Clostridium difficile Containment Properties of a Fecal Management System: An In Vitro Investigation

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Abstract

Clostridium difficile can cause diarrhea of varying severity; C. difficile cross-contamination is a serious concern in healthcare institutions. The purpose of this study was to evaluate the ability of a fecal management system (FMS) (including both charcoal-filtered and nonfilter collection bags) to contain C. difficile using a stringent, clinically relevant, in vitro model. Fecal management devices were challenged with a high dose of C. difficile-inoculated medium in a simulated fecal effluent over a period of up to 31 days, and microbiological swab samples were taken from different external parts of the device at daily intervals. The medium also was applied to two disposable absorbent underpads, and cultures were obtained daily for a period of 5 days. Microbiological air counts and settle plates were used to collect any airborne C. difficile in close proximity to the FMS and the underpads. Transmission of C. difficile through the absorbent underpad was not detected, but considerable lateral spread of the pathogen across the inner absorbent surface and beyond the perimeter of the test model was observed, indicating suboptimal containment properties. C. difficile was not detected on any part of the external surface of the FMS, including the outer surface of the charcoal filter in the filtered collection bag. No airborne dispersal of C. difficile in the immediate vicinity of the devices was detected. These results show the FMS tested can contain C. difficile and may help reduce the risk of cross-contamination in incontinent patients with C. difficile-associated diarrhea. Observations regarding absorbent pads suggest these products have suboptimal containment properties. Study limitations prevented further exploration of this finding; the study was not designed to evaluate the potential contamination risk associated with rectal leakage around the catheter. Studies comparing the potential role of various fecal containment devices in controlling the spread of C. difficile are warranted.

Keywords: Clostridium difficile, infection control, fecal management system

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Fecal incontinence is a debilitating condition that, if not managed effectively, can cause significant physiological complications and psychological distress to the patient and also can be detrimental to caregivers and healthcare institutions.2 Closed fecal management systems (FMS) are increasingly used to contain and control incontinent diarrhea, an important step not only to maintaining skin integrity and preventing associated complications such as pressure ulcers and infection,1 but also to minimizing the spread of potentially infectious micro-organisms. The pathogen Clostridium difficile is frequently associated with diarrhea and creates a major cross-infection risk due to its survival characteristics. C. difficile is an anaerobic, toxin-producing, spore-forming bacterium reported to inhabit the gut of up to 70% of newborns and 3% of healthy adults.4 Most frequently, it exists as an intruder within the dominant normal gut microflora; when the latter is disrupted (eg, by antibiotic therapy), the C. difficile may proliferate and cause C. difficile infection (CDI). C. difficile virulence is expressed via toxins that cause inflammation and increased permeability of the intestinal cell wall, subsequent diarrhea, and...
degradation of epithelial cells, resulting in the formation of characteristic pseudomembranes. As part of C. difficile's life-cycle, spores are formed and excreted in the diarrhea, rendering it infectious. The spores (containing dormant living cells) are environmentally tolerant and have been reported to survive for as long as 5 months on a floor surface. In the US, it is estimated that up to 20% of hospitalized patients become infected with C. difficile, resulting in almost 3 million cases of diarrhea and colitis every year and making C. difficile the most recognized cause of hospital-acquired infectious diarrhea in the country. This infection is responsible for twice as many deaths of hospitalized patients as methicillin-resistant Staphylococcus aureus. In a recent retrospective, observational clinical study of 278 patients, CDI was associated with a 6.1% mortality rate and extended hospital stays of 2.2 and 4.5 days, respectively.

The economic burden of healthcare-acquired C. difficile infection is widespread, and has recently been investigated using an economic computer simulation model from hospital, third-party payor, and societal perspectives. Median costs per case were up to US $11,456 from the hospital perspective, $11,679 from the third-party payor perspective, and $16,464 from the societal perspective. The model suggests the annual economic burden of CDI in the US would be approximately $1.84 billion. In a recent large, multihospital retrospective study, healthcare-associated CDI was shown to be associated with a higher mean cost and longer length of hospital stay than those of matched controls.

Environmental surfaces (eg, floor, bedrails) in close proximity to hospitalized patients have been shown to be a primary source for transmission of pathogens by direct contact, allowing C. difficile to spread rapidly. In a prospective clinical study, a patient with an infected roommate was found to become infected within an average of 3.2 days following admission, compared with 18.9 days for patients without an infected roommate. In the same clinical study, C. difficile was found on the hands of 59% of hospital personnel caring for patients with CDI. A prospective clinical study showed that within a hospital environment, C. difficile contamination was detected on 49% of sites sampled in proximity to patients with CDI; floors and bedrails were most heavily contaminated, but the pathogen was also frequently found on windowsills, toilets, bed sheets, and medical equipment. Recently, recovery of C. difficile from air samples, as well as environmental surfaces in the vicinity of patients with symptomatic CDI, was demonstrated in a clinical study. C. difficile survives because the spores it produces are highly resistant to environmental challenges, including tolerance to many biocides (eg, alcohol) that are widely used in healthcare institutions.

