

# Prospective, Randomized, Controlled Trial Assessing the Clinical Performance of a Transparent Chlorhexidine Gel Pad Intravascular Catheter Dressing

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## Abstract

**Background:** Intravascular catheter-associated bloodstream infections (CA-BSI) are a significant medical problem. Novel means to prevent CA-BSI are needed.

**Objective:** To assess the clinical performance of an innovative catheter dressing that has the potential to inhibit the growth of microbes at the catheter insertion site.

**Methods:** Prospective, controlled, randomized, clinical trial comparing the 3M™ Tegaderm™ CHG (chlorhexidine gluconate) IV Securement Dressing (3M Healthcare, St Paul, MN) to a standard transparent dressing (IV3000™, Smith & Nephew, London, UK).

**Results:** 60 of 69 adult subjects granting informed consent completed the study (3-7 days of dressing wear). Subjects were randomized to dressing type stratified by catheter insertion site (internal jugular, subclavian, antecubital PICC), and were evenly matched with regard to demographics and means of catheter securement. The mean time to first dressing change was 4.3d ± 2.2d vs 4.8d ± 2.0d (p=0.36) for the comparator and Tegaderm CHG dressing, respectively. The mean total study dressing wear time was 5.4d ± 1.5d vs 5.5d ± 1.4d (p= 0.87) for the comparator and Tegaderm CHG dressing groups, respectively. The Tegaderm CHG dressing was regarded as superior to the comparator dressing with regard to catheter securement (p = 0.0019) and overall satisfaction (p = 0.0033). There were no significant differences between the groups with regard to ease of dressing application, dressing edge lift, ability to visualize the catheter insertion site, skin condition at insertion site (erythema, edema, maceration, skin stripping, moisture), blood under the dressing, ease of removal, or patient assessment of discomfort. 18 subjects completed 7 days of dressing wear without a dressing change and, at the time of dressing removal, 10 comparator and 8 Tegaderm CHG subjects, underwent aerobic microbiologic swab cultures of the skin at the insertion site. This method recovered no microbes from 7 comparator and 5 Tegaderm CHG insertion sites. The mean colony count was 44 ± 122 and 17 ± 35 for the comparator and Tegaderm CHG dressing, respectively (p = 0.84). Of the 6 skin cultures in which microbes were recovered, 5 yielded coagulase-negative staphylococci (range: 10 cfu to 390 cfu) and 1 yielded *Candida parapsilosis* (100 cfu). Adverse events were reported in 6 subjects (3 comparator, 3 Tegaderm CHG): none were regarded as due to the study dressing.

**Conclusions:** The Tegaderm CHG dressing containing a chlorhexidine gel pad is an innovative means to potentially minimize CA-BSI. The Tegaderm CHG dressing is well-tolerated and judged to be superior to the comparator dressing with regard to catheter securement and overall satisfaction. These results justify adequately powered trials to examine the clinically relevant endpoint of CA-BSI and the surrogate endpoints of catheter colonization and insertion site skin colonization.

## Introduction

Eight million central venous catheters and 160 million peripheral intravenous catheters are utilized in the United States each year. Approximately 250,000 persons experience catheter-associated bloodstream infections annually. A central venous catheter-associated bloodstream infection (BSI) results in an attributable mortality of 2%, extension of hospital stay of 7-14 days, and can cost in excess of \$50,000 per episode. Improved means to prevent catheter-associated BSIs are needed.

Microbial adherence and colonization of the catheter is a crucial step in the pathogenesis of central venous catheter-associated BSI. Technology-based measures to minimize the risk of central venous catheter-associated BSI include: antibiotic or antiseptic coated catheters or hubs, antimicrobial catheter lock solutions, and antiseptic impregnated catheter dressings.

The purpose of this study was to assess the clinical performance of an innovative catheter dressing that is designed to minimize the growth of microbes at the catheter insertion site.

## Methods and Materials

**Study Design:** Prospective, randomized, controlled, single-center, clinical trial. The University of Nebraska Medical Center Institutional Review Board reviewed and approved this study.

**Setting:** The Nebraska Medical Center is a 689 bed, university-associated, tertiary care center.

### Dressings:

- **Investigational Dressing:** 3M™ Tegaderm™ CHG Securement Dressing (3M, St. Paul, MN) is a transparent, semi-permeable, film dressing that contains a gel pad containing 2% (w/w) chlorhexidine gluconate.
- **Control Dressing:** IV3000™ (Smith & Nephew, London, UK) is a transparent, semi-permeable, polyurethane dressing.

**Subjects:** 60 subjects stratified by catheter insertion site (20 internal jugular, 20 subclavian or femoral, and 20 antecubital PICC).

**Inclusion Criteria:** Adult patients with a central venous catheter that was likely to remain in place at least 3 days.

**Exclusion Criteria:** Hypersensitivity to chlorhexidine; dermatitis, burns, or other dermatologic condition at the catheter insertion site; use of skin protectants at the catheter insertion site.

