

*Evolving Strategies for the
Management of*

Fecal Incontinence

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Disclosures

▶ none

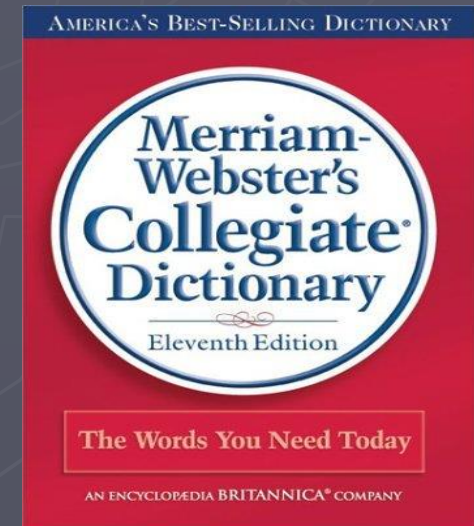


Introduction

- ▶ devastating physical disability
 - affects self-confidence, personal image
 - social isolation, job loss
- ▶ \$400 million annually in US for adult diapers in 1988
- ▶ leading cause of nursing home placement
- ▶ *more common than dementia*

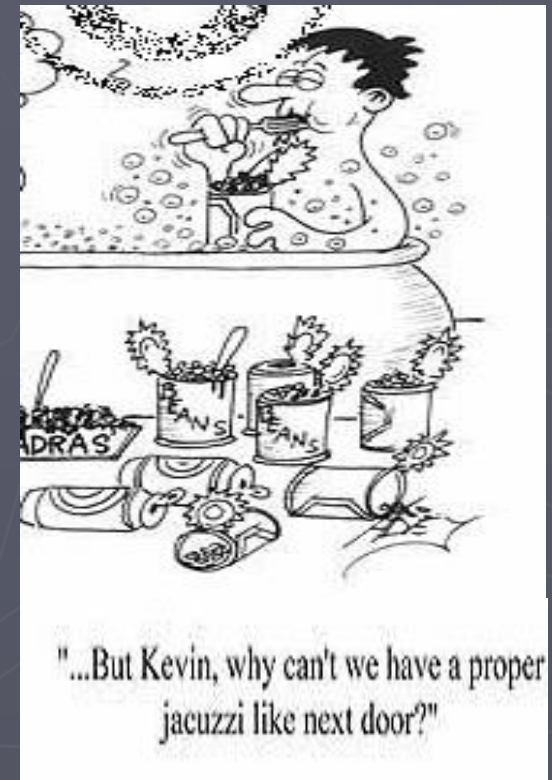
Definitions

- ▶ highly variable
- ▶ **“continuous or recurrent uncontrolled passage of fecal material (>10cc) for at least one month, age>3yo”**
- ▶ MINOR INCONTINENCE
 - inadvertent release of flatus
 - partial soiling with liquid stool
- ▶ MAJOR INCONTINENCE
 - involuntary excretion of feces

