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A Controlled Randomized Prospective Comparative Pilot Study to Evaluate the Ease of Use of a Transparent Chlorhexidine Gluconate Gel Dressing Versus A Chlorhexidine Gluconate Disk in Healthy Volunteers

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Abstract

Products and technologies that aid health care professionals in vascular access practice save staff time, and while promoting patient safety and prevention of infection can provide excellent opportunities for evaluations to support evidence-based practice. This was an industry sponsored, prospective, single site, controlled, randomized clinical evaluation pilot study of two catheter dressings, 3M™ Tegaderm™ Chlorhexidine Gluconate (CHG) IV Securement Dressing (CHG gel dressing) (3M Health Care, St. Paul, MN) and BIOPATCH® Antimicrobial Dressing with Chlorhexidine Gluconate (BIOPATCH® Protective Disk with CHG, Johnson & Johnson, Somerville, NJ). Twelve intravascular (IV) therapy health care professionals (Clinicians) were asked for their professional evaluations of the catheter dressings: the ease of application and performance factors featured in specific questions. Catheters were secured on 12 healthy volunteers to simulate inserted jugular catheters (IJ) and peripherally inserted central catheters (PICC) using StatLock® PICC Plus and 3M™ Steri-Strip™. Each clinician applied and removed one CHG gel dressing and one CHG disk on one simulated PICC and one simulated IJ site, according to the manufacturers' instructions.

The clinicians concluded, based upon a 1 to 5 rating scale, that the CHG gel dressing is better in regard to ease of application, ease of applying correctly, ease of removal, ability to visualize the insertion site, ease of training another clinician to apply the dressing, and more intuitive application. Twelve out of 12 clinicians favored the CHG gel dressing over the CHG disk in overall performance.

Review of Literature

Intravascular catheters are necessities in medical practice. Vascular access devices enable health care professionals to administer medications, nutritional support, blood products and other therapies to patients. These invasive devices may also put patients at risk for local and systemic infections, including catheter-related bloodstream infections (CR-BSI) (Centers for Disease Control and Prevention, 2002). Numerous publications have suggested that most CR-BSI, for central venous catheters in place for 10 days or less, are of cutaneous origin and stem from the insertion sites (Mermel, McCormick, Springman & Maki 1991;

Maki, 1982). New devices and technologies to prevent skin flora colonization around catheter insertion sites have helped health care professionals in vascular access practice and infection prevention. Transparent, semipermeable polyurethane dressings have become a popular means of protecting the catheter insertion site (O'Grady, Alexander, Dellinger, Gerberding, Heard, Maki et al., 2002.) However, the use of some devices is not intuitive and may result in potential misuse (MAUDE 2007).

Methodology

Purpose

The purpose of this study was to have the clinicians compare the practicality of using the CHG gel dressing versus the CHG disk on simulated PICC and IJ sites in healthy volunteers (subjects). The primary objective was to compare the devices for ease of application and time required to apply and remove the

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devices. The secondary end-point was to assess which device allowed easier training of application.

Study Design

In a prospective, single site, controlled, randomized pilot study, 12 intravascular (IV) therapy health care professionals (clinicians) were asked for their professional evaluations on two antimicrobial containing catheter dressings: 3M™ Tegaderm™ Chlorhexidine Gluconate (CHG) IV Securement Dressing (CHG gel dressing) and BIOPATCH® Antimicrobial Dressing with Chlorhexidine Gluconate (CHG disk). The CHG gel dressing consists of a Tegaderm™ transparent adhesive dressing with an integrated, transparent, CHG gel pad. The CHG disk consists of an opaque disk impregnated with CHG on one side. The clinicians were asked to compare the ease of use, and performance factors featured in specific questions. The study was conducted using healthy volunteers in a testing facility.