### Procedures:

- Study personnel applied the study dressing per manufacturer's recommendations according to randomization schedule and insertion site/catheter type stratification.
- At the time of dressing application and dressing change an application assessment was performed
- The dressings were evaluated daily for adherence (edge lift), catheter securement (catheter migration), transparency, skin condition (erythema/edema), presence of moisture or blood, and patient comfort (Figure 1).
- At the time of dressing removal the reason for removal was noted as well as ease of removal, presence of dressing residue, and skin condition (maceration, skin stripping, erythema, edema) (Figure 2).
- Day 7/patient discharge/catheter removal assessment: In addition to the daily assessment an assessment of overall clinician satisfaction was performed.
- Day 7 Microbiologic Assessment: For subjects with 7 days of continuous study dressing wear, a swab culture of 10 cm<sup>2</sup> of skin at the catheter insertion site was performed (Figure 3).

### Statistical Analysis:

- The primary outcome of overall satisfaction with dressing securement was assessed using Student's t-test. Variables assessed daily were averaged (mean score or average percent occurrence) and differences between groups were analyzed using Student's t-test. Significance was assessed at p<0.05, 2-tailed.

Figure 2. Dressing Application and Removal Assessment Form



Figure 3. Skin culture template

Figure 1. Daily Assessment Form

## Results



Figure 4. Typical appearance of 3M™ Tegaderm™ CHG Securement Dressing

Table 1. Baseline demographics, securement, and dressing wear time

	Tegaderm HCG	Control	P
Age (years) mean (SD)	53.2 (17.8)	60 (14.7)	0.13
Gender: Males N (%)	18 (60)	19 (63.3)	0.99
Female N (%)	12 (40)	11 (36.7)	
Securement: N (%)			0.34
Suture	21 (70)	19 (63.3)	
Tape	4 (13.3)	8 (26.7)	
Other	5 (16.7)	3 (10)	
Mean Time to 1 <sup>st</sup> Dressing Change: Days (SD)	4.8 (1.99)	4.3 (2.19)	0.36
Mean Total Study Dressing Wear Time: Days (SD)	5.5 (1.4)	5.4 (1.5)	0.87
Average Number of Dressing Changes (SD)	1.27 (.52)	1.43 (.62)	0.27

## Results (continued)

Table 2. Initial, Daily, and Final Assessment Results. Unless otherwise noted, the application, site assessment, and satisfaction scores were numerically ranked (see assessment forms) with lower scores being more desirable (eg. 1 = very good or very easy; 5 = very poor or very difficult).

	Tegaderm CHG	Control	P
<b>First Application (Score, SD)</b>			
Ease of Application	1.57 (.89)	1.5 (.68)	0.75
Ease of Correct Application	1.63 (.85)	1.47 (.68)	0.41
<b>During Dressing Wear (Score, SD)</b>			
Ease of Application	1.51 (.75)	1.58 (.71)	0.71
Ease of Correct Application	1.59 (.77)	1.55 (.71)	0.82
Edge Lift	0.78 (.56)	1.02 (.65)	0.15
Transparency	1.3 (.49)	1.4 (.43)	0.42
Erythema	0.17 (.30)	0.13 (.28)	0.60
Skin Stripping, Edema, Maceration, Migration, Dislodgement	0	0	-
Patient Discomfort	0.08 (.2)	0.05 (.13)	0.45
Ease of Removal	2.12 (.98)	1.91 (.69)	0.35
Moisture (% Assessments, SD)	0.48 (2.6)	0	0.33
Blood (% Assessments, SD)	17.3 (35.7)	11.14 (27.5)	0.46
Residue (% Assessments, SD)	8.6 (29.6)	1.7 (9.3)	0.20
<b>End of Study (Score, SD)</b>			
Satisfaction with Securement	1.63 (.72)	2.27 (.78)	<b>0.0019</b>
Overall Satisfaction	1.63 (.61)	2.2 (.81)	<b>0.0033</b>

### Microbiologic Results:

18 subjects completed 7 days of dressing wear without a dressing change and, at the time of dressing removal, 10 comparator and 8 Tegaderm CHG subjects, underwent aerobic microbiologic swab cultures of the skin at the insertion site. This method recovered no microbes from 7 comparator and 5 Tegaderm CHG insertion sites. The mean colony count was 44 ± 122 and 17 ± 35 for the comparator and Tegaderm CHG dressing, respectively (p = 0.84). Of the 6 skin cultures in which microbes were recovered, 5 yielded coagulase-negative staphylococci (range: 10 cfu to 390 cfu) and 1 yielded *Candida parapsilosis* (100 cfu).

### Adverse Events:

Adverse events were reported in 6 subjects (3 comparator, 3 Tegaderm CHG): none were regarded as due to the study dressing.

## Conclusions

1. The Tegaderm CHG dressing containing a chlorhexidine gel pad is an innovative means to potentially minimize CA-BSI.
2. The Tegaderm CHG dressing is well-tolerated and judged to be superior to the comparator dressing with regard to catheter securement and overall satisfaction.
3. Comparative studies utilizing swab cultures and the "cup-scrub" method should be performed to assess cutaneous microbial colonization.
4. These results justify adequately powered trials to examine the clinically relevant endpoint of CA-BSI and the surrogate endpoints of catheter colonization and insertion site skin colonization.

Disclosure: This study was supported by a research contract to the University of Nebraska Medical Center from 3M