Stool Management: Advanced Technology Performance with a Safe Solution for Fecal Containment in Incontinent Patients

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ABSTRACT

PURPOSE: To evaluate the safety and efficacy of a novel intrarectal device intended to manage fecal incontinence in hospitalized bedridden patients through non-clinical and clinical testing.

BACKGROUND: In an acute care setting the incidence of fecal incontinence (FI) can occur from 17% to 33%, according to the Wound Ostomy Continence Nursing (WOCN) Society's Continence Committee. "Intended for use primarily in acute care settings, intra-anal management systems are developed for insertion into the rectal vault for diversion of liquid stool away from the skin in immobile patients" (WOCN Society's Continence Committee, 2013, p. 12). A new stool management system has been designed to manage FI in non-ambulatory patients and has proven to be efficacious in wound management and prevention, effective in infection control, provide safer patient outcomes, and enhance ease of nursing.

METHODS: 20 patients were studied in a controlled study by Consure Medical (2016) where "pre and post-sigmoidoscopy was performed on all enrolled patients and all maintained the health of their rectal mucosa" (p.5). An uncontrolled pilot evaluation in 20 patients was done as part of a value-based purchasing evaluation at a tertiary hospital in Tucson, Arizona to assess safety and efficacy in infection control and wound care. Engineering bench-top studies of radial, insertion and withdrawal forces of the novel device versus existing intrarectal balloon catheters was evaluated.

RESULTS: The novel device has wider patient eligibility and potentially allows three times more FI patients to be safely managed. It has lower intra-rectal pressures compared to indwelling balloon catheters. This in-vitro study, along with pilot clinical findings, suggests that advanced technology minimizes the pressure exerted on the rectal wall. Forces against the anorectal mucosa were significantly less compared to cuff-based catheters during insertion, withdrawal, and accidental expulsion.

CONCLUSIONS: A major concern with the use of intra-anal management systems is the potential harm to the rectal mucosa and the advanced technology with this device greatly reduces that risk. The intuitive device applicator and innovative self-expanding stool diverter of the devices may help reduce the risk of anorectal injury during insertion, withdrawal, or accidental device expulsions. The device design comparatively decreases undesired leakage outcomes by maintaining a larger lumen during both resting and peristaltic states, and by completely avoiding the need for balloon cuff-based anchoring. These in-vitro observations are in line with observations in clinical studies conducted at tertiary care centers.

BACKGROUND

Diarrhea and liquid fecal incontinence (FI) are prevalent conditions affecting **18-37% of acute care patients**.[1] Exposure to **fecal pathogens presents a significant infection control challenge**, leading to severe skin breakdown, bloodstream infections, and spread of harmful pathogens. Complications like **FAPU, CAUTI, and hospital-acquired *Clostridium difficile* can add up to $10,700–$30,049 per hospitalization**.[2,3] Conventional closed-system intrarectal balloon catheters (IBCs) have an inflatable retention balloon that is manually inserted into the anorectal junction. Although IBCs have shown to reduce the incidence of skin breakdown and spread of nosocomial infections, **clinical use of IBCs has reported secondary complications like mucosal bleeding, anal erosion, sphincter dysfunction and persistent discomfort.** [5-17]

Intrarectal Balloon Catheters (IBCs) rely on a large silicone retention balloon that anchors on the anorectal junction. **Poor sphincter tone precludes patients for management with IBC**, as it puts them at high risk for device expulsion. Documented clinical findings suggest in-situ **pressures exerted by IBCs can increase beyond the hydrostatic pressure of rectal microvasculature**.[16] Clinical literature indicates 14-22 mmHg is an optimal range for creating sufficient seal without risking necrosis.[18] Higher cuff pressures are known to compress mucosal arteries and impair blood flow, with total occlusion of arteries occurring at 36 mmHg.[19] Furthermore, IBCs require manual placement into the rectal vault, creating a large insertion profile and exposing rectal mucosa to high shear forces.

The structure inherent to **IBCs provides a substantially smaller in-situ drainage cross-sectional area** compared to the cross-sectional area of the rectum. Poor drainage increases intrarectal pressure and increases risk of spontaneous expulsion. Additionally, normal peristaltic contractions may collapse or occlude the balloon cuff, especially if overinflated, compromising integrity of the rectal seal and causing leakage of stool.

BACKGROUND (Continued)

A novel, **non-balloon based stool management kit (SMK) was developed at Stanford Byers Center for Biodesign and Stanford University Hospital**. The soft, pliable, self-expanding fecal diverter is anatomically placed so to **avoid foreign body sensation**, **remain in-situ independent of anal tone**, **provide a custom recto-mucosal seal**, and **maintain the natural rectal lumen diameter**. Benchtop and clinical evaluation of this novel technology present a **potentially safer and more widely applicable alternative to IBCs**.

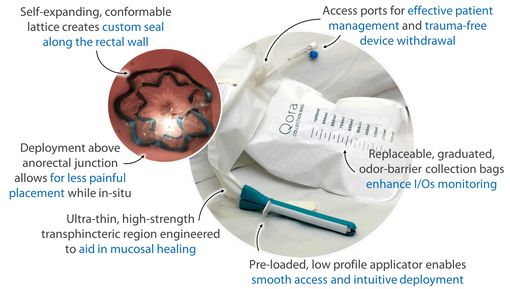

Figure 1 *Qora™ (Consure Medical) is FDA cleared for fecal management in bedridden adults for use up to 29 days.*

METHODS

Five Qora™ samples were tested, while data on **three IBCs** (A: FlexiSeal SIGNAL, ConvaTec; B: InstaFlo, Hollister; and C: DigniCare, CR Bard) were gathered via literature review and/or parallel testing. **Radial pressure** exerted by Qora™ was measured in-vitro using equivalent test method used to measure radial forces of cardiovascular stents. I**nsertion, withdrawal, and expulsion forces** were measured using a linear tensile testing machine and a foam based anorectal model. Pre-insertion diameters and **catheter lumen cross-sectional areas** were measured. All samples were then photographed during rest and simulated peristaltic contractions in the model rectum. Expulsion force was measured by withdrawing the devices without following indicated removal process. A systematic literature review was conducted on **sphincter dysfunction** in patients with FI. Relevant search terms were used in the Pubmed database. Articles were included if they reported prevalence or data enabling calculation of crude prevalence, and excluded if they focused on any specific disease state.

A **controlled, prospective, single-arm, two-phase clinical study** was performed with **20 patients** admitted to the **Neurological Unit** of a tertiary care hospital in New Delhi, India. Patients were followed from the insertion of Qora™ until their discharge, or end of their enrollment period, whichever was earlier. Effectiveness was measured by **assessing fecal diversion and amount of device leakage.** The **anorectal mucosa was inspected via sigmoidoscopy** before and after device deployment.

A **value-assessment evaluation of Qora™** was done with **20 patients** having **multiple co-morbidities** admitted to **Medical Surgical ICU and Acute Care Telemetry** unit of a tertiary care hospital in Tucson, Arizona. **Device efficacy** (diversion, expulsion) was evaluated. **Hospital-acquired CDI rate** and **nursing preference** over existing IBC was surveyed throughout the study.

RESULTS (Non-clinical Validation)

Radial Pressure: In-vitro testing and analysis of clinical literature revealed average **radial pressure exerted by Qora™ on rectal mucosa was lower compared to all three IBCs** (21.2 mmHg vs A: 81.2 mmHg, B: 77.8 mmHg, C: 32.1 mmHg) (Figure 2).[20,21] **Insertion and withdrawal forces of Qora™ was lower** as compared to Flexi-Seal SIGNAL™ (Figure 3). Accidental expulsion force for Qora™ was found to be 10.38 ± 0.92 N; the same test could not be completed on IBCs due to the destruction of test fixture by the inflated balloon traversing the anal canal.

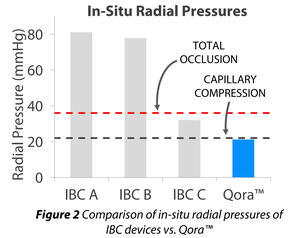

Figure 2 *Comparison of in-situ radial pressures of IBC devices vs. Qora™*

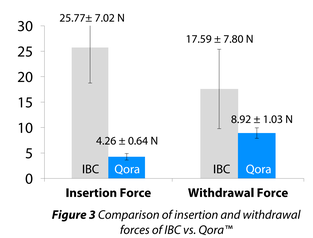

Figure 3 *Comparison of insertion and withdrawal forces of IBC vs. Qora™*

The self-expanding **lattice conforms to anatomy during peristaltic contractions**, unlike a balloon which collapses and creates possible leakage points (Figure 4). **Qora™ maintains a larger lumen** (3.8in^2 vs A: 0.55in^2, B: 0.55in^2, C: 1.4in^2) **than IBCs during both resting and simulated peristalsis states.**

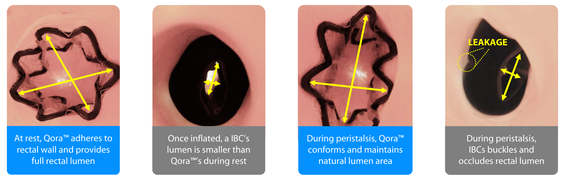

Figure 4 *Comparison of diverter lumen during simulated rest and peristalsis*

Majority of incontinent patients (70.4%, Table 1) have dysfunction of external anal sphincter (EAS), internal anal sphincter (IAS) or both.[22-26]

	NO DYSFUNCTION	SPHINCTER DYSFUNCTION		
		IAS Dysfunction	*EAS Dysfunction*	*IAS + EAS Dysfunction*
Mandaliya, et al 2015	26% (43/162)	30% (48/162)	11% (18/162)	33% (53/162)
Korah, et al 2010	34% (44/128)	35% (45/128)	2% (3/128)	28% (36/128)
Karoui, et al 1999	35% (117/335)	12% (40/335)	28% (94/335)	25% (84/335)
Deen, et al 1993	13% (6/46)	20% (9/46)	41% (19/46)	26% (12/46)
		21.2%	20.0%	27.6%
Maeda, et al 2009	19% (21/109)		81% (88/109)	
Weighted Prevalence Sphincter Function	**29.6%**		**70.4%**	

Table 1 *Sphincter dysfunction in FI patients; Qora™ does not rely on strong anal tone while in-situ*

RESULTS (Clinical Validation)

20 patients were enrolled in a controlled clinical study (Table 2). Majority were admitted due to a cerebrovascular accident. All devices were successfully deployed on first attempt. Pelvic radiograms confirmed proper expansion of fecal diverter above anorectal junction in all instances (Figure 5). Most (n=17) patients revealed successful fecal diversion while device was in-situ. Of 186 assessment points, no leakage was seen in 174 (93.5%) and minor leakage in 12 (6.4%) time points. There was no episode of major leakage. Device was removed within an hour of deployment in two patients due to inadvertent dislodgement and on request of physician due to deterioration of patient's underlying condition. One patient experienced device expulsion after 74.5 hours due to change in stool consistency to formed stool. Two patients experienced device dislodgement due to inadvertent pulling of device by patient, caregiver, or other external interferences. Devices remained in-situ for 21±0.17 hours and 84.5±38.9 in Phase I and II, respectively. There was no episode of anorectal bleeding or other serious adverse events. Post-removal sigmoidoscopy revealed minor mucosal erythema at site of diverter in two patients; neither patient had device dislodgement or spontaneous expulsion.

DISTRIBUTION	VALUE
Enrolled	**20 patients**
Age, yrs (mean±SD)	56.7 ±13.6
Did not complete at least 1 follow-up	**2 patients**
Dislodgement	*1*
Device retrieved	*1*
Completed at least 1 follow-up	**18 patients**
Completed study protocol	*15*
Dislodgement	*2*
Spontaneous expulsion	*1*
In-situ Use Period	
Phase I, hours (mean±SD)	21 ± 0.17
Phase II, hours (mean±SD)	84.5 ± 38.9

Table 2 *Safety & efficacy performance*

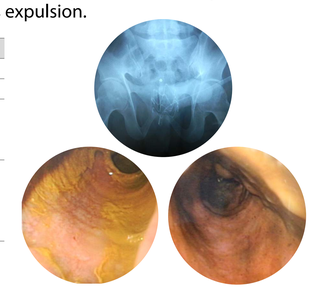

Figure 5: *X-ray was done to confirm correct deployment; pre/post sigmoidoscopy to confirm mucosal health*

Majority of patients during the **value-assessment pilot** were suffering from ***Clostridium difficile* infection (CDI), gastrointestinal bleeds, or large sacral/perineal wounds**. Qora™ successfully **contained effluent in unconscious and conscious** patients; 2 cases of expulsion. Majority (86%) of patients saw minor or no leakage. **No adverse events** observed. **No hospital-acquired CDI cases despite 8 cases on admission**. Multiple cases of Qora™ success after IBC dislodgments. Majority (75%, n=49) of surveyed nurses stated they would be an advocate for Qora™ and **prefer Qora™ as replacement over intrarectal balloon catheters**.[28]

PERFORMANCE	VBP PILOT
Age, years, mean	74.0 ± 12.3
Sex	60% (male)
Use Duration, mean, days	3.54 ± 2.90
Devices Reinsertions, mean	1.1
Spontaneous Expulsion	10%
Peripheral Diverter Leakage	*Major:* 14%
	Minor or none: 86%
Adverse Events	0%

Table 3 *Clinical performance during VBP pilot*

CONCLUSION

Non-clinical and clinical testing demonstrated that Qora™ Stool Management Kits may be a superior alternative to existing closed-system solutions. **Qora™ exerts significantly less force upon the anorectal mucosa compared to IBCs** during insertion, in-situ use, withdrawal, and accidental expulsions. Poor sphincter tone precludes fecal management with IBCs putting patients at risk for dislodgement and leakage. The **self-expanding diverter design obviates the need to anchor upon the anorectal junction**, **expanding the eligibility of closed-system fecal containment by 3x** to patients with weak or no sphincter tone. By assuming full rectal lumen, Qora™ may be used in-situ for longer periods as stool consistency improves. **Clinical validation in both controlled and uncontrolled settings successfully established the use of Qora™** in adult patients as a safe and effective alternative to diverting liquid to semi-formed fecal exudate and to provide a barrier for perineal and sacral skin. The validations demonstrated the device was easy to use and diverted fecal matter with minimal leakage. There was **no adverse effect of the device on anorectal mucosa**. This device **may be a safer alternative to IBCs that can be used in more patients** with multiple co-morbidities. Further studies may help further quantify the clinical and economic benefits.

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