

Cuff Pressure and Friction in the Design of Indwelling Fecal Drainage Catheters

D. Claire Gloeckner, PhD^a and Steven A. Carleo, MS^a

^aEmployees of C. R. Bard, Inc., Covington, Georgia

KEY WORDS

Fecal incontinence
Friction
Indwelling fecal drainage catheter
Laboratory test
Retention cuff pressure
Shear

Abstract

Background. The ideal indwelling fecal drainage (IFD) catheter contains stool and is safe for patients. Pressure and friction exerted by the retention cuff on rectal mucosa are thought to contribute to the risk of tissue necrosis and other device-related trauma in patients with fecal incontinence. We hypothesized that a device could be designed with a compliant material that would better conform to the patient's anatomy, optimizing sealing and minimizing leakage. Ideally, the cuff material would also contribute to minimizing pressure.

Methods. We performed two laboratory tests on IFD catheters manufactured by Bard (DigniShield™ Stool Management System with PERMALENE™ polymer tubing or DIGNICARE® SMS), ConvaTec (FlexiSeal® Signal FMS), and Hollister (ActiFlo™ Indwelling Bowel Catheter System); a clinical study was conducted on the same devices. To evaluate retention cuff pressure, we measured resting cuff pressure at 10-mL increments to the rated fill volume for each device (35 or 40, and 45 mL). To evaluate coefficient of friction at the outer diameter of the cuff, we used American Society for Testing and Materials (ASTM) standards in wet condition. To evaluate retention cuff pressure in healthy adult volunteers, Marchetti et al¹ conducted a randomized pilot study and measured pressure with subjects in three body positions and three head-of-bed elevations.

Results. Average resting retention cuff pressures at maximum recommended fill volumes for each IFD catheter were 20.2 mmHg for Bard, 53.3 mmHg for ConvaTec, and 40.8 mmHg for Hollister. Corresponding average coefficients of friction were 0.28, 0.52, and 0.51. Average cuff pressures for each IFD catheter with subjects in supine position were 32.1 mmHg for Bard, 81.2 mmHg for ConvaTec, and 77.8 mmHg for Hollister. Corresponding averages at 30° head-of-bed elevation were 35.1, 82.4, and 73.8 mmHg.

Conclusions. The Bard IFD catheter was associated with an average resting cuff pressure that was 57% lower than that of the control IFD catheters at rated fill volumes and a coefficient of friction that was 46% lower than that of the control IFD catheters. The Bard IFD catheter was also associated with a cuff pressure that was 60% lower than that of the control IFD catheters with subjects in supine position and 55% lower at 30° head-of-bed elevation. More studies are needed to determine the relevance of these findings.

Introduction

Fecal incontinence is problematic because of patient complications related to leakage. Fecal incontinence occurred in 33% of tube-fed and non-tube-fed patients in acute and critical care units in a study by Bliss et al² and 46% of inpatients in a long-term care hospital in a study by Borrie et al.³ In a literature review, Gray et al⁴ determined that 10% to 15% of hospitalized patients treated with antibiotics will develop antibiotic-associated diarrhea. Fecal incontinence can cause medical complications that range in severity from mild skin irritation to profound perineal dermatitis, dehydration, electrolyte imbalance, and sepsis.^{5,6} Skin necrosis, the precipitating event for many of these complications, occurred in 43% of incontinent patients in a surgical intensive care unit as reported by Benoit et al.⁶

Indwelling fecal drainage (IFD) catheters are designed to overcome the limitations of conventional stool management methods (eg, continence pads) by providing dedicated devices to divert and contain feces in bedridden patients. In the clinical setting, the ideal IFD catheter effectively contains stool and is safe for patients. It is widely reported that tissue necrosis is further aggravated by the combined forces of friction and shear.⁷⁻¹¹ Friction, the result of movement between the IFD catheter and rectal mucosa, often occurs during patient repositioning. Shearing force, the result of an opposite, parallel sliding motion, may also occur. These mechanical effects are exacerbated in incontinent patients by the presence of liquid stool contacting the skin and increasing the risk of ischemia and tissue necrosis. Use of an IFD catheter as part of an aggressive decubitus ulcer prevention program was associated with a lower prevalence of skin necrosis as reported by Benoit et al.⁶

