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Odor barrier performance of bowel catheter collection bags

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Introduction

Bowel catheters are used to divert incontinent stool away from the perianal skin and to help prevent contamination of existing wounds and dressings.[1] Appropriate use of bowel catheters has been associated with a reduction in pressure ulcer prevalence,[2] infections,[3] and the cost of linens and dressing changes.[4] One of the most common concerns expressed by clinicians who use these products, however, is fecal odor; they ask about product improvements that could help reduce the odor.

Although there are other sources of odor such as the tubing or leakage, human stool and flatus found within the collection bags can be a source for odors during the use of bowel catheter systems. Many gases are found in human stool and flatus, but the results of prior studies have shown that hydrogen sulfide (H_2S) and methyl mercaptan (MM) are two of the most common malodorous gases found in these substances.[5, 6] Thus, permeation breakthrough time for these gases is an indicator of odor containment performance (higher breakthrough time indicates better odor containment).

The two tables below show the results of two studies conducted on human stool and flatus. The first table shows that when examining malodorous substances of human feces, hydrogen sulfide, and methyl mercaptan were the only sulfur-containing compounds detected.[5]

Table 1: Concentrations of Sulfur-Containing Compounds in Human Feces (n=50)

Type of Gas	Gas	Concentration (ppb)
Sulfur-Containing	Hydrogen sulfide	5-26
	Methyl mercaptan	2-15
	Methyl sulfide	Not detected
	Dimethyl disulfide	Not detected

(Source: Sato, et al, 2002)

In a study of flatus composition,[6] the two sulfur-containing gases comprising the largest percentage of total gas composition for human flatus were hydrogen sulfide and methyl mercaptan.

Table 2: Percentage of Gas in Total Flatus Passed in 4-Hour Period (n=16)

Type of Gas	Gas	Percentage of Total
Non-Odorous	Hydrogen	34.3±17.5
	Carbon dioxide	34.7±14.7
	Methane	5.6±10.4
	Oxygen	3.3±1.9
	Nitrogen	22.2±12.2
Sulfur-Containing	Hydrogen sulfide	2.9±4.0 (x10-3)
	Methyl mercaptan	0.58±0.67 (x10-3)
	Dimethylsulfide	0.19±0.2 (x10-3)

(Source: Suarez, et al, 1997)

Purpose

The purpose of this study was to quantify the odor containment provided by bowel catheter system collection bags. The specific aim was to determine the gas permeation breakthrough of two gases, hydrogen sulfide and methyl mercaptan, through the collection bag film.

Methods

The films of three brands of bowel catheter collection bags were subjected to the study compounds in two separate tests. The test procedures were performed by an independent company (Microanalytics, A MOCON Company, Round Rock, Texas). The test method referenced for this analysis was ASTM F739-85. Each film was analyzed in triplicate.

The first compound used was hydrogen sulfide. The detector for this phase was the Arizona Instruments, Jerome – 631X Hydrogen Sulfide Specific detector. Detection Range: .005 ppm - 50 ppm +/- 5% for Hydrogen Sulfide.

The second compound used was methyl mercaptan in a concentration of 100 ppm using Nitrogen as the carrier gas. The detector for this phase was an Agilent 6890 GC with a Mass Spectrometer.

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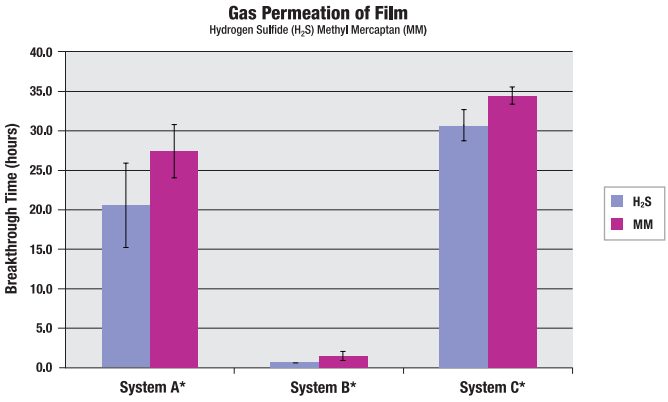
Results



A.ActiFlo Indwelling Bowel Catheter System, Hollister Incorporated, Libertyville, IL
B.DigniCare Stool Management System, Bard Medical Division, Covington, GA
C.Flexi-Seal FMS, ConvaTec Inc., Skillman, NJ

The collection bag films of Systems A and C had a range of MM permeation breakthrough times of 25.3-31.3 and 33.7-35.7, respectively, while the collection bag film of System B had a significantly lower range of MM permeation breakthrough time of 0.9-2.1. The differences in gas permeation times between systems were statistically significant at $p<0.05$.

Similarly, the collection bag films of Systems A and C had a range of H_2S permeation breakthrough times of 17.0-26.7 hours and 29.4-33.0 hours, respectively, while the collection bag film of System B had a significantly lower range ($p<0.05$) of H_2S permeation breakthrough time of 0.5-0.6 hour.

Conclusions

It is reasonable that bowel catheter collection bags would be changed one to two times per day, thus gas permeation breakthrough times of at least 12 hours are desirable. The results of this study show that some, but not all, bowel catheter collections bags exhibit odor containment properties. The collection bags of systems A and C had significantly better odor containment than the collection bag of system B, which had gas permeation breakthrough times of two hours or less. These findings are important to the users of bowel catheter systems, as odor containment is one of the most common concerns expressed by these users.

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ActiFlo Indwelling Bowel Catheter System
Product Information

NON STERILE: The ActiFlo indwelling bowel catheter is constructed primarily of silicone materials. All system components are latex-free. Single patient use only.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician or other healthcare practitioner licensed under state law to order this product. Refer to the complete ActiFlo indwelling bowel catheter system Instructions for Use supplied by the manufacturer for directions on how to properly use this product.

INTENDED USE: The ActiFlo indwelling bowel catheter system is intended for diversion of fecal matter to minimize external contact with the patient's skin, to facilitate the collection of fecal matter for patients requiring stool management, to provide access for colonic irrigation, and to administer enema/medications.

CONTRAINDICATIONS

- Do not use in patients having known sensitivities or allergies to the materials used in this device.
- Do not use if the patient's distal rectum cannot accommodate the inflated volume of the retention cuff or if the distal rectum/anal canal is severely strictured (e.g., secondary to tumor, inflammatory condition, radiation injury, scarring).
- Do not use on patients having impacted stool.
- Do not use on patients with a recent (less than 6 weeks old) rectal anastomosis, or a recent (less than 6 weeks old) anal or sphincter reconstruction.
- Do not use on patients with compromised rectal wall integrity (e.g., ischemic proctitis).
- Do not connect irrigation bag to an IV.
- Do not use irrigation bag for enteral feeding.

WARNINGS

(Failure to comply with the following warnings may result in patient injury)

- Do not use if package is open or damaged.
- Do not use improper amount or type of fluids for irrigation or cuff/balloon inflations. NEVER use hot liquids.
- Do not over inflate retention cuff or stop-flow balloon.
- Inflation of the stop-flow balloon causes complete catheter occlusion. Do not leave stop-flow balloon inflated in an unattended patient. To verify complete deflation of the stop-flow balloon, aspirate all air until RED connector (STOP FLOW 25 mL AIR) pilot balloon is collapsed when the syringe is removed from the connector.
- Use only gravity or slow manual irrigation. Do not connect manual pumping devices to catheter irrigation lumen. Do not irrigate patient with compromised intestinal wall integrity.
- Extreme caution should be exercised in patients at risk for the development of toxic megacolon. Occluding the tube by inflating the stop-flow balloon could aggravate this situation.
- Perform irrigations, and enema/medication administrations, via the CLEAR connector (IRRIG/Rx) AND NOT via the BLUE connector (CUFF 35-40 mL H2O) or RED connector (STOP FLOW 25 mL AIR).
- Blood per rectum should be investigated to ensure no evidence of pressure necrosis from the device. Discontinue use of the device if evident.
- Abdominal distention that occurs while using the device should be investigated.
- Excessive prolonged traction on the catheter, resulting in the retention cuff migrating into the anal canal, could result in temporary or permanent clinical sphincter dysfunction, or catheter expulsion.

PRECAUTIONS

- Do not sterilize.
- The ActiFlo indwelling bowel catheter system is not intended for use longer than 29 days.
- Caution should be used in patients who may bleed easily due to anticoagulant/antiplatelet therapy or underlying disease conditions. Immediately consult a physician if rectal bleeding is suspected
- The ActiFlo indwelling bowel catheter system is not recommended for pediatric use.
- To avoid damage to retention cuff or stop-flow balloon, DO NOT contact either with ANY sharp edge including the enclosed lubricating jelly packets.
- The ActiFlo indwelling bowel catheter system may not be effective in individuals who have had their distal rectum significantly altered by surgical resection or reconstruction.
- Patients with very weak sphincter function may expel the catheter under normal use, or sphincter function.
- Caution should be observed in patients whose rectum may be altered by stricture due to radiation or affected with radiation proctitis.
- Patients with severe tenesmus, or patients who experience tenesmus or severe pain after insertion of device, may not tolerate the catheter in place.
- Avoid inserting anything (e.g., thermometer, suppository, etc.) into the anal canal with the catheter in place to minimize patient injury or catheter damage.
- Care should be taken when disconnecting syringe from the CLEAR connector (IRRIG/Rx). Fluids may drain or splatter from the connector when it is disconnected.
- Use WATER ONLY to inflate retention cuff. Do not use saline solution, which may adversely affect valve function.
- Use AIR ONLY to inflate the stop-flow balloon. Do not use water or any other fluid.
- Do not use vigorous aspiration to remove fluid from the retention cuff or to remove air from the stop-flow balloon. Vigorous aspiration may collapse the inflation lumen and/or pilot balloon and may prevent retention cuff or stop-flow balloon deflation.
- Do not allow ointments or lubricants having a petroleum base (e.g., Vaseline®, petroleum-based hand/body lotion) to contact the catheter. They may damage the silicone and may compromise the integrity of the device.
- Use only Hollister branded bowel catheter collection bags with the ActiFlo indwelling bowel catheter.
- Feces contains infectious material. Protect from splatter which may occur when disconnecting or emptying the collection bags or during catheter removal.
- After use, this system is a biohazard. Handle and dispose of in accordance with institutional protocol and universal precautions for contaminated waste.

ADVERSE EVENTS

- The following adverse events may be associated with the use of any rectal device:
- Perforation
- Pressure necrosis
- Loss of sphincter tone
- Obstruction
- Infection
- Excessive leakage of fecal contents

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