first dressing change longest for ISD (49 h, IQR 25–77). Dressing integrity varied between the groups, report of dressing lifting a great deal (ISD 1%; BPU 8%; TA 5%), prompting dressing change was highest in BPU and TA (75%) compared to ISD (13%). Skin reaction was reported more frequently in ISD (18%) compared to BPU (11%) and TA (9%).

3.6. Microbiology outcomes

There was large variability in bacterial growth found on exit site swab and PIVC tip, although less difference was detected on the actual pressure relieving foam, as described in Table 4. When NSF was placed under the hub of the PIVC in the BPU, ISD and TA groups at least some CFUs were detected (71%), (100%) and (56%) respectively, however when SF was placed under the PIVC hub in the ISD arm, bacterial growth was detected (44%) (Table 4). Despite the increased bacterial growth cultured from the NSF placed under the TA PIVC hub, bacterial colonisation was only detected (12%) at the wound site, and > 15 cfu grown from PIVC tip (4%), compared to the BPU wound site (100%) and BPU PIVC tip (7%). Similarly, PIVC tip (0%) and skin colonisation at wound site (18%) of ISD was low in comparison to growth on the foam (44%).

4. Discussion

Non-standard dressing and securement practices have been cited in previous studies as contributing to PIVC failure in paediatric patients, with calls for more evidence to inform optimal practice [6,8,29]. Although a pilot trial, internationally, this is the first paediatric RCT to begin to examine the effectiveness of new generation dressing and securement strategies for PIVCs. The results confirm the feasibility of a large efficacy trial since most elements of feasibility were met, excepting the eligibility. To ensure future trial feasibility, additional strategies might include; extended ReN hours, recruitment from additional inpatient areas within the hospital and inclusion of other paediatric health services.

This study aimed to evaluate the feasibility of future efficacy trials to reduce PIVC failure and provide point estimates for sample size calculations. ISD was observed to significantly reduce the risk of PIVC failure, and although not statistically significant, TA demonstrated a similar reduction in relative risk, which warrants further investigation in an efficacy trial. This pilot trial generates important clinically relevant evidence highlighting the need for further testing in the unique paediatric population. Previous studies comparing these products in adult populations did not find reductions in PIVC failure [5,11]. The basis for such variation in outcome is unclear, however the additional securement properties might prove more beneficial in preventing dislodgement and micromotion in an active paediatric patient.

Skin complications, such as erythema and itch were observed across all groups.Previous studies have documented increased risk of skin injury in patients of extreme age, with comorbidities, receiving chemotherapy and increased irritation caused by dressing changes [30]. Although not significantly higher, ISD reported the most skin complications and the lowest incidence of dressing edges lifting. This might be attributed to enhanced adhesive properties of the primary dressing, which might in turn increase the risk of skin injury on removal. In clinical practice dressings are changed when they become soiled or start to lift from the skin, adhesive remover is not routinely used to remove PIVC dressings. Whilst less frequent dressing changes may reduce skin damage, the more adhesive properties of some dressings can also damage the skin. A risk benefit of the competing properties (enhanced adhesive -v- risk of frequent dressing change) should be considered in the context of individual patients when choosing an appropriate dressing to minimise medical device related skin damage.

Previous *in vitro* use of TA to secure PIVC demonstrated inhibition of growth of *Staphylococcus aureus* and *Staphyloccus epidermidis* [21]. This is consistent with the findings of this pilot RCT, which demonstrated reduced tip colonisation in the TA group compared to BPU when a piece of NSF was applied under the PIVC hub of both BPU and TA. In this study the skin swab at the wound insertion site and tip cultures in the TA group demonstrated low microbial load compared to BPU suggesting prelimary positive antimicrobial properties of TA. However, it contradicts the clinical findings of previously reported RCT of PIVC securement (n = 1807 adult patients) which demonstrated no statistically significant difference in tip (> 15 cfu; 2 versus 1; p = > 0.05)

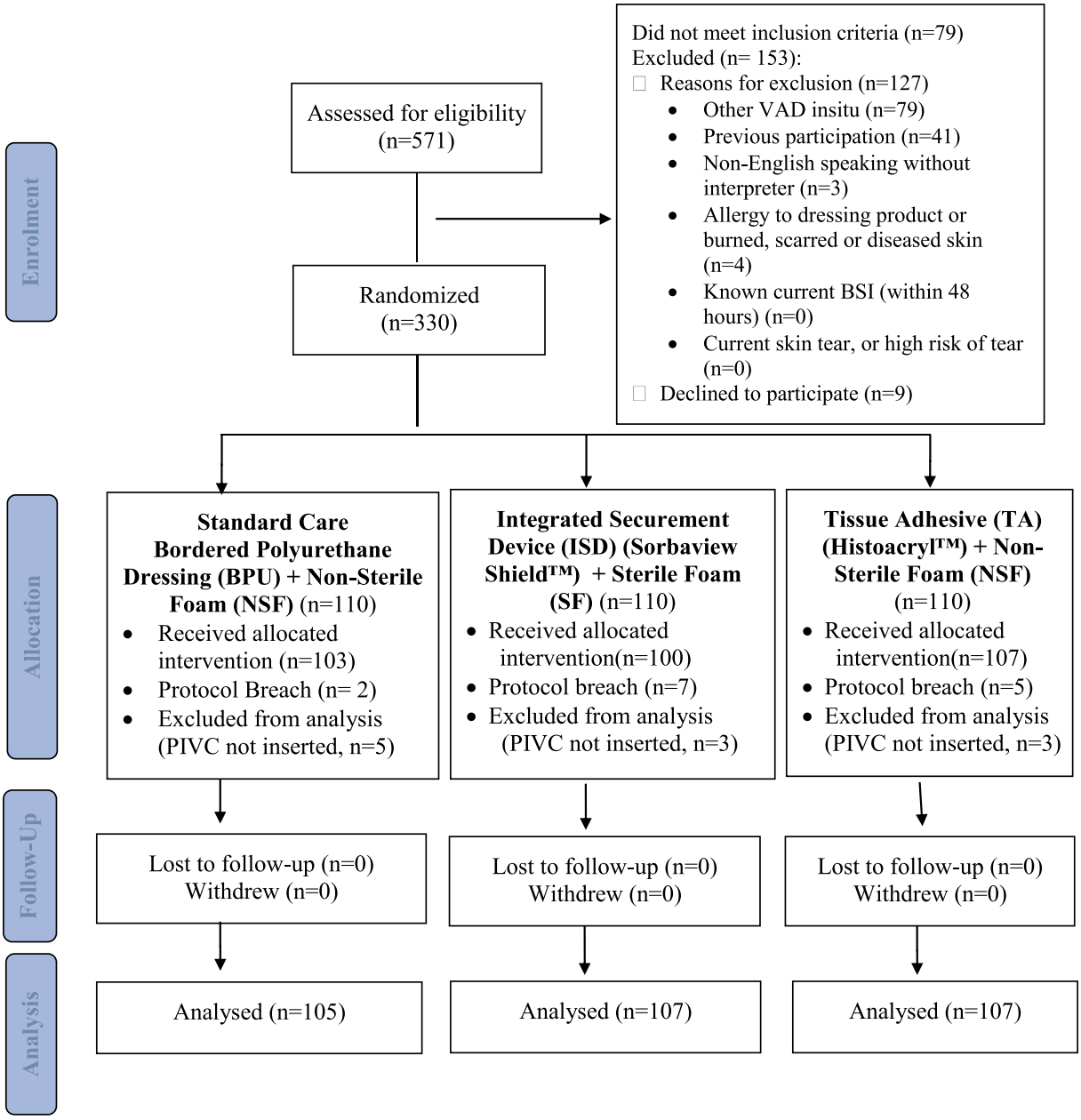


Fig. 2. CONSORT Flowchart of study participants.

and skin (> 0 cfu; 19% versus 13%; p = > 0.05) colonisation when TA + PU (non-bordered polyurethane) was compared to standard care (PU) [5]. Despite the application of SF in the ISD group, the SF had similar microbial growth to NSF which might be attributed to a breakdown in aseptic technique on insertion. Like the TA group, low colonisation was observed at the wound site and PIVC tip of the ISD group, suggesting the additional securement might prevent PIVC micromotion, limiting microorganism entry through wound created by the PIVC insertion.

Non-modifiable risk factors contributing to PIVC failure identified in this study included young age and infection at baseline, confirming results of previous paediatric studies [31]. Modifiable variables that might improve the functional dwell of PIVC include use of 22-gauge PIVC compared to the smaller 24-gauge PIVC. This is the first paediatric study to demonstrate an association between accidental dislodgment and size of PIVC; previously found to be predictive of PIVC failure in adults [16]. Additionaly, PIVC insertion by VAS compared to medical officers reduced risk of PIVC failure by 60%, consistent with trials in Australian adult healthservices [32]. Internationally, vascular access teams are common and PIVC insertion is rarely a task delegated to junior medical officers as is the case in this healthcare service. Worldwide the healthcare landscape is changing; consumers are more aware of their healthcare rights and demand improved outcomes. To meet consumer expectations healthservices should consider how the implementation of a sustainable vascular access service might improve patient experiences and optimise vascular access outcomes in the context of PIVCs.

As anticipated, this pilot trial did not show a significant reduction in PIVC failure in multi-variate analysis, ISD however approached statistical significance in the multivariate model ($p < 0.20$) and warrants

Table 2
Device and other outcomes.

	N	BPU	ISD	TA + BPU
Group sizes[a]	319	105 (33)	107 (34)	107 (34)
Device failure[b]	319	47 (45)	31 (29)	34 (32)
		reference	$p = 0.017$[c]	$p = 0.052$[c]
Dwell time[d] (hours)	319	51 (30–94)	51 (26–93)	50 (26–76)
Total dwell time (device-hours)	319	7071	7049	6596
IR (95% CI, per 1000 device-hours)	319	6.65 (4.99–8.85)	4.40 (3.09–6.25)	5.15 (3.68–7.21)
IRR (95% CI)		reference	0.66 (0.41–1.06)	0.78 (0.48–1.23)
Securing device (including protocol breaches, multiple answers)[e]				
additional transparent dressing	319	16%	20%	18%
foam tape	319	5%	5%	4%
non-woven fabric tape	319	4%	1%	1%
sterile tape at hub	319	3%	1%	1%
additional bordered transparent dressing	319	1%	3%	1%
non-sterile tape	319	1%	0%	0%
Number of dressing changes (total)	319	4	7	4
Life of first dressings (hours)[d]	319	48 (29–93)	49 (25–77)	48 (25–73)
Dressing appearance (ever, multiple answers)[e]				
lifting a great deal	319	8%	1%	5%
lifting slightly	319	5%	3%	3%
dried blood	319	1%	6%	1%
serous fluid under dressing	319	1%	3%	1%
blood leaking	319	0%	1%	0%
other	319	1%	2%	1%
Dressing change prompted by (multiple answers)[e]				
lifting dressing	4	75%	13%	75%
leakage	4	25%	25%	0%
sweating	4	25%	0%	0%
Skin reaction (any type, ever)[e]	319	11%	18%	9%
Reason device was removed[b]:	319			
treatment complete; complications		6 (6)	3 (3)	1 (1)
treatment incomplete; no complications		41 (39)	28 (26)	33 (31)
treatment complete; no complications		57 (54)	75 (70)	69 (64)
other		1 (1)	1 (1)	4 (4)
Complication at removal (multiple answers)[b]				
infiltration/extravasation/leak	319	24 (23)	18 (17)	19 (18)
occlusion	319	14 (13)	5 (5)	13 (12)
phlebitis or too painful	319	11 (10)	6 (6)	6 (6)
dislodged/accidental removal	319	8 (8)	4 (4)	3 (3)
suspected bloodstream infection	319	0 (0)	0 (0)	0 (0)
suspected local infection	319	0 (0)	0 (0)	0 (0)
Serious adverse events (multiple answers)[a]				
bloodstream infection	319	1 (1)	0 (0)	0 (0)
intensive care admission	319	6 (6)	0 (0)	2 (2)
Patient acceptability[f]	162	9.2 (1.7)	9.4 (1.2)	9.2 (1.3)
Infection during study[b]	319	31 (30)	24 (22)	40 (37)

[a] Frequency and row %.
[b] Frequency and column %.
[c] Chi-squared test.
[d] Median (25th and 75th percentiles).
[e] Average proportion of non-missing observations; IR = incidence rate; CI = confidence interval; IRR = incidence rate ratio.
[f] Mean (standard deviation) shown.

further investigation in a full-scale trial; TA showed a similar (non-significant) trend. These preliminary, but clinically relevant findings, contribute important data to the body of work examining dressing and securement products to prevent PIVC failure. However, evaluation in a full efficacy trial is urgently needed [33]. The different actions of these two-new generation products further suggest a large trial investigating their potential synergistic effect (i.e. TA + ISD) may also be explored.

4.1. Limitations

Despite robust methodology, this pilot trial has limitations. The study was undertaken in a single, tertiary referral paediatric hospital, and the number of patients recruited are insufficient for multiple comparisons of two separate interventions. Patient recruitment was limited to acute inpatient medical and surgical wards, limiting its generalisability to other populations such as intensive care, emergency department and outpatient settings. Additionally, it was not possible to blind the study products from clinical and research staff due to the nature of the interventions. However, much of the outcome data were attributed by a blinded infectious disease physician and laboratory scientist, and analysed by a blinded statistician.

5. Conclusion

High PIVC failure rates indicate the inadequacy of current PIVC dressing and securement practices in paediatric populations. Although this pilot trial was not powered to show a statistically significant difference the results are clinically promising with lower PIVC failure

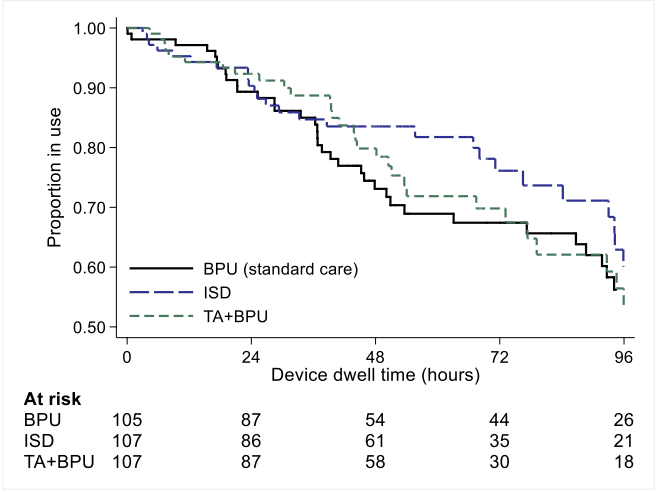


Fig. 3. Kaplan-Meier curve of device failure.

associated with the use of new generation dressing and securement products (integrated securement and dressing and tissue adhesive). This pilot study demonstrates a full efficacy RCT is feasible and necessary to test the full efficacy of these new generation dressing and securement products to reduce PIVC failure.

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Contributors' statement

TMK conceptualized and designed the study and data collection instruments, carried out the initial analyses, drafted the initial manuscript, and reviewed and revised the manuscript.

CMR, AJU conceptualized and designed the study, carried out the initial analyses and reviewed and revised the manuscript.

JS critically reviewed and revised the manuscript for important intellectual content.

HX drafted the initial manuscript, reviewed and revised the manuscript.

MB was responsible for the microbiology analyses, reviewed and revised the manuscript.

VG, EL designed the data collection instruments coordinated and supervised data collection, collected data, reviewed and revised the manuscript.

GM, carried out the initial analyses, and critically reviewed the manuscript for important intellectual content.

NM conceptualized and designed the study and data collection instruments and reviewed and revised the manuscript.

PC collected data and reviewed the manuscript.

All authors approved the final manuscript as submitted and agree to be acc ountable for all aspects of the work.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Griffith University has received unrestricted investigator-initiated research or educational grants to support the research of TMK, NM, CRM, JS, EL, AJU from product manufacturers 3M, Access Scientific, Adhezion, Angiodynamics; Bard, Baxter; BBraun, Becton Dickinson; Centurion Medical Products; Medtronic. The other authors have indicated they have no financial relationships relevant to this article to disclose.

Table 3
Cox regression.

	Hazard Ratio (95% CI)	
	univariable	multivariable (N = 308)
Study group:	*	
ISD	0.67 (0.42–1.05)	0.72 (0.45–1.14)*
TA + BPU	0.78 (0.50–1.22)	0.74 (0.47–1.18)
Age (1 year increase)	0.95 (0.91–0.99)**	0.92 (0.88–0.96)***
Female gender	1.02 (0.71–1.48)	$
Excessive adipose	0.59 (0.30–1.17)*	^
Inserted on dominant side	1.19 (0.75–1.90)	$
Skin type (ref = pale white):		$
white	1.20 (0.69–2.10)	
light brown	0.89 (0.43–1.86)	
moderately brown	1.16 (0.57–2.35)	
dark brown or deeply pigmented	1.12 (0.55–2.30)	
Fair/poor skin integrity	0.98 (0.66–1.46)	$
Medical admission	0.85 (0.58–1.25)	$
Surgical emergent admission	1.06 (0.70–1.60)	$
Surgical elective admission	1.03 (0.69–1.52)	$
Infection at baseline	1.58 (1.09–2.30)**	1.95 (1.28–2.98)***
Comorbidities (ref = none):		$
one	0.70 (0.45–1.11)	
two	0.97 (0.54–1.74)	
three or more	0.66 (0.33–1.33)	
Wound at baseline	1.27 (0.84–1.91)	$
Subsequent device	1.00 (0.68–1.45)	$
Inserted by VAS (ref = medical officer)	0.69 (0.47–1.02)*	0.40 (0.26–0.64)***
Inserting department (ref = ward):		$
operating theatre	1.18 (0.73–1.91)	
procedure room	1.27 (0.82–1.98)	
Device size 24 g (ref = other)	2.25 (1.37–3.70)***	^
Placement (ref = cephalic):		$
dorsal venous arch	0.90 (0.55–1.46)	
median cubital	1.08 (0.58–2.02)	
other	1.17 (0.68–2.02)	
Location in wrist (ref = other)	1.85 (0.93–3.71)*	^
Ultrasound guided	0.86 (0.59–1.26)	$
Difficult insertion	1.27 (0.87–1.86)	$
Multiple attempts	1.44 (0.97–2.12)*	^
Medication risk med/high (ref = low):	1.03 (0.69–1.53)	$

CI = confidence interval; ref = reference category; ISD= Integrated Securement Device (Sorbaview Shield); TA = tissue adhesive and BPU; VAS = vascular access specialist; g = gauge; IV = intra-vascular; *p < 0.20, **p < 0.05 and ***p < 0.01, indicate likelihood ratio test significance in the univariable column, and Wald test significance in the multivariable column; $ = ineligible for multivariable analysis; ^ = dropped from multivariable model at p ≥ 0.05.

Table 4
Microbiology sub-study.

Location	cfu	BPU	ISD	TA + BPU
PIVC tip	> 15	n = 43 3 (7%)	n = 40 0 (0%)	n = 45 2 (4%)
Skin swab	> 0	n = 41 41 (100%)	n = 40 7 (18%)*	n = 42 5 (12%)*
Non-sterile foam (Microfoam™)	> 0	n = 38 27 (71%)	n = 2 2 (100%)	n = 46 26 (57%)
Sterile foam (Hubguard®)	> 0	n = 0 0 (0%)	n = 36 16 (44%)^	n = 0 0 (0%)^

*p < 0.05 Fisher's exact test (reference group = BPU); ^ cannot be tested.

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