Minimizing Exposure to Contamination during Indwelling Fecal Drainage System Bag Changes through Closed-System Design

Mary I. Woodell

Abstract

Background: In patients, unmanaged fecal incontinence may trigger a cascade of events that can increase the risk of skin breakdown and decubitus ulcers. For healthcare providers and facilities, the risks include exposure to infectious agents, compromising the environment in which they operate and potentially jeopardizing the health and safety of other patients and healthcare workers. As a result, industry has made a significant effort to improve the management of fecal incontinence through the development of indwelling devices designed to isolate fecal matter from the patient, the provider, and the environment.

The ideal indwelling fecal drainage (IFD) system is designed to contain both feces and odor, thereby reducing contamination risk. During bag exchanges, the typical system is disassembled, resulting in potential exposure to infectious stool. This has significant health and safety implications for patients, healthcare providers, and the environment. We hypothesized that containment system design is a critical determinant of effective management of fecal incontinence and infection control.

Methods: We performed a series of laboratory tests to assess the containment efficacy of various fecal management systems during bag changes. For the purposes of this experiment we used three IFD systems, two with an “open” system design: the ConvaTec FlexiSeal™ Signal™ Fecal Management System and the Hollister InstaFlo™ Indwelling Bowel Catheter System, and one with a “closed” system design: the BARD® DIGNISHIELD® Stool Management System (SMS). Using the manufacturers’ instructions, technicians simulated bag exchange over an absorbent pad and used a UV-sensitive solution to determine the amount of simulated fecal matter that escaped each system.

This procedure was repeated for 30 samples of each manufacturer’s product series. The last sample (sample #30) of each collection system was tested an additional four (4) times with new bags to simulate clinical usage. After each simulated bag change, we examined each device under UV light and measured staining on the collection bag and absorbent pad.

Results: Simulated fecal contamination during bag exchanges was observed as follows. ConvaTec FlexiSeal™ Signal™ Fecal Management System: contamination was found on all thirty-four (34/34) collection bags; staining ranged from 0.009 inches² to 6.790 inches² (average: 1.068 inches²). Sixteen (16/34) absorbent pads were contaminated; staining ranged from 0.023 inches² to 12.410 inches² (average 2.266 inches²). Hollister InstaFlo™ Indwelling Bowel Catheter System: contamination was found on each of the thirty-four (34/34) collection bags tested; staining ranged from 0.001 inches² to 7.651 inches² (average 0.485 inches²). Sixteen (16/34) absorbent pads were contaminated; staining ranged from 0.017 inches² to 7.261 inches² (average 1.015 inches²). BARD® DIGNISHIELD® SMS: Bag changes did not result in any UV-sensitive liquid contamination to either the collection bag or the absorbent pad.

Conclusions: The BARD® DIGNISHIELD® SMS unique self-closing mechanism was designed to prevent leakage of liquid or semi-liquid stool to reduce contamination risk. In this series of simulated bag exchanges, no contamination occurred on or under the collection bag during testing of the DIGNISHIELD® SMS system, which suggests significant reduction of contamination risk, thus protecting patients, healthcare providers, and facilities.
Introduction

Indwelling Fecal Drainage (IFD) systems collect and divert liquid or semi-liquid fecal matter in bedridden patients to minimize skin contact. The systems typically consist of a cuff that is placed in the patient’s rectum, a collection tube, and a replaceable collection bag. In addition to protecting patients from dermal irritation, perineal dermatitis,1 and contamination risk, collection and diversion of stool provides a level of containment, helping to isolate the stool from the caregiver and the clinical environment. The risk to caregivers and to the healthcare environment is significant: Unmanaged fecal incontinence is associated with the potential for outbreaks of diarrhea caused by pathogens such as *Clostridium difficile*, *Escherichia coli*, *Pseudomonas aeruginosa*, and *Klebsiella* spp. Of these, *C. difficile* is especially problematic because it produces many spores that are readily disseminated by direct contact, local airborne spread, and other mechanisms.2 3

IFD systems follow one of two basic design concepts in relation to bag changes. The more common design is an open system design that requires the user to actively manage the fecal matter. The second, a closed system design, does not require active management of fecal material.