IFD catheters are available from three manufacturers (Table 1). The retention cuffs on all three devices are made of silicone, a synthetic polymer used for decades in many medical devices because of its biocompatibility and rubber-like properties.^{12,13} The cuffs are distinguished by differences in design and dimensions (Figure 1). The cuff on DIGNISHIELD™ SMS was engineered to provide atraumatic, low-pressure sealing through its design features. This cuff has a large surface area, intended to distribute the force of the cuff over a large area of the mucosal surface. This force distribution translates to low pressure on the rectal mucosa according to a basic formula. Additionally, this cuff is identical to the DIGNICARE® SMS retention cuff; its low-pressure design has been demonstrated clinically in a recently published study of adult volunteers.¹

$$\text{Pressure} = \frac{\text{Force}}{\text{Area}}$$

Table 1. Indwelling fecal drainage catheters

Manufacturer	Device Name	Rated Fill Volume (mL)
Bard Medical, C. R. Bard, Inc., Covington, Georgia	DIGNISHIELD™ SMS with PERMALENE™ polymer tubing or DIGNICARE® SMS	45
ConvaTec Professional Services, Skillman, New Jersey	FlexiSeal® Signal FMS	45
Hollister Inc., Libertyville, Illinois	ActiFlo™ Indwelling Bowel Catheter System	35 or 40



Figure 1 Differing designs and dimensions of indwelling fecal drainage catheter retention cuffs

We hypothesized that these design features would result in a device with reduced cuff pressure and friction. To test this hypothesis, we studied the relative pressures exerted by the retention cuffs of available IFD catheters and their coefficients of friction in laboratory models. We also reviewed a clinical study.¹

Objective

- To determine the relative pressure exerted by the retention cuff of the Bard IFD catheter and its coefficient of friction compared with those of two control IFD catheters in a laboratory model
- To determine the pressure observed in the cuff of the Bard IFD catheter compared with that of two control IFD catheters in human volunteers

Methods

Laboratory testing was performed to compare the resting cuff pressures and coefficients of friction of three IFD catheters (data on file). A pilot clinical study was conducted to compare the retention cuff pressures of three IFD catheters; this study has been published and is described briefly.¹

Resting retention cuff pressure was measured by digital manometer. After evacuation of residual air from the cuff, the pressure manometer (Dwyer Series 477, Michigan City, Indiana) and a 60-mL syringe (Becton Dickinson, Franklin Lakes, New Jersey) were attached to the inflation port of the catheter via three-way stopcock (Qosina, Edgewood, New York). The stopcock was turned toward the catheter and manometer, and the device was set to zero. The stopcock was turned toward the catheter and syringe, and each cuff was inflated with 10 mL of water (ie, suboptimal fill). The stopcock was turned toward the manometer, and cuff pressure was measured and recorded. The process was repeated at 10-mL increments to a cumulative total of 40 mL. The process was repeated at 45 mL to simulate the rated fill volume for the Bard and ConvaTec IFD catheters; the process was not repeated at 45 mL for the Hollister IFD catheter because its rated fill volume was 35 or 40 mL. All three rated volumes were determined from the respective product instructions for use. The sample size of 10 per device was based on historical data for cuff pressure testing of a similar device. The statistical hypothesis tested was that each control device would have a maximum pressure that was at least 5 mmHg greater than that of the Bard IFD catheter using a 95% confidence level.¹⁴ Data normality was verified before using a t-test to compare each control device against the Bard IFD catheter, with a values of <.05 deemed to indicate statistically significant between-group differences.

The coefficient of friction on the cuff outer diameter was determined by American Society for Testing and Materials (ASTM) standards in wet condition. Specifically, the coefficient of friction was determined in general accordance with ASTM G133 Procedure A (2005)¹⁵ with minor modifications to accommodate the physical characteristics of test samples. Testing was performed by EP Laboratories, Inc. (Irvine, California), an independent testing laboratory that specializes in providing high-quality testing and characterization of materials. Fifteen coefficient of friction tests were conducted on the Bard IFD catheter and five on each of the other IFD catheters.

Cuff pressure was determined by manometry in a randomized, crossover, open-label study of 10 healthy adult volunteers in three body positions (supine, right side, and left side) and three head-of-bed elevations (20°, 30°, and 40°). Sample size was based on convenience and feasibility.¹

Results

Average IFD catheter resting retention cuff pressures at the rated fill volume of 45 mL were 20.2 mmHg for Bard and 53.3 mmHg for ConvaTec (Figure 2). Average pressure at the rated fill volume of 40 mL was 40.8 mmHg for Hollister. Statistical analysis indicated that average pressure in the Bard cuff was lower than in the two control IFD catheter cuffs at these maximum rated fill volumes based on a t-test at the 95% confidence level ($P < .0001$).