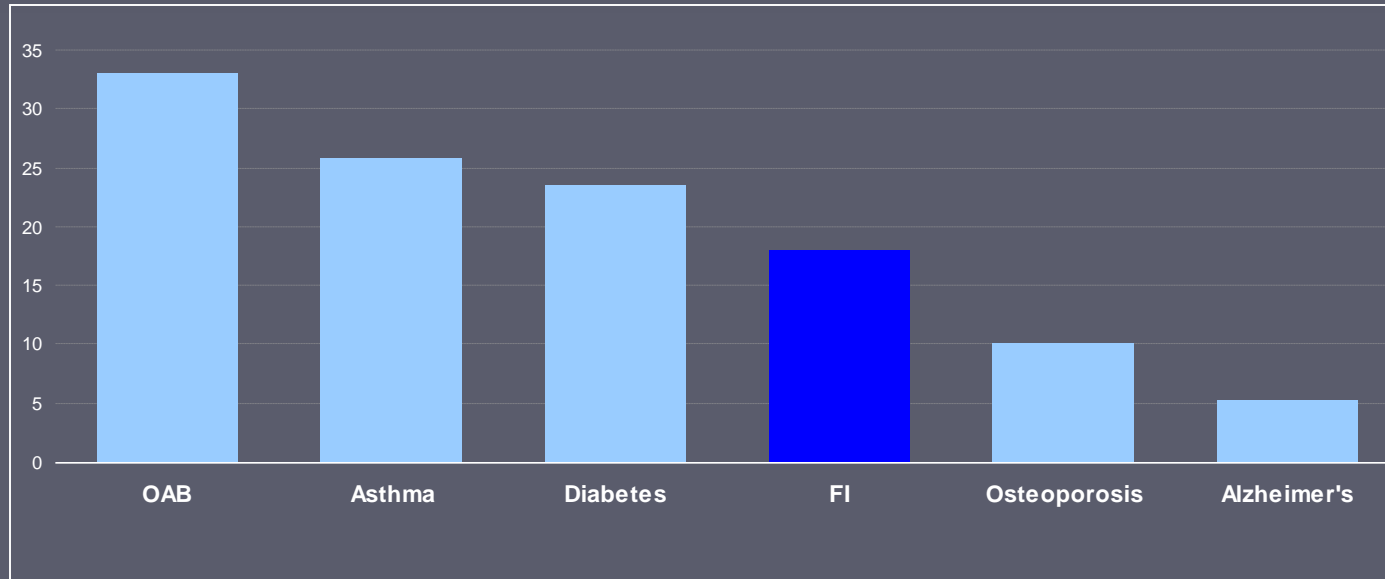


Epidemiology

- ▶ UNDER-REPORTED
- ▶ prevalence variable (1-24%)
 - 11-15% community-dwelling adults
 - 47% nursing home residents
- ▶ depends on definitions
 - 7% fecal soiling
 - 0.7% gross incontinence
- ▶ *only 15-45% of patients will discuss with PMD*



Epidemiology



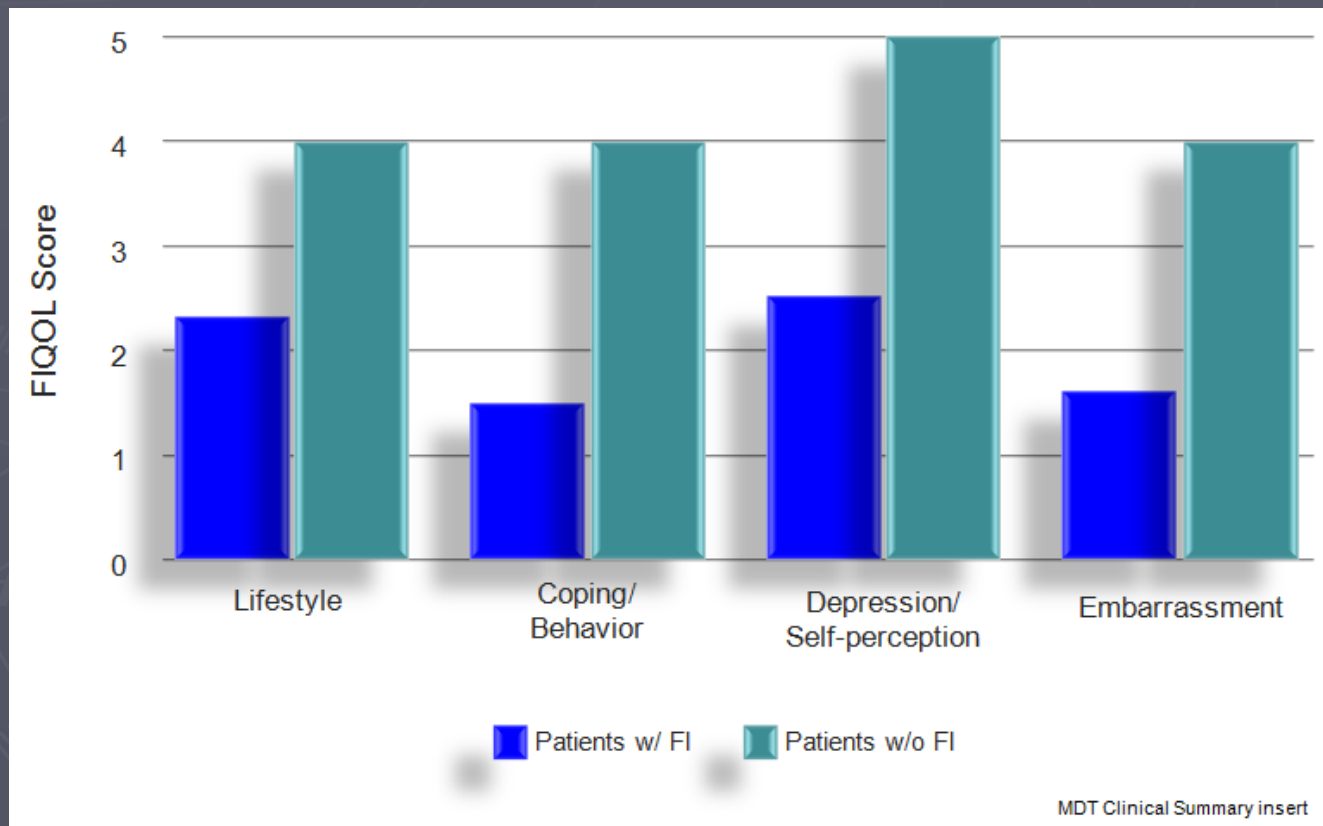
- ▶ It is estimated that more than **18 million adults** in the United States – 1 in 12 – suffer from fecal incontinence (FI)⁵
- ▶ FI is nearly as prevalent as many other chronic diseases and more prevalent than other illnesses well-known to impact many Americans.^{1-4,6-7}