Considering the ability of C. difficile to spread rapidly by direct contact, tolerate environmental conditions for long periods, and resist eradication by many biocides, infection control measures such as appropriate hand hygiene, use of personal protective equipment (eg, disposable gloves and gowns), environmental decontamination, and patient isolation are key to restricting and confining this bacterium and reducing the burden of CDI within the hospital environment. In patients with C. difficile-associated diarrhea, the use of enclosed fecal management devices may be an additional consideration in the containment of this hardy pathogen. FMS generally include products that contain diarrhea (eg, absorbent pads or diapers) or rely on a tube to drain effluent away from the patient (ie, external fecal collectors and indwelling retention drainage devices). However, absorptive products do not provide closed-system and are associated with frequent changing of dressings and soiled linens; additionally, these methods do not adequately remove fecal material from the perineal area, which may lead to skin breakdown and infection. Fecal collectors or pouches are considered a better option to contain diarrhea. These devices can be left in place for several days, but external fixation of the skin barrier can be problematic in cases of denuded skin or a lack of potential adherent surface.

Modern indwelling rectal catheters are designed to collect and direct liquid stool away from the bodies of immobilized patients. One such device, the Flexi-Seal® Fecal Management System (FS FMS) (Convatec Inc., Skillman, NJ), is indicated for patients who are temporarily incontinent (≤ 29 days) of liquid or semi-liquid stool. This FMS consists of a soft silicone catheter that is inserted directly into the rectum and held in place by a retention balloon. The closed-end system has a bag at the distal end to collect liquid stool, diverting it away from the patient’s skin, minimizing contact with effluent, and thereby helping maintain skin integrity (see Figure 1).

The objective of the current study was to assess the effectiveness of the FS FMS in containing C. difficile using a stringent in vitro model that closely simulated clinical use.

Materials and Methods

The FMS catheter was tested with and without charcoal-filtered collection bags (see Figure 2). A generic flat disposable
Absorbent underpad, commonly used in the management of fecal incontinence, was tested as a comparator. Test material selection was based on comparison between the most advanced type of technology and a traditional and widely used containment method.

The microbiological culture media used in this study included reinforced clostridial medium (RCM) containing a low concentration (0.55%) of bacteriologic agar (to grow C. difficile in a slushy, oxygen-deficient medium to simulate semi-liquid stool), fastidious anaerobe agar (FAA) plates (to culture C. difficile following sampling), blood agar plates (for environmental settle plates), and blood agar contact plates (for air sampling). The C. difficile challenge organism was a clinical isolate previously recovered from a chronic leg ulcer.

The RCM semi-liquid medium was inoculated with single colonies of C. difficile from a plate culture and incubated at 35°C for 48 hours to achieve a working concentration of >1 x 10⁷ colony forming unit (CFU)/mL. A subsequent plate culture and Gram stain also were performed to confirm the presence and viability of C. difficile (including spores). The number of spores visualized by light microscopy was reported semi-quantitatively (i.e., + = few spores, ++++ = copious spores).

C. difficile-containment properties of both the test and positive control devices then were investigated over a period of up to 31 days using several traditional microbiological methods. First, four study FMS devices were assembled according to the manufacturer’s instructions and positioned as they would be in clinical use (i.e., the retention balloon end of the device placed at a level approximately 1 meter above the fecal collection bag). The base of the silicone catheter was clamped to prevent the collection bag from filling excessively (1,000-mL capacity). The retention balloon then was filled via the balloon inflation port.

To ensure that C. difficile cells would penetrate the test device if breaches naturally existed, a positive control also was included in the study by deliberately creating pinholes (using a sterile needle) in the upper, middle, and lower sections of a FMS silicone catheter and also on the front and back of the fecal collection bag.

Sterile swabs were used to sample multiple sites on the outside of each device (e.g., silicone catheter, catheter and...
balloon irrigation ports, and fecal collection bags (see Figure 3) on a daily basis (excluding weekends). Sampled swabs then were transferred to FAA plates and incubated at 35°C for at least 48 hours under anaerobic conditions to culture C. difficile. Additionally, 90-mm blood agar settle plates were placed on a flat surface up to 300 mm in distance from each test model for approximately 2 hours to collect any settling airborne C. difficile cells that may have been dispersed from the devices. Finally, a surface air sampler (SAS, Cherwell Laboratories, UK) was used to sample air in close proximity to the test devices to capture any airborne cells that may have dispersed from the test devices. Settle and air count plates were similarly incubated under anaerobic conditions for a minimum of 48 hours.

Second, to provide a clinically relevant comparison, an in vitro bacterial barrier model was used to assess the effectiveness of a disposable, flat, absorbent underpad containing C. difficile over a 5-day period (see Figure 4). Two underpads were separately sandwiched between sterile glass flanges, and the patient contact side of the pad was challenged with C. difficile-inoculated medium (>1 x 10^7 CFU/mL) added via the U-shaped inlet port (see Figure 4). C. difficile transmission through the underpad was assessed by swabbing the outer unchallenged side of the pad over a 5-day period (days 1, 2, and 5) via the outer flange portholes. Swabs then were transferred to separate FAA plates, incubated anaerobically for ≥48 hours, and observed using the same methods as described for the FMS devices.

Additional testing was performed with the FMS device using a fecal collection bag that contains a 3-µm pore size charcoal filter for odor control (this collection bag is used in the FMS-S device. See Figure 2). Three bags were connected to separate FMS devices and the models situated as described previously. C. difficile-inoculated medium was introduced via the retention balloon end of the silicone catheter, and the filtered collection bag was challenged with approximately 300 mL of medium (1,000-mL bag capacity). The base of the silicone catheter then was clamped and an additional 300 mL of C. difficile-inoculated semi-liquid medium was added to fill the catheter up to the position indicator line. To more closely simulate clinical use, the clamp from the base of the catheter was removed on a daily basis and approximately 150 mL of challenge medium in the silicone catheter was flushed into the filtered collection bag. The base of the catheter then was clamped again and the catheter was refilled with 150 mL of new C. difficile-inoculated medium. When the filtered collection bags were filled almost to capacity (days 4 and 8), they were aseptically removed and replaced with new bags. This study was performed over 11 days, which was sufficient to rigorously investigate the containment properties of the filtered fecal collection bag.

A positive control filtered collection bag also was included in the study. Pinholes were deliberately created (using a sterile needle) on the front and rear of the bag, behind the front flange connector, and through the charcoal filter. Daily swab samples were taken from the outer surface of the filtered collection bags and processed as described previously. Airborne contamination with C. difficile in the immediate vicinity of the test models devices also was measured using settle plates and air sampling as described previously.

The viability of C. difficile was confirmed for the FMS devices (including positive controls) and the absorbent underpads at the start and end of the test period.

**Results**

C. difficile was not recovered from the outside of any of the FMS devices over the challenge period (see Table 1 and Table 2). Settle plate and air samples taken in close proximity to the devices also were not contaminated with C. difficile.

The positive control devices (punctured FMS devices with filtered and nonfiltered collection bags) failed to contain C.
difficile; growth was detected at the sites where the pinholes were created (see Figure 5). Additionally, C. difficile was detected on the blood agar settle plates positioned around the FMS positive control device, but air samples were negative for C. difficile.

Vertical transmission of C. difficile to the outside of the underpad was not detected over the 5-day test period (see Table 3). However, the underpad was observed to absorb and laterally wick much of the C. difficile-inoculated medium across the absorbent inner surface and beyond the perimeter of the test model, causing the volume of the challenge medium to fall within the barrier models, making it necessary to add extra C. difficile-inoculated medium to ensure the entire surface area of the underpad was continually challenged throughout the test period. Despite lateral spread of C. difficile beyond the perimeter of the test apparatus, no environmental contamination from the air samples or settle plates was observed.

At the conclusion of testing, a culture of the C. difficile-inoculated medium confirmed a high population of C. difficile (including spores) and hence bacterial viability throughout the test periods.

Discussion

Best practice in the management of fecal incontinence is essential to minimizing the burdens on patients and healthcare institutions. Fecal management also may be an important consideration along with standard methods (eg, adequate disinfection, disposable gloves and aprons, hand hygiene, patient isolation) to minimize the spread of infection, particularly regarding patients colonized with C. difficile or with CDI. The environmental and biocide tolerance of this bacterium, together with its potential virulence, make it a formidable pathogen that must be contained.
The objective of the current study was to stringently challenge a FMS using a large population of viable C. difficile bacteria and determine whether the device was able to contain the bacterium in a model that simulated clinical use. Rigorous sampling of intact devices (FMS with filtered and nonfiltered collection bags), demonstrated no outward transmission of the pathogen, and C. difficile containment was supported further by the fact that no environmental contamination was detected in the vicinity of the test models. Despite two bag changes in the filtered collection bag study over an 11-day period, transmission and airborne dispersal of C. difficile were not detected. None of the air samples taken in close proximity to any of the devices (including positive controls and absorbent underpads) detected airborne C. difficile. This suggests that airborne transmission of the pathogen is less likely than direct contact (e.g., via hands, bed linen, and medical equipment). However, Best et al. have recently demonstrated in the clinical setting that airborne transmission of C. difficile was evident in the vicinity of seven out of 10 patients with symptomatic CDI, compared with environmental surface contamination in nine out of the same 10 patients. Although culture results were also negative for the absorbent underpads, lateral wicking of the simulated infectious diarrhea across the underpad and beyond the perimeter.