This was a prospective, single site, controlled and randomized pilot study. The Institutional Review Board (IRB) from the testing facility, approved the study protocol and informed consent form, and ensured that the study was conducted in conformity with ethical principals of research. Subjects were given information regarding the study and were informed that data collected in the study may be used for publications. Their confidentiality would be protected and their names would not be revealed in any publications or other documents intended for public examination. Time was given to each subject to review the informed consent form. All subjects' informed consents were obtained prior to any study procedures. The testing facility in which the study was conducted is not a covered entity; therefore subjects' Health Insurance Portability and Accountability Act (HIPAA) authorizations were not obtained. Twelve subjects, who met the inclusion and exclusion criteria and were willing and able to consent, were enrolled from the testing facility. Subjects were compensated for their participation time in the study. Inclusion criteria for subjects were males or females 18 years of age or older.

Exclusion criteria for subjects included:

1. Subjects who had a sensitivity/allergy to adhesive products, such as medical tapes, or acrylates.
2. Subjects who had sensitivity to the antimicrobial agent CHG.
3. Subjects who had psoriasis, a history of dermatitis, or skin conditions that might be exacerbated by the action of removing adhesive materials.
4. Subjects who had active dermatitis (rash), sunburn, blemishes, broken skin or cuts, or skin infection on his or her neck and both upper arms.
5. Subjects who were pregnant or thought they might be pregnant or were nursing.
6. Subjects who had a history of diabetes.

Twelve clinicians (all were Registered Nurses; some had additional credentials such as BSN-CRNI-RN, CRNI-RN, and BSA-RN) were recruited from local health care facilities (acute care facilities, home health, outpatient infusion clinic.) They were health care professionals specializing in vascular access and infusion therapy and were experienced in applying

and changing IV dressings in their practices. The clinicians were compensated for their time and commute to the testing facility. These clinicians had not used the CHG gel dressing in their practices, but some had experience using the CHG disks. The clinicians were informed of the study objectives and were shown a video of the applications of both devices before the study was conducted. The video of applications of the CHG gel dressing and CHG disk according to the manufacturers' instructions was recorded by a contract photographer at the testing facility. Application of the CHG gel dressing was demonstrated by a vascular access clinician (BSN, RN) from the testing facility. Application of the CHG disk was demonstrated by an IV infusion therapy health care professional (BSA, RN) recruited from a local hospital, who regularly used the device in her practice. After viewing the video, the clinicians were asked to apply and remove both catheter dressings according to the manufacturers' instructions. The clinicians were also provided with written instructions for use of each device before the conduct of the study.

Catheters were secured on the right and left sides of the subject's neck to simulate the internal jugular (IJ) catheter placement using 3M™ Steri-Strip™. Catheters were also secured on the subject's right and left arms around the vein area to simulate the Peripherally Inserted Central Catheter (PICC) secured with StatLock® and Steri-Strip™. See Figure 1 and 2.

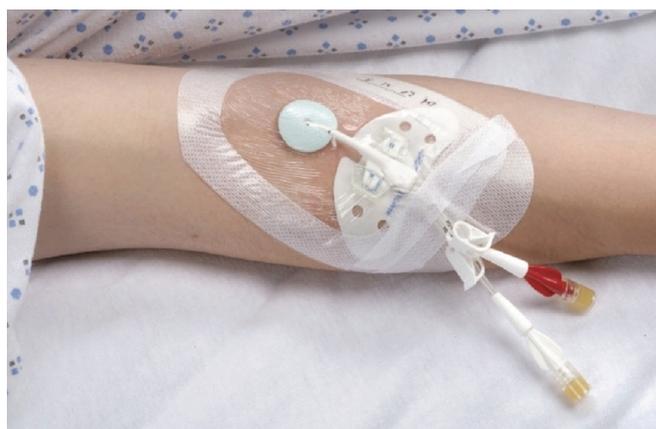


Figure 1: Application of CHG Disc on Simulated PICC Line with StatLock®.



Figure 2: Application of CHG Gel Dressing on Simulated PICC Line with Steri-Strip™.

