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STOOL MANAGEMENT SYSTEM

Containment in the Design of Indwelling Fecal Drainage Catheters: Hydrogen Sulfide Permeation Testing

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KEY WORDS

Clostridium difficile
Containment
Contamination
Fecal incontinence
Indwelling fecal drainage catheter
Laboratory test

Abstract

Background. The ideal indwelling fecal drainage (IFD) catheter is designed to contain both feces and odor, which has implications for patients, healthcare providers, and the environment. In patients, unmanaged fecal incontinence may trigger a cascade of events that have the potential to increase the risk of skin breakdown and decubitus ulcers. Managing fecal incontinence and maintaining infection control practices places a substantial burden on healthcare providers. We hypothesized that the use of a material with low permeability would result in a device that would help contain feces and fecal odor.

Methods. We performed a series of laboratory tests on the tubing of four IFD catheters manufactured by Bard (DigniShield® SMS with Permalene™ polymer tubing), ConvaTec (Flexi-Seal® Signal™ FMS and Flexi-Seal® Control™ FMS), and Hollister (ActiFlo™ Indwelling Bowel Catheter System). Three samples of each product were used to create 22 test articles. To evaluate the permeability of the tubing of each IFD catheter to hydrogen sulfide, we recorded the maximum concentrations escaping through the tubing wall.

Results. Maximum hydrogen sulfide concentrations detected over 8 hours for the tubing of each IFD catheter were 4.7 ppm for Bard, 20.0 ppm for ConvaTec Flexi-Seal® Control™, 21.6 ppm for ConvaTec Flexi-Seal® Signal™, and 17.0 ppm for Hollister ($P < .0001$, t-test). There was no statistical difference between the maximum sulfide concentrations for ConvaTec Flexi-Seal® Signal™ and ConvaTec Flexi-Seal® Control™.

Conclusions. The Bard IFD catheter with Permalene™ polymer tubing was associated with a maximum hydrogen sulfide concentration that was 76% lower than the other three IFD catheters tested. More studies are needed to determine the relevance of these findings.

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Introduction

Fecal incontinence is problematic in the healthcare setting because of its effects on the patient, healthcare providers, and the environment. Unmanaged fecal incontinence can trigger a cascade of events resulting in incontinence-associated dermatitis, erosion of superficial layers of skin, and decubitus ulcers.[1]

Unmanaged fecal incontinence is also associated with environmental problems such as contamination and 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 spores that are readily disseminated by direct contact, local airborne spread, and other mechanisms.[2, 3] Healthcare workers can become inadvertent vectors while caring for infected or colonized patients.[2] Managing fecal incontinence and maintaining infection control practices place a substantial burden on healthcare providers.[4]

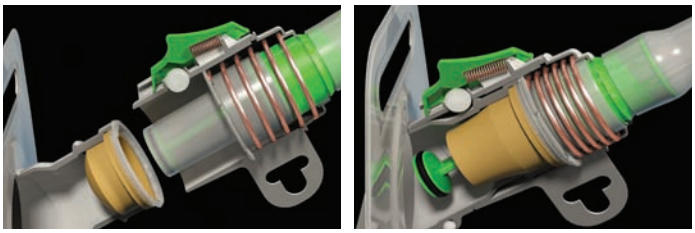
In addition to its impact on healthcare providers and the healthcare environment, fecal incontinence is one of the more psychologically and socially debilitating conditions for patients.[4] Fecal incontinence is embarrassing and can lead to social isolation.[5] Fecal incontinence interferes with quality of life and is one of the reasons for placement in long-term care facilities.[5]

Indwelling fecal drainage (IFD) catheters are designed to overcome the limitations of conventional methods (eg, continence pads) by providing dedicated devices to divert and contain feces in bedridden patients. Use of an IFD catheter was associated with a trend toward a lower prevalence of decubitus ulcers in the surgical intensive care unit in a study by Benoit et al.[6]

IFD catheters are available from three manufacturers and are distinguished by differences in design, dimensions, and construction materials. The Bard IFD catheter (DigniShield® SMS) has been engineered to provide containment of both feces and odor through its design features (Figure 1). The valves on both the catheter and collection bag are self-sealing to minimize the risk of splatter and spill during bag changes (Figure 2). The Bard IFD catheter has a sampling port that can be used to facilitate sampling of feces for microbiologic culture and other studies (Figure 3). The proprietary tubing (Permalene™ polymer) is designed to reduce the permeability of the tube to odor-producing compounds.