The **Bard** IFD catheter (**digniShield**® SMS) has been engineered to provide containment of both feces and odor through closed system design (Figure 1). The valves on both the catheter and collection bag are self-closing to minimize the risk of splatter and spill during bag changes (Figure 2). The proprietary tubing (**Permalene™**) reduces the permeability of the tube to odor-producing compounds.

**Objective**

To assess the efficacy of containment design of the **Bard** **digniShield**® Stool Management System in minimizing release of and exposure to fecal matter during bag exchange, in comparison with other leading commercially available IFD systems.

**Methods**

Three IFD systems were selected for testing, as shown in Table 1; two have an open-system design and one has a fully enclosed system design.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Indwelling Fecal Drainage System</th>
<th>Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>ConvaTec</td>
<td>FlexiSeal™ Signal™ Fecal Management System</td>
<td>418000</td>
</tr>
<tr>
<td></td>
<td>FlexiSeal™ Collection Bags</td>
<td>411102</td>
</tr>
<tr>
<td>Hollister</td>
<td>InstaFlo™ Indwelling Bowel Catheter</td>
<td>33004</td>
</tr>
<tr>
<td></td>
<td>Disposable Collection Bags</td>
<td>31008</td>
</tr>
<tr>
<td>C.R. Bard</td>
<td><strong>digniShield</strong>® Stool Management System</td>
<td>SMS002</td>
</tr>
<tr>
<td></td>
<td><strong>digniShield</strong>® Collection Bags</td>
<td>SMS2B1L</td>
</tr>
</tbody>
</table>

**Testing**

To demonstrate the risk of contamination, a solution composed of water, alcohol, apple butter, and GlitterBug® fluorescent powder was used to simulate fecal matter. The UV-sensitive nature of the solution provided a visible means of quantifying the amount of simulated fecal matter that escaped the system during bag changes, contaminating the exterior surfaces of the bag and/or the absorbent pad.

Following the manufacturer’s instructions included in each IFD system’s packaging, a trained technician connected the bag to the catheter. The GlitterBug® UV solution (1000±25mL) was poured into a funnel such that a pool of fluid would build up without overflowing, and the catheter was milked as necessary to facilitate flow into the collection bag. The technician then separated the collection bag from the catheter, as directed by the manufacturer’s instructions, over the absorbent pad to collect any spillage. The collection bag was then placed on a clean section of drape to be photographed under UV light. This procedure was repeated thirty (30) times with each IFD system.
All catheters were used once except catheter # 30 of each set. In these cases, the same catheter was used with a total of 5 bags to simulate bag exchange for patients requiring multiple bag changes. This method was used to investigate whether repeated bag changes on the same catheter leads to changes in containment efficacy.

Data Analysis
An initial photograph was taken of the first bag sample with a calibrated ruler to establish a linear scale to define measurements for data analysis. All subsequent bags were photographed at the same magnification and distance. Every color digital image was converted to black and white so that each pixel had an intensity value between 0 and 255, where 0 is black and 255 is white.

A target value of 155 was chosen by visual inspection to be the threshold above which the UV-sensitive solution appeared white and below which the uncontaminated surfaces appeared black. In some instances it was necessary to slightly modify the threshold value due to the angle of the full bag in comparison to the UV light source.

The threshold value function within the image analysis software was then applied to the image so that all pixels with intensity above the target value were converted to white and all values below the target value were changed to black. The number of pixels in each contaminated area was then analyzed to provide a total contamination area measurement.

Results
Bag changes completed with the closed system (DIGNISHIELD® SMS) produced no UV-sensitive liquid contamination of exterior surfaces (absorbent pad or collection bag). In addition, repeat analysis of sample #30 did not yield any contamination on the surfaces tested. Bag changes using the two open systems resulted in widely varying degrees of simulated contamination of both the absorbent pad and collection bag, including those used in a repeat analysis of sample # 30. Table 2 presents a summary of results. See Figure 3 for images demonstrating observed contamination.