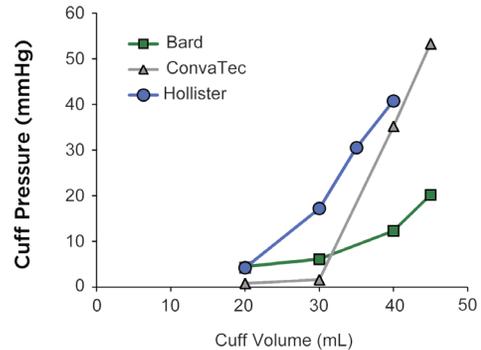


Figure 2 Lower average cuff pressure for Bard IFD catheter versus controls.

Average coefficients of friction on IFD catheter cuff outer diameters were 0.28 for Bard, 0.52 for ConvaTec, and 0.51 for Hollister (Figure 3).

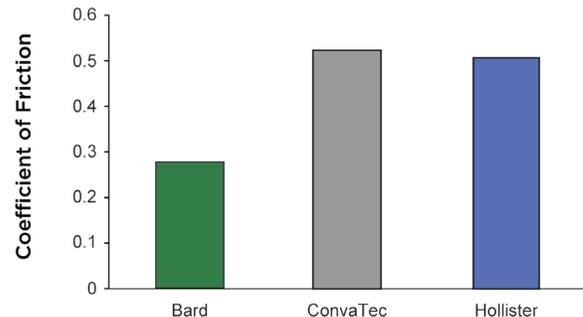


Figure 3 Lower coefficient of friction for Bard IFD catheter versus controls

Average IFD catheter cuff pressures with subjects in supine position were 32.1 mmHg for Bard, 81.2 mmHg for ConvaTec, and 77.8 mmHg for Hollister (Figure 4). Corresponding averages at 30° head-of-bed elevation were 35.1, 82.4, and 73.8 mmHg. Similar findings were observed for other body positions and elevations.¹

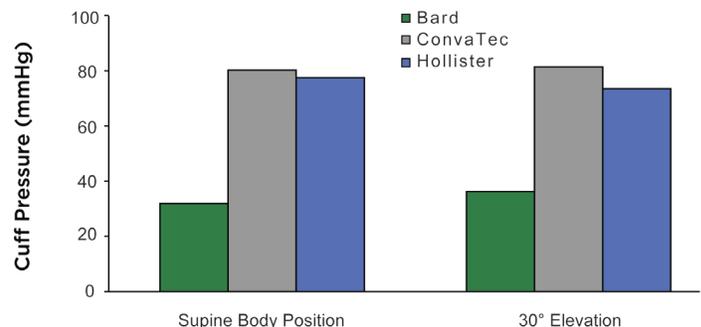


Figure 4 Lower retention cuff pressure with subjects in supine position and at 30° head-of-bed elevation for Bard IFD catheter versus controls. Adapted from Marchetti et al, 2011.¹

Discussion

The Bard IFD catheter was consistently associated with lower retention cuff pressure than those of two control IFD catheters. The average resting cuff pressure of the Bard IFD catheter was 57% lower than those of the control devices at rated fill volumes in a laboratory study. As expected, cuff pressures of each IFD catheter were higher in humans than in the laboratory. Nonetheless, the cuff pressure of the Bard IFD catheter was 60% lower than those of the control devices with subjects in supine position and 55% lower with 30° head-of-bed elevation.¹

The amount of pressure transmitted to the rectal mucosa and other clinical implications of these findings are unknown. The exact microvascular pressure in the human rectum is unknown, but the capillary hydrostatic pressure elsewhere in the body ranges from approximately 17 mmHg at the venous end to 35 mmHg at the arterial end.¹ The cuff pressures measured for the two control IFD catheters exceeded these capillary pressure values both in the laboratory and in human volunteers, whereas the cuff pressure for the Bard IFD catheter was consistently within this range.

The Bard IFD catheter was also associated with a coefficient of friction on the cuff outer diameter that was 46% lower than those of the two control IFD catheters.

