

## Current and Novel Treatments for Fecal Incontinence

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### Learning Objectives

- Understand the prevalence and impact of fecal incontinence
- Identify the various etiologies of fecal incontinence
- Describe the medical and surgical treatments for fecal incontinence, including new and investigational options.

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### Disclosures

I disclose the following financial relationships with commercial entities that produce healthcare-related products or services relevant to the content I am planning, developing or presenting:

- American Medical Systems

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### Why should we care about FI?

- Devastating medical condition for individual
- Effect on self-confidence and personal image
- Leads to isolation / depression
- Second leading cause of admission to nursing homes
- Patients are often reluctant to discuss with health care professionals.

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### Incidence of Fecal Incontinence After Childbirth

- Population-based survey in Oregon (April – Sept 2002)
- 8,774 women responded (40%) at 3 – 6 months
  - 2,569 (29%) reported FI
    - 46% stool incontinence
    - 38% flatal incontinence only
- FI associated with
  - Higher BMI
  - Forceps delivery
  - Longer 2<sup>nd</sup> stage
  - 3<sup>rd</sup> / 4<sup>th</sup> degree episiotomy
  - smoking

Guise JM et al. Obstet Gynecol. 2007;109:281–8

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### Fecal Incontinence in U.S. Women

- Population-based postal survey in WA state
  - 6,000 women
  - Age 30 – 90
- Fecal Incontinence at least once a month
- Prevalence of FI = **7.3%**
  - **3.6%** of 30 – 39 year olds
  - **15.2%** of 80 – 90 year olds

Melville J. Am J Obstet Gynecol. Dec 2005

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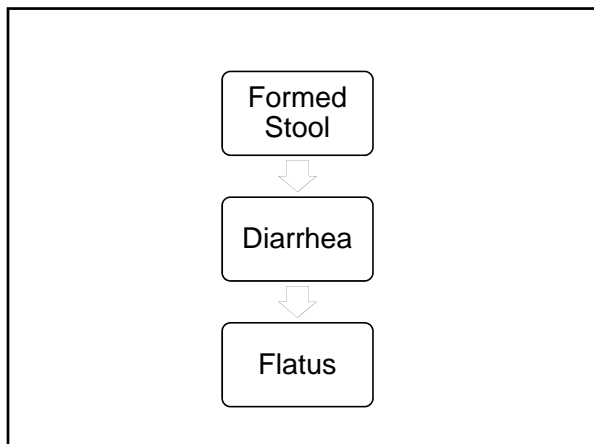
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**Fecal Incontinence**

*recurrent, uncontrolled passage of fecal material over a period of at least one month, in an individual with a developmental age of at least 4 years*

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**Minor Fecal Incontinence**

*inadvertent escape of flatus or partial soiling of undergarments with liquid stool*

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**Major Fecal Incontinence**  
*involuntary excretion  
of solid feces*

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**Continenence Factors**

- Stool volume and consistency
- Mental function
- Colon transit
- Rectal distensibility
- Anorectal reflexes
- Anorectal sensation
- Anatomic factors

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**Internal Anal Sphincter (IAS)**

- Responsible for 80% resting tone
- Continuation of circular smooth mm of rectum
- Innervated by parasympathetics (S2 – S4)
- Rectoanal Inhibitory Reflex
  - 20 – 40 cc
  - “Sampling” rectal contents

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### External Anal Sphincter (EAS)

- Striated muscle under voluntary "squeeze" control
- Innervated by pudendal nerve (S<sub>2-4</sub>)
- Commonly injured during vaginal delivery

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### Pelvic floor muscles

- Puborectalis / pubococcygeus
- Innervated by levator ani nerve
- Responsible for Anorectal angle
- Maintains stool in rectum
- Relaxes for defecation

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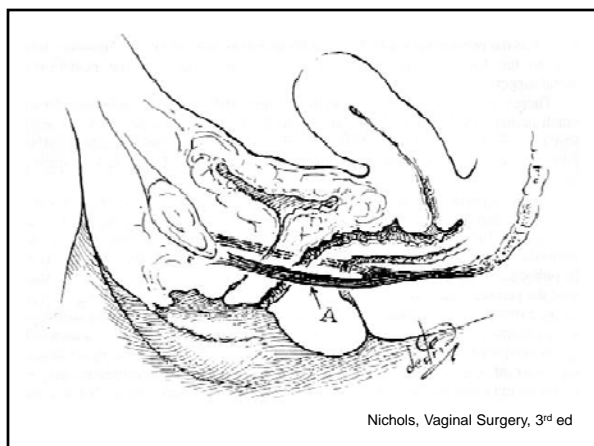
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Nichols, Vaginal Surgery, 3<sup>rd</sup> ed