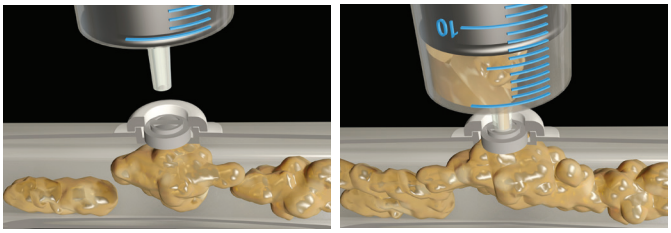
We hypothesized that these design features would result in a device with reduced permeability, which in turn would help contain feces and fecal odor. To test this hypothesis, we studied the relative permeability of available IFD catheter tubings to a gas that is a normal constituent of feces[7, 8] and that can be measured with available testing methods. The IFD catheter tubing was tested as it comprises the most surface area of the IFD catheter.

Figure 1 The Bard IFD catheter (DigniShield® SMS with Permalene™ tubing) is clinically engineered to contain both feces and odor.



Disengaged **Engaged**

Figure 2 The Bard IFD catheter has a unique closed design system to reduce the risk of environmental contamination.



Pre-sampling **Sampling in progress**

Figure 3 The Bard IFD catheter has a sampling port to facilitate stool sampling while minimizing the risk of exposure.

Objective

The objective of this study was to determine the permeability of the Bard IFD catheter tubing to hydrogen sulfide compared with those of three other commercially available IFD catheters in a laboratory model.

Methods

A series of laboratory tests was performed to compare the permeability of the tubing of four IFD catheters:

- Bard: DigniShield® SMS with Permalene™ tubing (Bard Medical, C. R. Bard, Inc., Covington, Georgia)
- ConvaTec: FlexiSeal® Control™ FMS (ConvaTec Professional Services, Skillman, New Jersey)
- ConvaTec: FlexiSeal® Signal™ FMS (ConvaTec Professional Services, Skillman, New Jersey)
- Hollister: ActiFlo™ Indwelling Bowel Catheter System (Hollister Inc., Libertyville, Illinois)

The permeability of the tubing to hydrogen sulfide was determined by Bard Medical Division. The tubing of three units of each type of IFD catheter was sectioned into 22 15-cm test articles. Each tubing section was clamped at one end, 2 mL of water saturated with hydrogen sulfide were added, and the other end was clamped. The test article was immediately inserted into a 19-L container adjacent to the sensor of an automated hydrogen sulfide detector (OdaLog, App-Tek International Pty Ltd, Brendale, Australia), which has a range of 0 to 50 ppm. The container was sealed, and the hydrogen sulfide concentration escaping through the tubing to the container space was measured and recorded every 10 seconds. After 8 hours, the containers were opened and data were downloaded. The maximum hydrogen sulfide concentration for each test article was recorded. The average of the 22 test articles was used as the overall permeability to hydrogen sulfide for each device. The sample size was based on an initial analysis of eight test articles from a single unit of each of the four devices. On the basis of standard deviations from that analysis, we estimated that as many as 22 test articles per device were required to test the statistical hypothesis with 95% confidence that each device would have a maximum average hydrogen sulfide concentration that was at least 2 ppm greater than that of the Bard IFD catheter. Data normality was verified before using a t-test to compare each device against the Bard IFD catheter, with α values of <.05 deemed to indicate statistically significant between-group differences. In cases where the dataset was non-normal, Kruskal-Wallis and Mood's median tests were used to determine statistical significance.

Results

The maximum hydrogen sulfide concentrations measured by Bard Medical Division over 8 hours for each IFD catheter tubing were 4.7 ppm for Bard, 21.6 ppm for ConvaTec Flexi-Seal® Signal™, 20.0 for ConvaTec Flexi-Seal® Control™, and 17.0 ppm for Hollister (Figure 4). Statistical analysis indicated that the hydrogen sulfide concentration measured for the Bard IFD catheter tubing was lower than those for the other IFD catheters tested based on a t-test ($P < .0001$).

