Promoting Haemostasis for Central Venous Access Devices

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Background & Objectives

Background:
CVAD insertion breaches the skin barrier, resulting in bleeding that compromises dressing integrity and increases CLABSI risk. CHG dressings lack haemostatic properties and may become ineffective when saturated with blood or haemoserrous fluid.

Primary Objective:
To compare potassium ferrate (StatSeal®) with CHG dressings (Tegaderm CHG® & Biopatch®) for reducing dressing failure at CVAD exit sites.

Eligibility Criteria:
- ≥18 years of age
- Expected to require a CVAD for ≥48 hours
- Currently admitted or anticipated to be admitted within 24 hours.

Safety Profile

No serious adverse events or CLABSI observed

Event	Standard	StatSeal
Raised Rash	0%	1.3%
Non-raised Rash	1.2%	0%
Blister	1.2%	0%
Skin tear	1.2%	0%
Bruising	23.2%	38.5%

Higher bruising was observed with StatSeal, likely due to performance of product

Primary Results

Absolute risk: All-cause dressing failure:

Standard dressing: 70.9% → **StatSeal: 52.6%**
(95% CI: 57.5–80.0 vs 39.4–62.9)

Absolute risk: Dressing failure from bleeding, leaking or lifting:

Standard dressing: 56.1% → **StatSeal: 30.7%**
(95% CI: 42.5–66.4 vs 19.1–40.7)

StatSeal more than doubled median dressing survival 6.9 days (IQR 3.1–7.2) vs 3.0 days (IQR 1.2–6.6).

Methods

Design: Two-centre superiority randomised controlled trial (Liverpool and Royal Women and Brisbane Hospitals) with 7-day follow-up

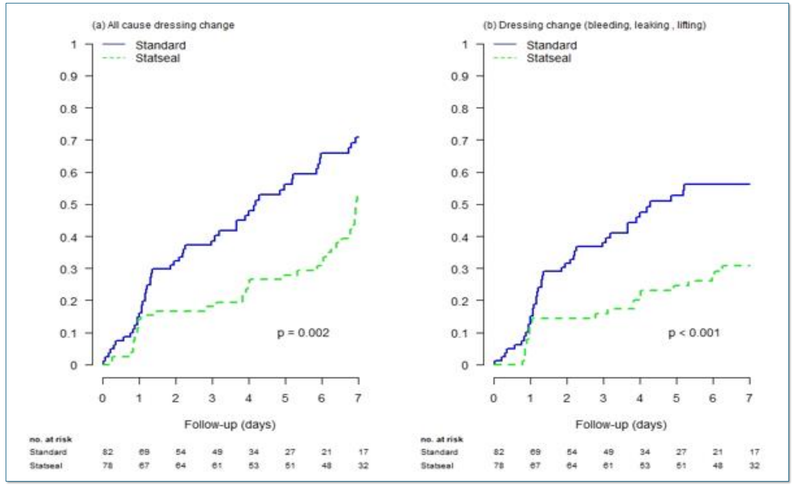
Participants: ≥18 years, CVAD required ≥48 hours, admitted/expected admission within 24 hours

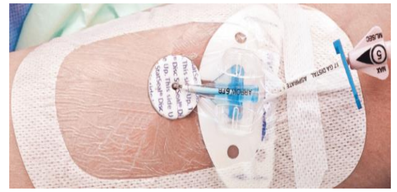
Intervention: StatSeal® disc + standard dressing

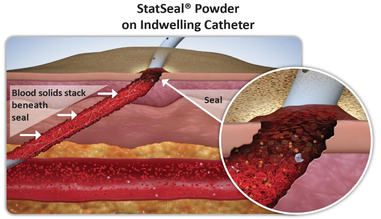
Control: CHG disc (BioPatch®) or CHG dressing (Tegaderm CHG®)

Primary outcome: Dressing failure before day 7 (lifting, leaking, bleeding)

Analysis: Time-to-event outcomes were analysed using Kaplan–Meier survival curves and compared using Cox proportional hazards regression to estimate hazard ratios (HRs) with 95% confidence intervals. Analyses were conducted on an intention-to-treat basis.







StatSeal halved all-cause dressing failure (HR 0.51, 95% CI 0.33–0.79; p=0.002) and reduced dressing failure from bleeding, leaking or lifting by 60% (HR 0.40, 95% CI 0.24–0.68; p<0.001).