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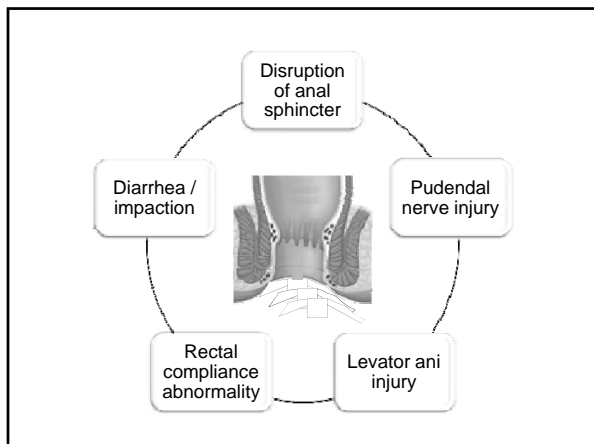
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### Obstetrical Risk Factors for FI

- Multiparity
- Instrumental delivery
- Large birth weight
- Prolonged second stage

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### Anal Disruption During Vaginal Delivery

- Prospective study of 150 women before and after delivery with anal U/S
- Results
  - Primiparous
    - No sphincter defects before delivery
    - 35% had defects after delivery
      - only 3% apparent at time of delivery
  - Multiparous
    - 40% had sphincter defects before delivery
    - 44% had defects after delivery

Sultan AH et al. NEJM 1993;329:1905-11

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### Evaluation of Fecal Incontinence

- History and Physical
- Digital Rectal Exam (DRE)
- Imaging studies
  - Endoanal Ultrasound
  - Defecography
  - Pelvic Floor MRI\*
- Functional studies
  - Anorectal Manometry
  - Pudendal Nerve Terminal Motor Latency\*

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### Traditional Treatment of Fecal Incontinence

- Non-surgical
  - Dietary modification
    - Bulking agents
  - Antidiarrheal medications
    - Loperamide (Imodium)
    - Diphenoxylate-atropine (Lomotil)
  - Biofeedback
- Surgical
  - Anal sphincteroplasty
  - Artificial anal sphincter

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### Long-Term Results of Overlapping Sphincter Repair

Place / Year	# Pt	Follow-up Average (months)	Totally Incontinent (%)	Incontinent of Flatus Only (%)	Totally Continent (%)
St. Marks, 2000	38	77	89	11	0
France, 2000	74	40	49	23	28
Cleveland Clinic, 2002	49	69	54	32	14
University of Minnesota, 2004	104	120	77	17	6

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### Anal sphincter defects in incontinent and continent women

- Endoanal US in 468 patients
  - 65% sphincter defects in incontinent Pts (n=335)
  - **43% sphincter defect in continent Pts (n=115)**
- *“Caution should be used in attributing incontinence to anal sphincter defects alone”*

Karoui S et al. Am J Roentgenol 1999 Aug;173 (2)

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### Artificial Anal Sphincter

- Multicenter, prospective, nonrandomized study of 112 patients (86 women)
  - Mean age 49 (18-81)
- Surgical revision in 51 patients (46%)
- Removal in 41 patients (37%)
- 53% successful outcome (intent-to-treat).

Wong W. Dis Colon Rectum 2002 Sep;45(9):1139-53.

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### Stimulated Dynamic Graciloplasty

- 52 patients underwent surgical repair\*
  - 73% continent after median 2 years
- 128 patients (multicenter trial)\*\*
  - 66% success (>70% improvement)
  - 39% major wound complications

\*Baeten C et al. N Engl J Med 1995 Jun 15;332(24):1600-5.  
\*\*Madoff R et al. Gastroenterology 1999 Mar;116(3):549-56.

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### Future Treatments of Fecal Incontinence

- Sacral Nerve Stimulation
- Injectable agents\*
- Magnetic Anal Sphincter\*
- Trans-Obturator Post Anal Sling (TOPAS)\*

\*Not FDA approved for fecal incontinence

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### Sacral Nerve Stimulation

- Electrical stimulation of sacral nerve roots
- Initially used for urologic indications
- First reported for FI in 1995\*
- *Received FDA approval for FI March, 2011*

\*Matzel, KE. Lancet 1995; 346:1124

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### SNS for fecal & urinary incontinence long-term follow-up

- 24 women with FI and UI
- Mean follow-up 28 months
- Results
  - 31.8% with improvement in FI / UI
  - 54.5% without any improvement in FI
  - 4 patients with colostomy
  - 4 patients had IPG explanted
    - infection or poor clinical response

El Gazzaz. Int J Colorectal Dis 2009;24(12)1377-81

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### Sacral Nerve Stimulation for Fecal Incontinence: Results of a 120-Patient Prospective Multicenter Study

- 133 patients underwent test stimulation
  - 120 (90%) patients received implant (110 women)
  - 12 month results
    - 83% success (>50% reduction in FI episodes)
    - 41% total continence
    - Incontinent episodes per week
      - 9.4 to 1.9
  - Adverse events
    - 25.8% implant site pain
    - 12.5% paresthesia
    - 10.8% implant site infection

Wexner, Collier, et al. Annals of Surgery, 2010

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### InterStim Therapy for Bowel Control Clinical Efficacy: Reduction in Episodes

Group	Baseline	12 Months
Modified Worst Case (MWC) (n=120)	9.4	3.1
Per-protocol (completers) (n=106)	9.2	1.9

1. Wexner SD, Collier JA, et al. Ann Surg. 2010 Mar;251(3):441-9.  
2. Medtronic-sponsored research. InterStim Therapy Clinical Summary - 2011.

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### InterStim Therapy for Bowel Control Clinical Efficacy: Complete Continence

Group	Percent of Patients with a 100% Reduction in Accidents at 12 Months
MWC (n=120)	36%
Per-protocol (n=106)	41%
Tjandra RCT <sup>3</sup> SNS group (n=53)	47%

1. Wexner SD, Collier JA, et al. Ann Surg. 2010 Mar;251(3):441-9.  
2. Medtronic-sponsored research. InterStim Therapy - Clinical Summary, 2011.  
3. Tjandra JJ et al. Sacral nerve stimulation is more effective than optimal medical therapy for severe fecal incontinence: a randomized, controlled study. Dis Colon Rectum. May 2008;51(5):494-502.

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### Injectable Agents for FI\*

- Contigen®
  - cross-linked collagen
- Permacol®
  - porcine dermal collagen
- Silicone
  - PTP, Bioplastique®
- Bulkamid®
  - hydrogel cross-linked with polyacrylamide
- Durasphere®
  - pyrolytic carbon coated beads

\*not FDA approved for FI

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### Intra-anal collagen injections for fecal incontinence

- 73 patients (59 women), median age 63
- Total 5 ml Contigen® injected
- 63% improved CCFIS at 12 months
  - Median pre-treatment score 10
  - Median post-treatment score 6
  - 5% completely continent
- No change in mean resting pressure

Stojkovic S et al. *Br J Surg* 2006; 93: 1514–1518

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### Magnetic Anal Sphincter

- 14 Pt with > 2 FI episodes/week, mean age 62
- No intraoperative complications
- Adverse events in 7 patients
- 2 devices removed and 1 passed spontaneously
- 5 patients at 6 months had significant decrease in FI
  - 7.2 to 0.7 per week
- Wexner Score 17.2 to 7.8

Lehur PA. et al. *Dis Colon Rectum* 2010;53 (12).

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### Methods

- Retrospective analysis of initial experience with Transobturator Posterior Pelvic Sling
- Pre-operative evaluation
  - Bowel diary
  - POP-Q, digital rectal exam
  - Pelvic floor MRI
  - Anorectal manometry / PNTML
  - FIQOL, (Wexner scale)
- Post-operative evaluation
  - Bowel diary
  - POP-Q, digital rectal exam
  - FIQOL, Wexner scale

Rosenblatt, Ferzandi, Sasson. IUGA 2007

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### Pre-operative Evaluation

<b>■MRI (n=12)</b>	
•EAS intact	9/12
•IAS intact	9/12
•Anorectal Angle (rest)	121.5° (99-160°)
•Anorectal Angle (strain)	129.9° (100-160°)
<b>■Anorectal Manometry (n=12)</b>	
•Max resting pressure (mean)	46.2 mm Hg
•Max squeeze pressure (mean)	72.6 mm Hg

Rosenblatt, Ferzandi, Sasson. IUGA 2007

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### Fecal Incontinence: Summary

- Fecal incontinence is a common, underreported disorder in women
- Etiology is often multifactorial
- Medical management & dietary changes may significantly improve FI
- Renewed interest with evolving minimally-invasive surgery

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