Table 1. Performance Comparison of CHG Gel Dressing Versus CHG Disk

	Mean	Median	SD	Min	Max	P-Value
Overall performance	1.67	2.0	0.49	1	2	<0.0001
Ease of application	1.58	2.0	0.51	1	2	<0.0001
Ease of applying correctly	1.75	2.0	0.45	1	2	<0.0001
Ease of removal	1.17	1.0	0.72	0	2	=0.0002
Ability to see IV site	1.75	2.0	0.62	0	2	<0.0001
Ease of training	1.58	2.0	0.67	0	2	<0.0001
Intuitive application	1.67	2.0	0.49	1	2	<0.0001

Note. Ratings were made on a 5-point scale (-2 = CHG gel dressing much worse, 2 = CHG gel dressing much better). Sample size = 12 clinicians. SD= Standard deviation.

The order of application of the devices (CHG gel dressing or CHG disk) and the locations (subject's right or left side) were randomized according to a computer generated balanced randomization schedule. For the CHG disk, the instructions call for securing the catheter and the disk to the skin with Bioclusive® Transparent Dressing by Johnson & Johnson™. In this study, 3M™ Tegaderm™ Transparent Dressing by 3M Company was used instead to remove the variable of different dressings.

Study staff recorded the time it took to apply and remove the device and if the device was applied correctly. The clinician evaluated and compared the ease of use and performance of each device after completing the application and removal of both devices on each catheter site (PICC or IJ). The clinicians also completed a comparative questionnaire on the overall product performance of the two devices at the completion of the study. Three study staff members timed the clinicians' application and removal of the products and assessed if the products were correctly applied. A trainer reviewed and trained the study staff on the timing procedure to minimize variability in the assessment.

The assessments of the following product performances were based on a five-point Likert type scale (1= much worse; 2= worse, 3= same as, 4 = better, 5 = much better).

- Overall performance of CHG gel dressing compared with CHG disk.
- Ease of applying CHG gel dressing compared with CHG disk.
- Ease of applying CHG gel dressing correctly compared with CHG disk.
- Ease of removing CHG gel dressing compared with CHG disk.
- Ability to see the IV site through dressing or disk.
- Intuitive nature of applying CHG gel dressing compared with CHG disk.
- Ease of training another clinician to use CHG gel dressing compared with training them to use CHG disk.

The CHG gel and the CHG disk were also assessed for the following on a 1-5 scale (1=very easy to 5=very difficult)

- Ease of applying the catheter dressing.
- Ease of applying the catheter dressing correctly.
- Ease of removal of the catheter dressing.
- Ease of training another clinician to use the device.

Data Analysis

The primary outcome variable was the comparative rating of ease of application of CHG gel dressing compared with that of the CHG disk. This evaluation was designed to detect a 1 point difference from a neutral score of 0, assuming a standard deviation of 1.1 points with 2 sided alpha=0.05 and 80% power. A sample of 12 clinicians was needed to detect this difference.

A one-sample t-test was conducted on the comparative rating scores. The scores were converted from a range of 1 to 5 to a range of -2 to +2 by subtracting 3 from each rating so that 0 is the neutral point. The times required to apply and remove the catheter dressings were analyzed using the paired t-test on the average across catheter sites and for each site separately. The ratings conducted separately on CHG gel dressing and CHG disk were compared using a paired t-test on the average ratings across catheter sites. In addition, each catheter site was analyzed separately. Fisher's exact test was used to test the difference in the percent of clinicians who applied the dressings correctly. Significance was assessed at $p < 0.05$ (2-tailed) for all analyses.

Results

Twelve subjects were screened and enrolled in the study. Fourteen clinicians were contacted, and 12 were recruited into the study. A total of 24 CHG gel dressings and 24 CHG disks were applied on the simulated PICC and IJ sites. No complications or adverse events were reported during the conduct of the study.

After applying and removing both dressings, the clinicians made comparative assessments of the two dressings. The CHG gel dressing was rated significantly better in overall performance ($p < 0.0001$) compared to the CHG disk. All 12 clinicians rated the CHG gel dressing better or much better. The CHG gel dressing was significantly easier to apply compared to the CHG disk ($p < 0.0001$). The CHG gel dressing was also significantly better compared to the CHG disk in ease of correctly applying ($p < 0.0001$), ease of removing ($p = 0.0002$), ability to see the IV site ($p < 0.0001$), ease of training another clinician to use ($p < 0.0001$) and more intuitive to use ($p < 0.0001$). Table 1 summarizes these results.