![Table 1. Fecal management system (FMS) C. difficile culture results (+ = few spores, ++++ = copious spores)](image-url)
of the test model was observed. This is the first published study evaluating the potential transmission and airborne dispersal of C. difficile using a FMS or underpad.

Although best efforts were made to simulate clinical use of the FMS in this in vitro study, it was not possible to replicate certain clinical procedures, such as insertion of the catheter retention balloon into the patient’s rectum. Consequently, this in vitro study could not account for potential leakage around the device where it is inserted into the patient’s rectum. In a prospective, single-arm clinical study,20 use of FMS in 42 patients was associated with minimal or no leakage in 83% of 198 daily assessments, and skin integrity was either maintained or improved in more than 92% of patients during the use of FMS.

Table 2. Fecal management system (FMS) filtered fecal collection bag C. difficile culture results (+ = few spores, ++++ = copious spores)

<table>
<thead>
<tr>
<th>Swab sites (sampled daily up to 11 days, inclusive of bag changes)</th>
<th>Swab sample data: FMS device coupled to a filtered fecal collection bag (3-µm charcoal filter)</th>
<th>Filtered Collection Bag Positive Control (punctured)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collection bag (behind front flange connector)</td>
<td>No growth</td>
<td>No growth</td>
</tr>
<tr>
<td>Collection bag (front pouch)</td>
<td>No growth</td>
<td>No growth</td>
</tr>
<tr>
<td>Collection bag (rear pouch)</td>
<td>No growth</td>
<td>No growth</td>
</tr>
<tr>
<td>Collection bag (charcoal filter)</td>
<td>No growth</td>
<td>No growth</td>
</tr>
</tbody>
</table>

C. difficile viability (spore count):

<table>
<thead>
<tr>
<th>Initial challenge (at start of test)</th>
<th>Growth (++++)</th>
<th>Growth (++++)</th>
<th>Growth (++++)</th>
<th>Growth (++++)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final challenge (at end of test – day 11)</td>
<td>Growth (++++)</td>
<td>Growth (++++)</td>
<td>Growth (++++)</td>
<td>Growth (++++)</td>
</tr>
</tbody>
</table>

Table 3. Disposable absorbent underpad C. difficile culture results (+ = few spores, ++++ = copious spores)

<table>
<thead>
<tr>
<th>Swab sites (sampled over 5 days)</th>
<th>Swab results: disposable flat absorbent underpad</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outer unchallenged side of pad (Porthole 1)</td>
<td>No growth</td>
</tr>
<tr>
<td>Outer unchallenged side of pad (Porthole 2)</td>
<td>No growth</td>
</tr>
<tr>
<td>Outer unchallenged side of pad (Porthole 3)</td>
<td>No growth</td>
</tr>
<tr>
<td>Outer unchallenged side of pad (Porthole 4)</td>
<td>No growth</td>
</tr>
<tr>
<td>Outer unchallenged side of pad (Porthole 5)</td>
<td>No growth</td>
</tr>
</tbody>
</table>

C. difficile viability (spore count):

<table>
<thead>
<tr>
<th>Initial challenge (at start of test)</th>
<th>Growth (++++)</th>
<th>Growth (++++)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final challenge (at end of test; day 5)</td>
<td>Growth (++++)</td>
<td>Growth (++++)</td>
</tr>
</tbody>
</table>
Preliminary clinical studies on the budget impact of FMS as part of a protocol-of-care suggest a potential to reduce the frequency of bedding and dressing changes and thus decrease the costs associated with consumables and nursing time.\textsuperscript{20,21} Certainly, the potential economic and clinical benefits with regard to the use of closed fecal containment systems such as the study FMS and the reduction of C. difficile transmission are complex and require additional clinical research encompassing device cost, nursing time, costs of antibiotic treatment, CDI incidence, and length of hospital stay. However, considering the high costs associated with CDI, the use of additional measures to help reduce the incidence of this infection may well be justified.\textsuperscript{22,23} Given the competing demands for nurses’ time and resources, multiple potential benefits are associated with implementing a method to manage fecal incontinence that optimizes patient care while minimizing the risk of cross-contamination.

Conclusion

The results from this 31-day in vitro study show that a FMS (with filtered and nonfiltered collection bags) contains C. difficile. Absorbent underpads contained C. difficile during 5 days of use, although lateral wicking beyond the perimeter of the test area was observed. Because C. difficile dissemination is known to occur by both airborne transfer and contact with environmental surfaces, a protocol-of-care that includes containment of fecal incontinence may help reduce the risk of CDI outbreaks in healthcare institutions. Further clinical evidence in support of current scientific observations are warranted.
Reference List