Collectively, these laboratory and pilot clinical findings suggest that the Bard IFD catheter should help to minimize pressure and friction, but these results may not correlate to performance in patients with fecal incontinence. Therefore, studies are needed to determine the relevance of these findings and whether lower resting retention cuff pressure and coefficient of friction will translate to improved patient safety or comfort.

Indication/Contraindications

DIGNISHIELD™ SMS with PERMALENE™ polymer 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 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.

Acknowledgment

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

Definitions

- ASTM: American Society for Testing and Materials
- Friction: the result of movement between two objects
- IFD: indwelling fecal drainage
- Pressure: the quotient of force divided by area
- Shearing force: the result of an opposite, parallel sliding motion

DIGNISHIELD is a trademark of C. R. Bard, Inc. All other trademarks are property of their respective owners.

References

1. Marchetti F, Corallo JP, Jr., Ritter J, Sands LR. Retention cuff pressure study of 3 indwelling stool management systems: randomized study of 10 healthy subjects. *J Wound Ostomy Continence Nurs.* 2011;38(5):569-573.
2. Bliss DZ, Johnson S, Savik K, Clabots CR, Gerding DN. Fecal incontinence in hospitalized patients who are acutely ill. *Nurs Res.* 2000;49(2):101-108.
3. Borrie MJ, Davidson HA. Incontinence in institutions: costs and contributing factors. *CMAJ.* 1992;147(3):322-328.
4. Gray M, Bliss DZ, Doughty DB, Ermer-Seltun J, Kennedy-Evans KL, Palmer MH. Incontinence-associated dermatitis: a consensus. *J Wound Ostomy Continence Nurs.* 2007;34(1):45-54; quiz 55-46.
5. Beitz JM. Fecal incontinence in acutely and critically ill patients: options in management. *Ostomy Wound Manage.* 2007;52(12):55-66.
6. Benoit RA, Jr., Watts C. The effect of a pressure ulcer prevention program and the bowel management system in reducing pressure ulcer prevalence in an ICU setting. *J Wound Ostomy Continence Nurs.* 2007;34(2):163-175; quiz 176-177.
7. Hanson D, Langemo DK, Anderson J, Thompson P, Hunter S. Friction and shear considerations in pressure ulcer development. *Adv Skin Wound Care.* 2010;23(1):21-24.
8. Nix D. Prevention and treatment of perineal skin breakdown due to incontinence. *Ostomy Wound Manage.* 2006;52(4):26-28.
9. Lahmann NA, Tannen A, Dassen T, Kottner J. Friction and shear highly associated with pressure ulcers of residents in long-term care - Classification Tree Analysis (CHAID) of Braden items. *J Eval Clin Pract.* 2010;17(1):168-173.
10. Bennett L, Kavner D, Lee BK, Trainor FA. Shear vs pressure as causative factors in skin blood flow occlusion. *Arch Phys Med Rehabil.* 1979;60(7):309-314.
11. Goossens RH, Zegers R, Hoek van Dijke GA, Sniijders CJ. Influence of shear on skin oxygen tension. *Clin Physiol.* 1994;14(1):111-118.
12. Colas A, Curtis J. Silicone Biomaterials: History and Chemistry. In: Ratner BD, Hoffman AS, Schoen FJ, Lemans JE, eds. *Biomaterials Science: An Introduction to Materials in Medicine.* 2nd ed. San Diego: Elsevier Academic Press; 2004:80-86.
13. Curtis J, Colas A. Medical Applications of Silicones. In: Ratner BD, Hoffman AS, Schoen FJ, Lemans JE, eds. *Biomaterials Science: An Introduction to Materials in Medicine.* 2nd ed. San Diego: Elsevier Academic Press; 2004:697-707.
14. Juran J, Godfrey AB. *Juran's Quality Handbook.* 5th ed. New York: McGraw-Hill Professional; 1998.
15. ASTM Standard G133 (2005) Standard Test Method for Linearly Reciprocating Ball-on-Flat Sliding Wear. In: ASTM International, ed. West Conshohocken, PA.

BARD | MEDICAL

C. R. Bard, Inc.
8195 Industrial Boulevard
Covington, GA 30014
1.800.526.4455
www.bardmedical.com

Please consult product inserts and labels for any indications, contraindications, hazards, warnings, cautions and directions for use.

Bard, DigniShield, DigniCare and Permalene are trademarks and/or registered trademarks of C. R. Bard, Inc. All other trademarks are property of their respective owners. ©2011 C. R. Bard, Inc. All Rights Reserved. 1102-31 R02/11