The time to apply the CHG gel dressing (mean = 70.7 seconds) was significantly shorter ($p = 0.0003$) than the time to apply the CHG disk (mean = 87.3 seconds). The difference in

Table 2: Time To Apply and Remove Catheter Dressings

	IJ (N=12)		PICC (N=12)		IJ and PICC (N=24)	
	CHG Disk	CHG Gel	CHG Disk	CHG Gel	CHG Disk	CHG Gel
Apply dressings						
Mean	88.42	69.83a	86.25	71.50b	87.33	70.67c
Median	84.0	73.5	82.0	68.5	82.0	72.0
SD	19.48	14.22	18.67	18.08	18.69	15.93
Min	66	46	64	46	64	46
Max	125	92	133	109	133	109
Remove dressings						
Mean	33.42	30.67	40.75	36.67	37.08	33.67
Median	33.5	28.5	37.5	36.5	35.5	33.5
SD	11.17	9.58	11.96	11.98	11.92	11.04
Min	15	19	22	18	15	18
Max	52	46	60	55	60	55

Note: a = $p < 0.0008$; b = $p < 0.0028$; c = $p < 0.0003$. Time measured in seconds.

application time was also statistically significant when IJ and PICC sites were analyzed separately ($p = 0.0008$ and $p = 0.0028$ respectively). The difference in removal time was not significantly different between the two products. Table 2 summarizes the time to apply and remove the dressings.

The clinicians also rated a number of factors after applying each dressing. Table 3 summarizes the results of these ratings. CHG gel dressing was rated significantly better than CHG disk for all variables except ease of removal. Ease of removal was not significantly different for PICCs or for PICC and IJ sites combined. For IJ sites, CHG gel dressing was significantly easier to remove than CHG disk ($p = 0.0261$). On average it took 6.46 steps to apply CHG disk and 4.42 steps to apply CHG gel dressing ($p < 0.0001$).

Clinicians applied the CHG gel dressing correctly in 91.7% of the IJ applications and 100% of the PICC applications (see Table 4). The clinicians applied the CHG disk dressings correctly in 83.3% of the IJ applications and 66.7% of the PICC applications. These differences were not statistically significant.

Discussion and Implications for Clinical Practice

The clinicians rated the CHG gel dressing to be statistically better than the CHG disk in the following attributes: overall performance, ease of application, ease of correctly applying, ease of removal, ability to see the IV insertion site, ease of training another clinician in dressing application, and more intuitive application. Twelve out of 12 clinicians rated CHG gel dressing to be statistically better in overall performance. The application of CHG gel dressing is more intuitive. It limits incorrect placement of the CHG gel pad and prevents it from being placed upside down. The application and removal of the CHG gel dressing is similar to that of the 3M™ Tegaderm™ Transparent Adhesive Dressing that is being used in standard practice. Therefore, minimal training is required for the CHG

gel dressing. The CHG disk also requires a standard transparent dressing for securement of the disk and coverage of the catheter insertion site, thus increasing the number of steps to apply and using more staff time.

The components of the CHG gel dressing (the gel pad and the adhesive dressing) are transparent. This allows the health care professionals to visually monitor the catheter insertion sites on a regular basis as recommended in the Centers for Disease Control guidelines (O'Grady et al, 2002). Both CHG gel dressing and CHG disk contain CHG, a well known antiseptic agent with broad spectrum antibacterial and antifungal activity (Denton 2001; Larson, 1995). Both dressings are designed to prevent colonization of skin flora around the catheter insertion site (O'Grady, 2002; Mermel et al, 2001).

Limitations

The study was limited due to the fact that the catheters were secured on the insertion sites using Steri-Strips™ rather than sutures as in actual practice. The study could not account for the challenge or care encountered in placing and removing the catheter dressings to ensure the catheters were not moved in or out of the insertion sites; however, this limitation applied to both the CHG gel dressing and CHG disk applications. Another limitation was the fact that the clinicians were not blinded to the products used. Many of the performance assessments in this study were subjective in nature.

This was a controlled pilot study conducted on healthy volunteers. It excluded many variables that are typically encountered in clinical practice, such as dressing wear time and accumulation of blood and exudates under the dressings. Limitations in methods include the use of a 1 to 5 point scale in detecting a one point difference, on a subjective scale, as statistically significant. The clinical significance of this study needs to be validated in a clinical practice setting.

Table 3. Comparison of CHG Gel Dressing Versus CHG Disk After Each Catheter Dressing Application

	CHG Disk			CHG Gel Dressing			P-value
	Mean	Median	SD	Mean	Median	SD	
IJ site, N=12							
Ease of application	3.92	4.0	0.90	4.75	5.0	0.45	0.0172
Ease of applying correctly	4.00	4.0	0.85	4.67	5.0	0.49	0.0388
Ease of removal	4.33	4.0	0.65	4.83	5.0	0.39	0.0261
Ease of training	3.92	4.0	1.00	4.75	5.0	0.45	0.0172
Conformability	3.83	4.0	0.94	4.83	5.0	0.39	0.0039
Steps to apply	6.67	6.5	1.56	4.42	4.0	1.73	0.0001
PICC site, N=12							
Ease of application	4.00	4.0	0.74	4.75	5.0	0.45	0.0015
Ease of applying correctly	3.92	4.0	0.90	4.83	5.0	0.39	0.0137
Ease of removal	4.00	4.0	0.95	4.50	4.5	0.52	0.1394
Ease of training	4.00	4.0	0.74	4.75	5.0	0.45	0.0055
Conformability	3.83	4.0	1.03	4.83	5.0	0.39	0.0039
Steps to apply	6.25	6.0	1.71	4.42	4.0	1.51	0.0001
IJ and PICC, N=24							
Ease of application	3.96	4.0	0.81	4.75	5.0	0.44	0.0049
Ease of applying correctly	3.96	4.0	0.86	4.75	5.0	0.44	0.0105
Ease of removal	4.17	4.0	0.82	4.67	5.0	0.48	0.0671
Ease of training	3.96	4.0	0.86	4.75	5.0	0.44	0.0061
Conformability	3.83	4.0	0.96	4.83	5.0	0.38	0.0033
Steps to apply	6.46	6.0	1.61	4.42	4.0	1.59	0.0001

Note. Ratings were made on a 5-point scale (1 = very negative, 5 = very positive).

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Conflict of interest statement: The following personnel who were involved in the study are employees of 3M Company (testing facility): Eyberg, volunteers (subjects), study staff who timed and evaluated the correct application of the catheter dressings, the vascular access nurse who demonstrated the application of the CHG gel dressing. The clinicians and the IV infusion therapy health care professional who demonstrated the application of the CHG disk were recruited from outside the testing facility.

3M Institutional Review Board (IRB) reviewed and approved the study protocol and Informed Consent.

This study was conducted according to the International Conference of Harmonization E6, regulation set forth in Part 812 of Title 21 of the *Code of Federal Regulations*, and Guidelines for Good Clinical Practice.

Chou Eyberg, B.S., B.S.,Ch.E., M.S., is a Clinical Research Associate (CRA) who has 6 years of experience working in the clinical research area on medical devices and pharmaceuticals. She has been working with 3M company for 29 years in the health care related Divisions. She is also a certified CRA with the Association of Clinical Research Associate (ACRP.) Conflict of interest: Eyberg is an employee of the testing facility (3M company.)

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Table 4. Frequency of Dressings Correctly Applied

Site	CHG Disk		CHG Gel Dressing	
	Frequency	%	Frequency	%
IJ, N=12	10	83.3	11	91.7
PICC, N=12	8	66.7	12	100.0
IJ and PICC, N=24	18	75.0	23	95.8

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