New Innovations in the Surgical Management of Incontinence

Geriatric Grand Rounds
December 2nd, 2011

Joshua I. S. Bleier, MD, FACS, FASCRS
Assistant Professor of Surgery
Division of Colorectal Surgery
University of Pennsylvania
Philadelphia, PA
Disclosures

- No financial relationships with industry
- Some slides provided by Medtronic
Outline

- Is this a worthwhile topic?
- History/Physical
- Evaluation – anorectal physiology lab
- Treatment
- New developments
Why should you care?

- Affects 2-7% of people

- 40-50% of people in nursing homes; one of most common reasons for placement in a nursing home
More reasons to care...

- Social stigma
- Embarrassment – pt’s stay confined to their homes
- Isolation/loss of self esteem
In young people – loss of jobs/dependence on welfare

Elderly – nursing home admission costs are high. Buying diapers/pads; treatment of depression
Stool Continence

- Stool consistency
- Compliance and reservoir function

- COLON
- RECTUM
- ANUS

- Sensory
- Motor
Types of incontinence

- Flatus
- Liquid Stool
- Solid Stool
- Partial incontinence
- Soiling
Bowel Habit

- Diarrhea
- IBS
- Urgency
- Severity of Incontinence
- Awareness of stool passage?
- Diarrhea or constipation promoting Rx
History

- Sexual history
- Obstetric History
- GYN History
- Previous prolapse history
- Neurologic disorders
- Surgery – large/small bowel resection
- Radiation
Fecal Incontinence
Sphincter Injury at Delivery

- 3-9% of deliveries
- Primary repair
  - Fecal incontinence 20%
Causes

- Congenital
- Pelvic floor denervation
- Radiation – ¾ pts receiving pelvic radiation experience acute anorectal symptoms; up to 20% late phase proctitis; 5% disabling symptoms
- Iatrogenic; ie 30-50% after LIS; also occurs after non sphincter cutting operations
Causes

- Traumatic – Obstetric Injury / Episiotomy
- Majority of elderly women with incontinence present with delayed symptoms DECADES after injury
Physical

- Abdominal – check for scars
- Is there a pad in place?
- Careful GYN Exam
  - Other pathology can be noted in geriatric female population
Anorectal exam

- Excoriation
- Patulous anus
- Observe for mucosal/complete rectal prolapse
  - Often hard to demonstrate in office
  - Ask for pictures
  - May need bedside commode
DRE

- Decreased tone
- Squeeze tone
- Possible bimanual
- Rectocele
- Impacted feces

- Report anatomically vs. o’clock
Evaluation of Fecal Incontinence

- History and clinical evaluation
- Physiological assessment
  - Anorectal manometry
  - Endoanal ultrasound
  - Defecography?
Anorectal Manometry

- Radial catheter - 1 cm intervals
- Pressures
  - Resting pressure
  - Squeeze pressure
- Sphincter length
- Sensibility
Endoanal Ultrasonography
Ultrasound - Normal Anatomy

- Upper sphincter
- Mid sphincter
- Distal sphincter
Endoanal Ultrasonography

- Normal
- Sphincter defect
Pudendal Latency

- Prolonged = nerve injury
Defecography

- Contrast in rectum + vagina
- Rectal emptying
- Sitting position
Rectal Prolapse
Rectal Intussusception
Defecography showing Internal Prolapse
Rectal Prolapse

- Mucosal Prolapse
- True (Full-thickness) Prolapse
Mucosal Prolapse
True Prolapse
Endoscopy

- Good opportunity to update appropriate health maintenance
  - Proctitis
  - Colitis
  - Villous adenoma
Prolapse Surgery

- Mucosal Prolapse
  - Surgical excision similar to hemorrhoidectomy
  - Good Long-term results

- True Prolapse
  - Perineal proctectomy
    - Well tolerated
    - Short hospital stay
  - Abdominal approach
    - Better long-term results
    - More potential morbidity
    - Rectopexy +/- sigmoidectomy depending on constipation symptoms
Treatment Options
Fecal Incontinence

- Diet / medication
- Biofeedback
- Sphincteroplasty
- Colostomy
- New treatment modalities
Conservative

- Diarrhea most common aggravating factor for incontinence
- Aim for 1-2 well formed bm/day
- Constipating agents
- Bulking agents
- Stop laxatives
Biofeedback

- Mild - moderate symptoms
## Biofeedback Results

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Cured</th>
<th>Improved</th>
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</thead>
<tbody>
<tr>
<td>Urge incontinence</td>
<td>60</td>
<td>55%</td>
<td>21%</td>
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<tr>
<td>Passive incontinence</td>
<td>22</td>
<td>23%</td>
<td>36%</td>
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</table>

*Norton & Kamm, BJ S 1999*
Sphincteroplasty
# Sphincteroplasty Results

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Good (%)</th>
<th>Suboptimal (%)</th>
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<tr>
<td>Fleshman 1994</td>
<td>55</td>
<td>72%</td>
<td>28%</td>
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<tr>
<td>Londono 1994</td>
<td>94</td>
<td>50%</td>
<td>49%</td>
</tr>
<tr>
<td>Oliveira 1996</td>
<td>55</td>
<td>70%</td>
<td>30%</td>
</tr>
<tr>
<td>Malouf 2000</td>
<td>47</td>
<td>34%</td>
<td>66%</td>
</tr>
<tr>
<td>Halvorsen 2002</td>
<td>49</td>
<td>38%</td>
<td>62%</td>
</tr>
<tr>
<td>Bravo Gutierrez 2004</td>
<td>130</td>
<td>41%</td>
<td>57%</td>
</tr>
</tbody>
</table>

**Early Experience**

**Later Experience**
Injectable Biomaterials

Technique

- Submucosal injection
  - Easy
  - No local anesthetic
  - 1-4 sites (max 2ml at each site)

- Intersphincteric injection
  - Ultrasound directed?
  - Local anesthetic
  - 1-4 sites
Preliminary Results

- Bioplastique (silicone based)
- Intersphincteric space
- Randomized +/- ultrasound (42/40 pts)
  - Ultrasound patients superior outcome
    - 69% vs. 40% had >50% improvement

_Tjandra et al. DCR 2004_
Recent developments

- Approval of Solesta
  - Injectable dextranomer / Hyaluronate
  - Submucosal anal canal injection

- Paucity of Long-term Data
  - 2 yr efficacy
  - 30-50% improvement in number of incontinent episodes

- Reports of Adverse events
Unresolved Questions
Injectable Bulking Agents

- Efficacy
- Optimal location
- Optimal material
- Durability and safety
Artificial Bowel Sphincter

- End stage fecal incontinence
- Intact anal sphincter not needed
- Success rate ~ 50-70%
  - Infection
  - Erosion
- Few specialized centers
- NOW UNAVAILABLE
Typical ABS Patient
Water Skiing Accident

- Manometric pressures minimal
- Nerve function intact
## Infection Rates

### Artificial Bowel Sphincter

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Infection rate</th>
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</thead>
<tbody>
<tr>
<td>Wong (2002)</td>
<td>112</td>
<td>31%</td>
</tr>
<tr>
<td>Parker (2002)</td>
<td>45</td>
<td>34%</td>
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<tr>
<td>Michot (2003)</td>
<td>25</td>
<td>12%</td>
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<tr>
<td>Devesa (2002)</td>
<td>53</td>
<td>18%</td>
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<tr>
<td>Ortiz (2002)</td>
<td>22</td>
<td>9%</td>
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# Neosphincter Surgery for Fecal Incontinence: A Critical and Unbiased Review of the Relevant Literature

**Orlin Belyaev, Christophe Müller, and Waldemar Uhl**

<table>
<thead>
<tr>
<th>First author</th>
<th>Year</th>
<th>No. of patients</th>
<th>Mean age (years)</th>
<th>Follow-up (years)</th>
<th>Success rate</th>
<th>Surgical revisions</th>
<th>Explantations (total)</th>
<th>Complications (total)</th>
<th>Level of evidence</th>
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<td>4.8</td>
<td>9</td>
<td>7</td>
<td>7</td>
<td>4</td>
<td>IV</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>444</td>
<td>46.8</td>
<td>2.6</td>
<td><strong>189 (42.6%)</strong></td>
<td><strong>202 (45.5%)</strong></td>
<td><strong>146 (33%)</strong></td>
<td><strong>746 (168%)</strong></td>
<td>Lowest level of evidence</td>
</tr>
</tbody>
</table>

Table 2. Summary of raw data from the 20 most recent relevant studies on artificial bowel sphincter (ABS) (March 2005)
ABS - Incisions
Sacral Nerve Stimulation

SNS delivers mild electrical pulses to the sacral nerves. This action modulates effector organs which the sacral nerves innervate: bladder, urinary and anal sphincters, pelvic floor, and colon.
SNS Therapy

1. **Tined lead** is placed parallel to the sacral (S2, S3, or S4) nerve.

2. **Implantable neurostimulator** generates mild electrical pulses that are delivered through the lead electrodes.

3. Clinician and patient programmers are used to set the parameters of the electrical pulses.
## History of SNS – 20+ years treating the pelvic floor

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1981</td>
<td>Department of Urology, University of California at San Francisco initiated clinical program</td>
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<tr>
<td>1985-92</td>
<td>Multi-center trial</td>
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<td>1994</td>
<td>CE mark for InterStim Therapy for treatment of: Pelvic Floor Disorders (Urinary and fecal incontinence)</td>
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<td>1997</td>
<td>FDA approval of InterStim Therapy for treatment of: Urge incontinence</td>
</tr>
<tr>
<td>1999</td>
<td>FDA approval of InterStim Therapy for treatment of: Urgency-frequency, Urinary retention</td>
</tr>
<tr>
<td>2011</td>
<td>FDA approval of InterStim Therapy for treatment of: Chronic fecal incontinence</td>
</tr>
</tbody>
</table>
Theories of method of action

Neuromodulation may affect the pre-existing activity in sensory fiber pathways that control:

- Muscular function
- Misplaced sensory signals
- Increased sensory input
- Dysfunctional neural reflexes
- NOT an ON/OFF switch for the sphincter
Chronic fecal incontinence

InterStim Therapy for bowel control is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.
**InterStim Therapy for Bowel Control**

**Patient Selection:**
Patients should be carefully selected to ensure that they meet the following criteria:
- They are appropriate candidates for surgery.
- They can properly operate the system.
- They received satisfactory results from test stimulation.

**Contraindication:**
This therapy is contraindicated for patients who will be exposed to diathermy (deep heat treatment).
InterStim Therapy test stimulation
Pragmatic patient selection

Minimally invasive test to gauge:
- Response of symptoms to stimulation
- Candidates for full implant

Test results, patients with:
- ≥ 50% reduction in symptoms are good candidates for full implant
- < 50% reduction in symptoms may have a 2nd test
Clinical studies of InterStim Therapy

Safety and efficacy of InterStim Therapy have been demonstrated in multiple single and multicenter trials.

The studies vary in design and number of patients.

There is general agreement that InterStim Therapy greatly improves continence and quality of life.¹

Four studies, different designs, similar results

1. InterStim Therapy for Bowel Control Prospective Clinical Study — a prospective, non-randomized, multi-center study. (n = 120) ¹, ²

2. Tjandra Study — a prospective, randomized, single-center study. (n = 113) ³

3. Leroi Study — a prospective, randomized, double arm, blinded, single-center study. (n = 27) ⁴

4. Hetzer Study — a prospective, non-randomized, single-center study. (n = 30) ⁵

². Medtronic-sponsored research. InterStim Therapy Clinical Summary Insert, 2010
Common endpoint:
≥ 50% reduction in weekly incontinent episodes

Patients who achieved endpoint at 12 months

InterStim Therapy for Bowel Control Prospective Clinical Study ¹, ²
83% per-protocol, 73% MWC
p < 0.0001

Tjandra Study ³
70.8%, p < 0.0001

². Medtronic-sponsored research. InterStim Therapy Clinical Summary Insert, 2010
Complete Continence
InterStim Therapy Bowel Control Study

12 months compared to baseline

Figure 2: Faecal incontinence episodes per week during chronic sacral spinal nerve stimulation
See table 2 for numbers of patients at every timepoint. *p<0.0001.
†p=0.0034. Error bars are SD.
Tjandra et al. Study — Reduction in Weekly Incontinent Episodes

SNS Group improvement is clinically relevant and statistically significant (p < 0.0001)

### Maximum degree of external sphincter defect

<table>
<thead>
<tr>
<th>Study</th>
<th>Maximum Degree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leroi Study(^1)</td>
<td>≤ 30°</td>
</tr>
<tr>
<td>InterStim Therapy for Bowel Control Prospective Clinical Study(^2, 3)</td>
<td>≤ 60°</td>
</tr>
<tr>
<td>Hetzer Study(^4)</td>
<td>≤ 90°</td>
</tr>
<tr>
<td>Tjandra Study(^5)</td>
<td>≤ 120°</td>
</tr>
</tbody>
</table>

3. Medtronic-sponsored research. InterStim Therapy Clinical Summary Insert, 2010
InterStim Therapy for Bowel Control Prospective Clinical Study — Safety Results

The most common adverse events (≥5%) reported during the implant phase:

- Implant site pain = 25.8%
- Paresthesia = 12.5%
- Implant site infection = 10.8%
- Change in sensation of stimulation = 8.3%
- Urinary incontinence = 6.7%
- Diarrhea = 5.0%
Mitigation of adverse events

Many of the adverse events were successfully treated with medication, or reprogramming of the device.
QOL: FI patients vs patients w/o FI

FIQOL — Improvement in Quality of Life

InterStim Therapy for Bowel Control

Mean FIQOL Score

Baseline 12 Months

- Depression & Self-perception
- Lifestyle
- Embarrassment
- Coping & Behavior
Phases of InterStim Therapy

- **Test stimulation period**
  - Up to 7 days (PNE)
  - Up to 14 days (tined lead)

- **Long-term therapy**
  - Implantation of neurostimulator (INS)
Benefits of Test Stimulation Period

- Verifies neural integrity
- Allows the patient to feel stimulation
- Provides an opportunity to assess the viability of InterStim Therapy
- Helps the physician and patient make an informed choice about the long-term therapeutic value of InterStim Therapy
Identify Landmarks Under Fluoroscopy
Identify Landmarks Under Fluoroscopy

- posterior superior iliac spine
- sacrum upper edge
- S1
- S2
- S3
- S4
- sacrum lower edge
Test Stimulation: Place the test lead
Look for Motor and Sensory Responses

<table>
<thead>
<tr>
<th>Nerve Innervation</th>
<th>Response</th>
<th>Sensation</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2 Primary somatic contributor of pudendal nerve for external sphincter, leg, foot</td>
<td>Pelvic Floor</td>
<td>Foot/calf/leg</td>
</tr>
<tr>
<td></td>
<td>“clamp”** of anal sphincter</td>
<td>Leg/hip rotation, plantar flexion of entire foot, contraction of calf</td>
</tr>
<tr>
<td>S3 Virtually all pelvic autonomic functions and striated muscle (levator ani)</td>
<td>“bellows”*** of perineum</td>
<td>Plantar flexion of great toe, occasionally other toes</td>
</tr>
<tr>
<td>S4 Pelvic autonomic and somatic</td>
<td>“bellows”***</td>
<td>No lower extremity motor stimulation</td>
</tr>
<tr>
<td>No leg or foot</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Clamp: contraction of anal sphincter and, in males, retraction of base of penis. Move buttocks aside and look for anterior/posterior shortening of the perineal structures.

** Bellows: lifting and dropping of pelvic floor. Look for deepening and flattening of buttock groove.
Connect the Lead to External Test Stimulator

When desired responses are achieved, the lead is secured and connected to an external test stimulator.
If Test Stimulation Successful, Implant System

- Implanted lead and InterStim implantable neurostimulator (INS) are placed in the OR
- Lead location (S3) is critical to the success of therapy
Treatment Summary - FI

- Non surgical treatment always first
  - Dietary Modification
  - Anti-diarrheal medications
  - Biofeedback
- Prolapse – Surgical Options
  - Sphincteroplasty for localized injuries
    - Must be localized temporally
    - Rare in elderly
    - Poor long-term results
- New treatment modalities
  - Injectable Materials
  - SNS
Conclusions

- Incontinence is a common problem
  - Profound social and economic impact
- H + P important
- Objective evaluation can help guide treatment
- Treatments continue to evolve
- SNS is a promising new modality