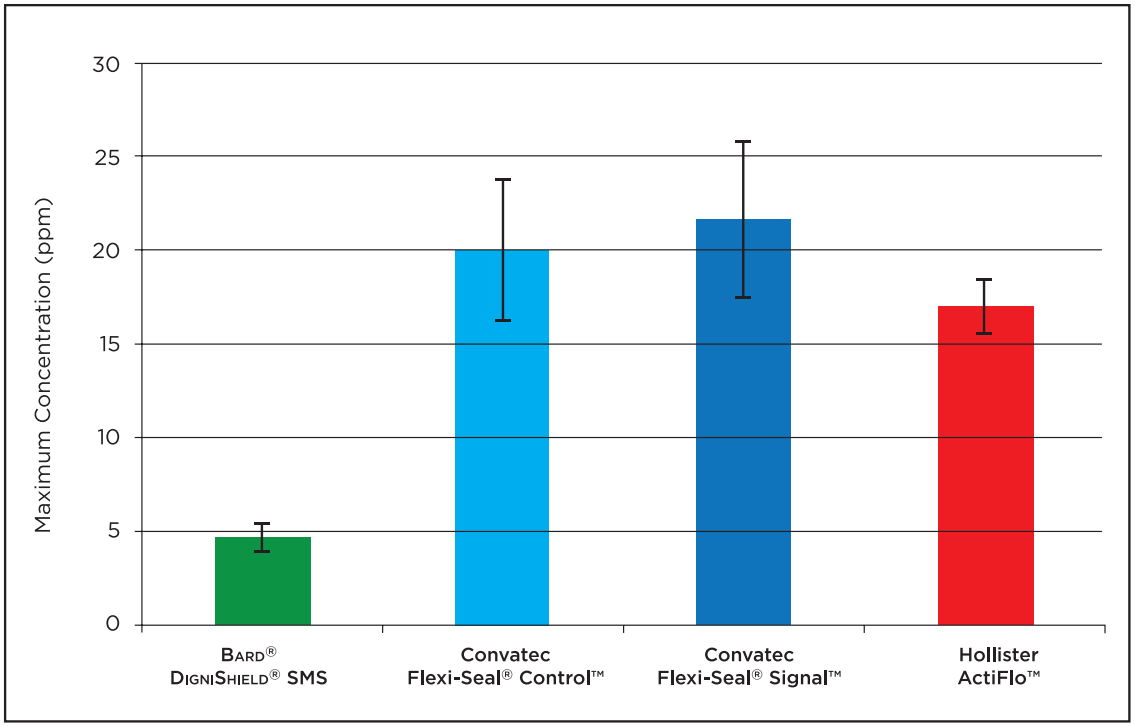


Figure 4 Lower permeability to hydrogen sulfide for Bard IFD catheter tubing versus competitive devices.

Discussion

Feces contain many volatile organic compounds that contribute to the characteristic odor.[7] We chose to evaluate permeability to hydrogen sulfide gas which smells like rotten eggs and is present at a concentration of 19 to 50 ppm in human waste.[8] It was necessary to limit the observation period because hydrogen sulfide degrades to sulfur. Our preliminary tests demonstrated that the hydrogen sulfide concentration detected in control chambers (without test articles) peaked within an hour. As we could not add fresh hydrogen sulfide without opening the container, we opted to measure the concentration over 8 hours.

The Bard IFD catheter tubing was associated with a maximum hydrogen sulfide concentration over 8 hours of only 4.7 ppm, which is 75% lower than the lower limit present in human feces and 76% lower than the average of the other three IFD catheters tested. The difference between the Bard IFD catheter and the other three competitive devices tested was statistically significant.

These laboratory findings suggest that the Bard IFD catheter tubing should help to minimize the risk of odor, but these results may not correlate to performance in humans. For example, the correlation between permeability to hydrogen sulfide measured in a laboratory and odor in the clinical setting is unknown. Therefore, studies are needed to determine the clinical relevance of these findings.

Indications/Contraindications

DigniShield® SMS with Permalene™ polymer tubing is intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in bedridden patients.

DigniShield® SMS with Permalene™ polymer tubing should *not* be used:

- for more than 29 days;
- on patients known to be sensitive or allergic to any components within the system;
- on patients who had lower large bowel or rectal surgery within the last year; or
- on patients with any rectal or anal injury, severe rectal or anal stricture or stenosis (or any patient if the distal rectum cannot accommodate the inflated cuff), confirmed rectal or anal tumor, severe hemorrhoids, or fecal impaction.

Please consult package insert for more detailed safety information and indications for use.

Acknowledgment

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Definitions

- IFD: indwelling fecal drainage
- ppm: parts per million

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