Table 2: Simulated fecal matter contamination levels documented during bag exchange

<table>
<thead>
<tr>
<th>System</th>
<th>Contamination</th>
<th>Absorbent Pad (inches)</th>
<th>Collection Bag (inches)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ConvaTec</td>
<td>Minimum = 0.023</td>
<td>Maximum = 12.410</td>
<td>Minimum = 0.009</td>
</tr>
<tr>
<td></td>
<td>Average = 2.2664</td>
<td></td>
<td>Maximum = 6.790</td>
</tr>
<tr>
<td></td>
<td>16/34 Samples</td>
<td>34/34 Samples</td>
<td></td>
</tr>
<tr>
<td>Hollister</td>
<td>Minimum = 0.017</td>
<td>Maximum = 7.261</td>
<td>Minimum = 0.001</td>
</tr>
<tr>
<td></td>
<td>Average = 1.0152</td>
<td></td>
<td>Maximum = 7.651</td>
</tr>
<tr>
<td></td>
<td>16/34 Samples</td>
<td>34/34 Samples</td>
<td></td>
</tr>
<tr>
<td>C. R. Bard</td>
<td>No Contamination</td>
<td>No Contamination</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0/34 Samples</td>
<td>0/34 Samples</td>
<td></td>
</tr>
</tbody>
</table>

Figure 3: Example image of contaminated collection bags and absorbent pads for each of the IFD systems as seen under UV light after bag removal. Glowing areas are representative of contamination. The hub components of all three systems, which connect the bag to the drainage tubing, naturally fluoresced under UV light.
Discussion

We set out to determine whether the design of various IFD systems has an impact on their relative risk of exposure to potentially infectious fecal matter contamination. We hypothesized that IFD system design features that fully enclose and contain stool, both while in use and when bags are changed, can limit and potentially eliminate these risks. We assessed and compared the efficacy of a closed containment system design (BARD® DigniShield®) in minimizing release of and exposure to fecal material during bag exchange to two commercially available open-design IFD systems.

Given the inherent risks of contamination during bag exchange, the efficacy of containment as a function of device design in IFD systems is a key factor in risk mitigation. This series of controlled simulations establishes that devices that do not provide fully enclosed containment of stool are highly likely to allow fecal matter to escape and that fecal matter may contaminate the bag and surrounding materials. In contrast, we established that a closed system such as the BARD® DigniShield® Stool Management System is effective in reducing or eliminating the risk of contamination of either the collection bag or the absorbent pad under the conditions used for this test.

To our knowledge this was the first study to compare the containment capabilities during bag exchange of multiple IFD systems on market. The implications of this work for both patients and their caregivers are clear: a closed IFD system design may provide a higher level of protection from exposure to and contamination by fecal material than open systems during bag exchange.

Indication/Contraindications

- The BARD® DigniShield® Stool Management System (SMS) is intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in bedridden patients.
- Do not use for more than 29 consecutive days.
- Do not use on patients known to be sensitive to or allergic to any components within the system.
- Do not use on patients who had lower large bowel or rectal surgery within the last year.
- Do not use on patients with any rectal or anal injury, severe rectal or anal stricture or stenosis (or on any patient if the distal rectum cannot accommodate the inflated cuff), confirmed rectal or anal tumor, severe hemorrhoids, or fecal impaction.
- Do not use on patients with suspected or confirmed rectal mucosa impairment, i.e. severe proctitis, ischemic proctitis, or mucosal ulcerations.
- Do not use on patients with indwelling rectal or anal device (e.g. thermometer) or delivery mechanism (e.g. suppositories) or enemas in place.
- Please consult package insert for more detailed safety information and instructions for use.

Bard and DigniShield are trademarks and/or registered trademarks of C. R. Bard, Inc. All other trademarks are property of their respective owners.

Acknowledgment

The laboratory tests and preparation of this white paper were funded by C. R. Bard, Inc.

References: