



Randomized Controlled Study of the Effects of Two Fecal Management Systems on the Incidence of Anal Erosion

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Background

- Adult ICU patients are vulnerable to fecal incontinence, that can result in incontinence associated dermatitis, pressure ulcers, C-Diff infections
- FMS use occurred most often in MICU
- Occurrence of anal erosion was within the first 14 days of use; ~ 40% erosion rate
- Development of anal erosion may be associated with the length of time FMS in place, presence of perianal edema, or other co-morbidities

Literature Search

- 3 published case studies documenting the presence of anal erosion or ano-vaginal fistula associated with the use of FMS
- No prospective, randomized studies found (prior to our study) looking at indwelling Fecal Management systems and anal erosion
- Most studies were product evaluations with 1 FMS and a non-randomized observational studies evaluating 2 different FMSs

Purpose and Hypotheses

- Purpose: Determine the prevalence of anal erosions within a 14 day period among adult ICU patients based on receiving one of two Fecal Management Systems through random assignment
- Null hypothesis: There is no difference in the rate of anal erosion between Flexi-Seal and Digni-Care fecal Management systems in a 14 day period

Outcomes

- **Primary: Development of anal erosion**
 - Anal erosion defined: any tear/erosion of skin in a 3 cm radius surrounding the anus
- **Secondary: Factors associated with anal erosion**

Methodology

Study Group

- **160 adults (18yrs+) in the MICU or SICU and have an FMS ordered by a physician/licensed independent practitioner**
- **Cleveland Clinic Main Campus**
 - Patients who meet inclusion criteria were randomly assigned to one of two fecal management systems

Inclusion Criteria

- Bedfast patients with liquid to semi-liquid stool requiring FMS (to prevent skin breakdown or contamination of existing wounds)
- Liquid to semi-liquid stool incontinence for past 3 days that is expected to last for extended period due to poor response to anti-diarrhea treatment

Exclusion Criteria

- Allergic to product components
- Rectal or anal injury or active bleeding
- Severe rectal or anal stricture or stenosis (distal rectum cannot accommodate the balloon), diseases of the rectal mucosa (i.e. severe proctitis, ischemic proctitis, mucosal lacerations)
- Rectal or anal tumors
- Severe hemorrhoids
- Fecal impaction
- Loss of rectal tone or prolapsed anal sphincter
- History of ileo-anal anastomosis or internal rectal pouch (e.g. S or J pouch)
- Large Bowel (Colon) surgery or rectal surgery within the last year
- On heparin drip

Measurement Methods

- 4 case report forms:
 - Insertion of FMS Form
 - Epic Chart Abstraction Form
 - Daily Assessment Form
 - FMS Removal Form
- Developed by researchers with expert feedback from APNs (face validity)
- Forms use:
 - Multiple choice options
 - Dichotomous (Yes/No) options
 - Short answer response

Data Collection

- RN data collector x1 was trained for FMS insertion and data collection of all subjects
- Core group of experienced RNs was trained for FMS insertion
- Data collection: May, 2011 - April, 2012
- Anal erosion assessed daily x 14 days or less if the FMS is discontinued
- If an anal erosion developed within the monitoring period (14 days), then the end point is met and monitoring is discontinued

Statistical Analyses

- Categorical factors summarized using frequencies and percentages
- Continuous measures summarized using mean (standard deviation), medians, (IQR)
- Frequency of anal ulcers between the two systems were compared with logistic regression models
 - Kaplan-Meier estimates
 - Log rank tests
- SAS software used; significance level set at $p= 0.05$

RESULTS: Mid-point Analysis

- 81 patients randomly enrolled
 - 79 subjects included in interim analysis
 - 41 patients received DigniCare
 - 38 patients received Flexi-Seal

Results: Mid-Point

Patient Demographics

- Age, mean (SD), 64 ± 13.6 years
- Female gender, 41 (51.9%)
- Body mass index, 30.1 ± 8.4 kg/m²
- Conscious at time of insertion, 44 (55.7%)
- Enrolled from:
 - 59 (74.7%) MICU
 - 3 (3.8%) SICU
 - 17 (21.5%) other nursing floors

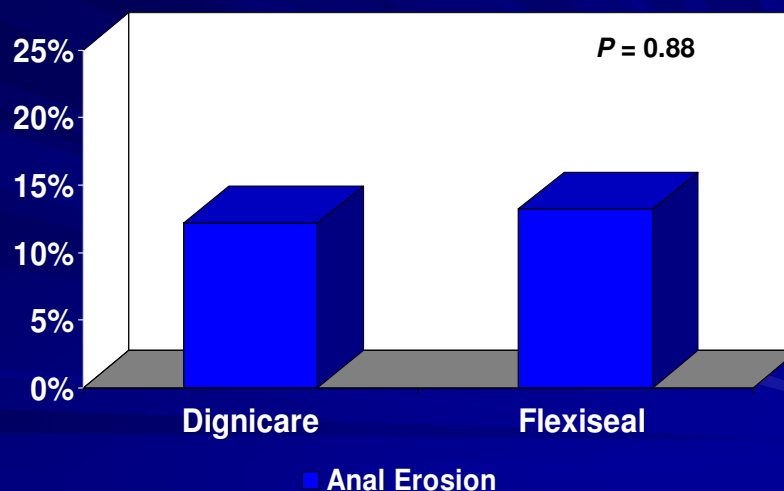
Results: Mid-Point

Baseline Patient Characteristics	Dignicare n = 41	FlexiSeal n = 38	<i>P</i> values
	Mean (SD) or n (%)		
Albumin, g/dL	2.6 ± 0.59	2.6 ± 0.68	0.31
Total Protein value, g/dL	5.5 ± 0.87	5.6 ± 0.85	0.80
Lymphocytes, %	10.3 ± 5.6	9.6 ± 6.3	0.64
Platelets, k/ul	181.2 ± 141.6	180.5 ± 118.1	0.75
ProThrombin Time, sec.	39.8 ± 14.7	38.0 ± 16.0	0.12
Characteristics at time of FMS Insertion			
Water in cuff, cc	42.7 ± 3.7	39.3 ± 6.1	0.008
Manometer reading, mmHg	25.9 ± 6.6	50.4 ± 22.0	<0.001

Results: Mid-Point

- No statistically significant difference in anal erosion between the two groups
- The documented percentage of anal erosions for all patients was 13%
- Study stopped for futility
 - Implausible that anal erosion rates would differ over time if data collection continued
 - Unlikely that more subjects will lead to statistically significance differences in anal erosion between groups

Results: Mid-Point



Results: Mid-Point

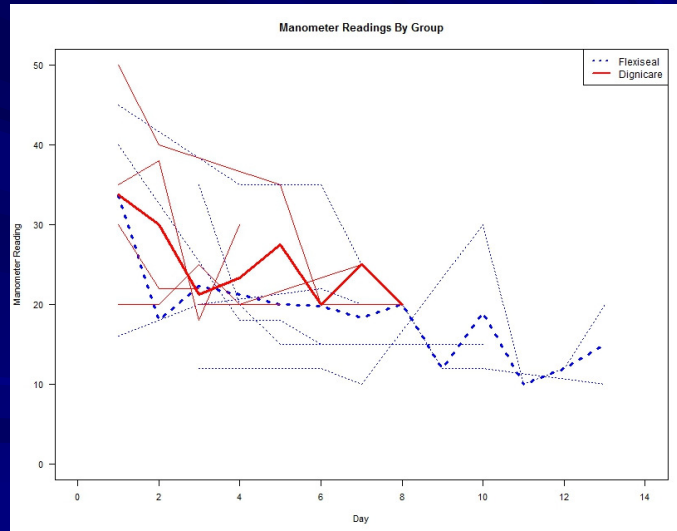


Factors Associated with Anal Erosion

Factors associated with anal erosion *in both groups*:

- Peri-anal stool leakage occurring anytime while FMS in place; $p = 0.027$
 - All anal erosion patients experienced leakage before anal erosion development
- Trends in higher anal erosion were found in patients with:
 - Less water in the balloon; $p = 0.072$
 - Lower balloon pressures in rectum; $p = 0.080$

Mean Rectal Manometer Readings by Day



**Bold lines
represent
mean
manometer
readings
per group**

Limitations

- Single center study with small sample size
 - Large quaternary care medical center
 - Results could be different in a different environment or in a different population of patients (lower or higher acuity)
- Did not reach intended sample size
- Nurses at our setting may have different procedures than nurses from other settings

Summary

- Anal erosion was well below the perceived rate by nurses
- Incidence of anal erosion did not differ based on FlexiSeal or DigniCare indwelling FMS
 - Incidence of anal erosion should not be a deciding factor in product choice
- Stool leakage was associated with anal erosion development
- Need to explore ways to prevent leakage; i. e., amount of water in balloon, etc.

Research Implications

- More research is needed on:
 - Ways to prevent erosions
 - Staging of anal erosions
 - Ways to heal erosions when an indwelling FMS in place

Clinical Implications

- ? Developing a rating scale for anal erosions
 - To standardize assessment of erosion
 - To determine clinical action
 - System removal
 - Treatment of erosions and outcome
- ? Daily assessment to prevent anal erosion
- ? Using other devices (i.e., fecal incontinence collector) prior to inserting FMS
- ? If a coordinated patient management plan involving medicine, nursing, and nutrition would improve patient selection of FMS

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