1. Stewart, W.F et al. Prevalence and Burden of Overactive Bladder in the United States. *World Jnl of Urol* 2003;20:327-336
2. Serels S. The wet patient: understanding patients with overactive bladder and incontinence. *Curr Med Res Opin.* 2004;20(6):791-801.
3. Centers for Disease Control and Prevention Website. <http://www.cdc.gov/asthma/brfss/03/lifetime/tableL1.htm>. Accessed October 18, 2010.
4. National Diabetes Information Clearinghouse Website. http://www.diabetes.niddk.nih.gov/dm/pubs/statistics/#y_people. Accessed October 18, 2010.
5. Whitehead W.E. et al. Fecal Incontinence in US adults: epidemiology and risk factors. *Gastroenterology.* 2009; 137:512-517.
6. National Osteoporosis Foundation Website. <http://www.nof.org/node/40>. Accessed October 18, 2010.
7. Alzheimer's Association Website. http://www.alz.org/alzheimers_disease_facts_figures.asp. Accessed October 18, 2010.

FI Impacts Quality of Life

Fecal Incontinence Quality of Life Scale (FIQOL) Scores

Note: Higher scores translate to higher quality of life



Risk Factors

▶ **AGE** (2.6% in twenties → 15% older than 70)

▶ chronic diarrhea

▶ IBS

▶ COPD

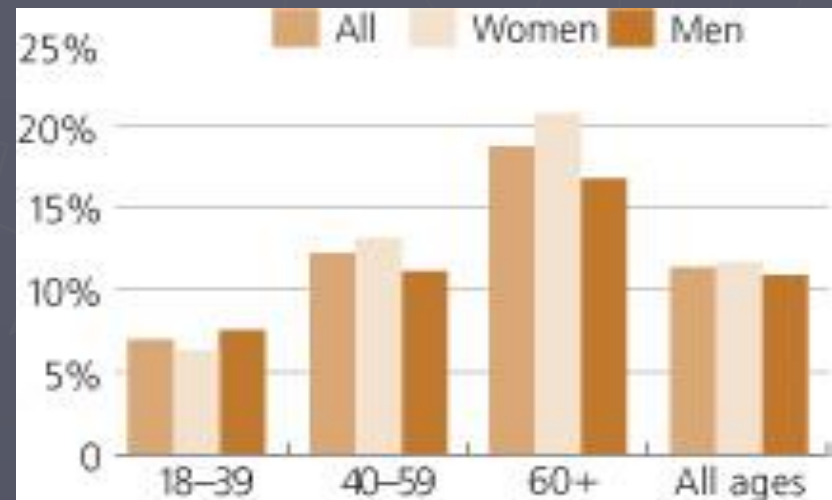
▶ urinary incontinence

▶ colectomy

▶ poor health, physical limitations

▶ *multiparity* only on univariate analysis

▶ *female gender??* conflicting data...



Pathophysiology

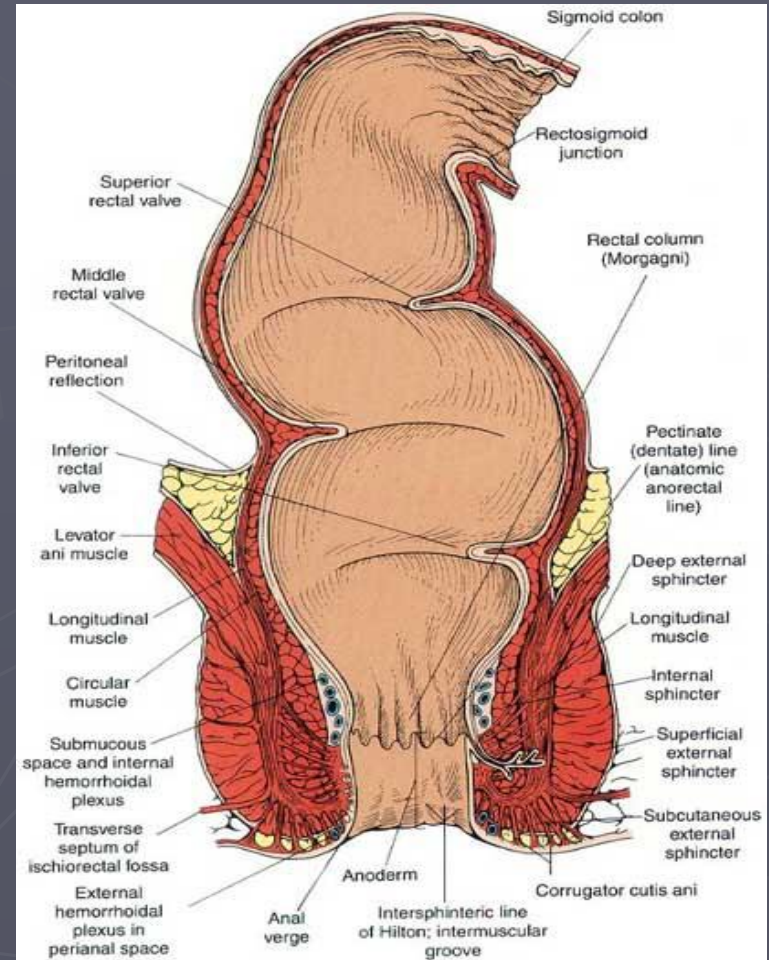


Normal Defecation



Maintaining Continence

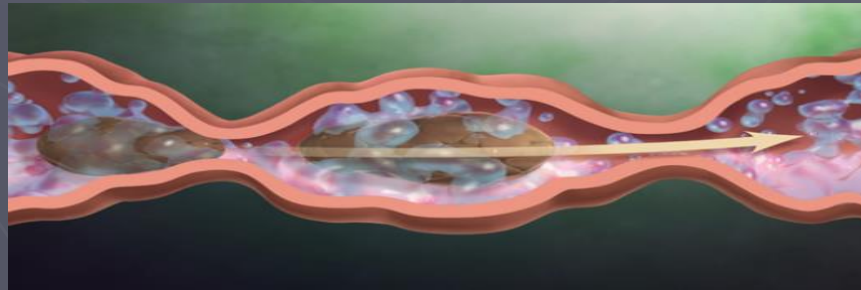
- ▶ mental function
- ▶ stool volume & consistency
- ▶ colonic transit
- ▶ rectosigmoid peristalsis
- ▶ rectal distensibility
- ▶ rectal compliance
- ▶ anorectal sensation
- ▶ anorectal reflexes
- ▶ pelvic floor function
- ▶ sphincter complex (IAS & EAS)



Anatomic Factors

▶ Rectosigmoid

- antiperistaltic waves
- reflex contraction when large volumes enter sigmoid



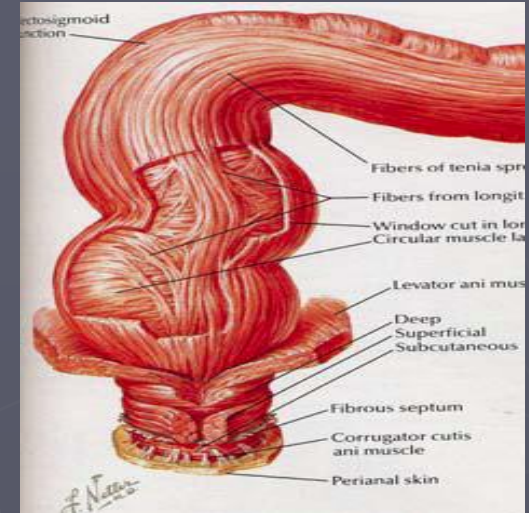
▶ Rectum

- valves of Houston, mucosal folds
- can accommodate 300cc without increase in pressure
- over 300cc → URGENCY

Anatomic Factors

► Internal Anal Sphincter

- circular smooth muscle
- enteric innervation
- 80-90% of resting anal pressure

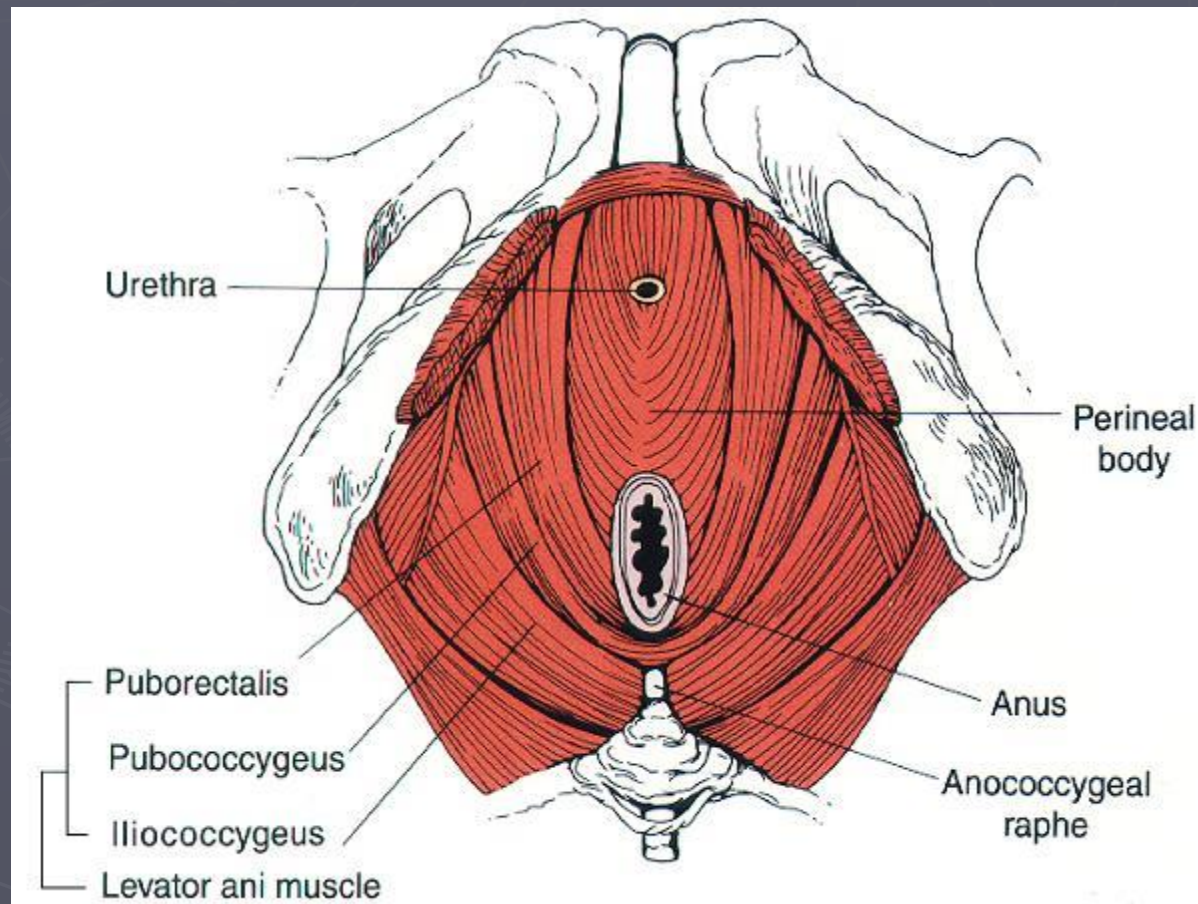


► External Anal Sphincter & Puborectalis

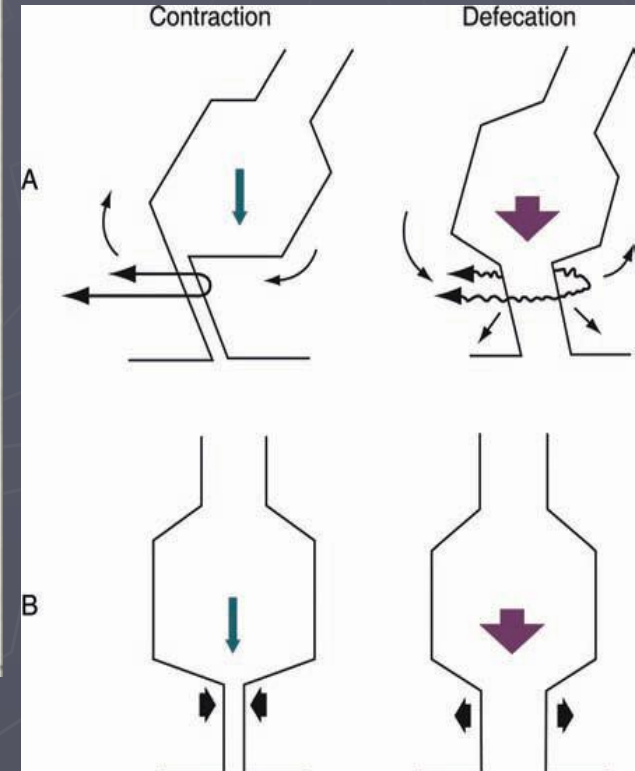
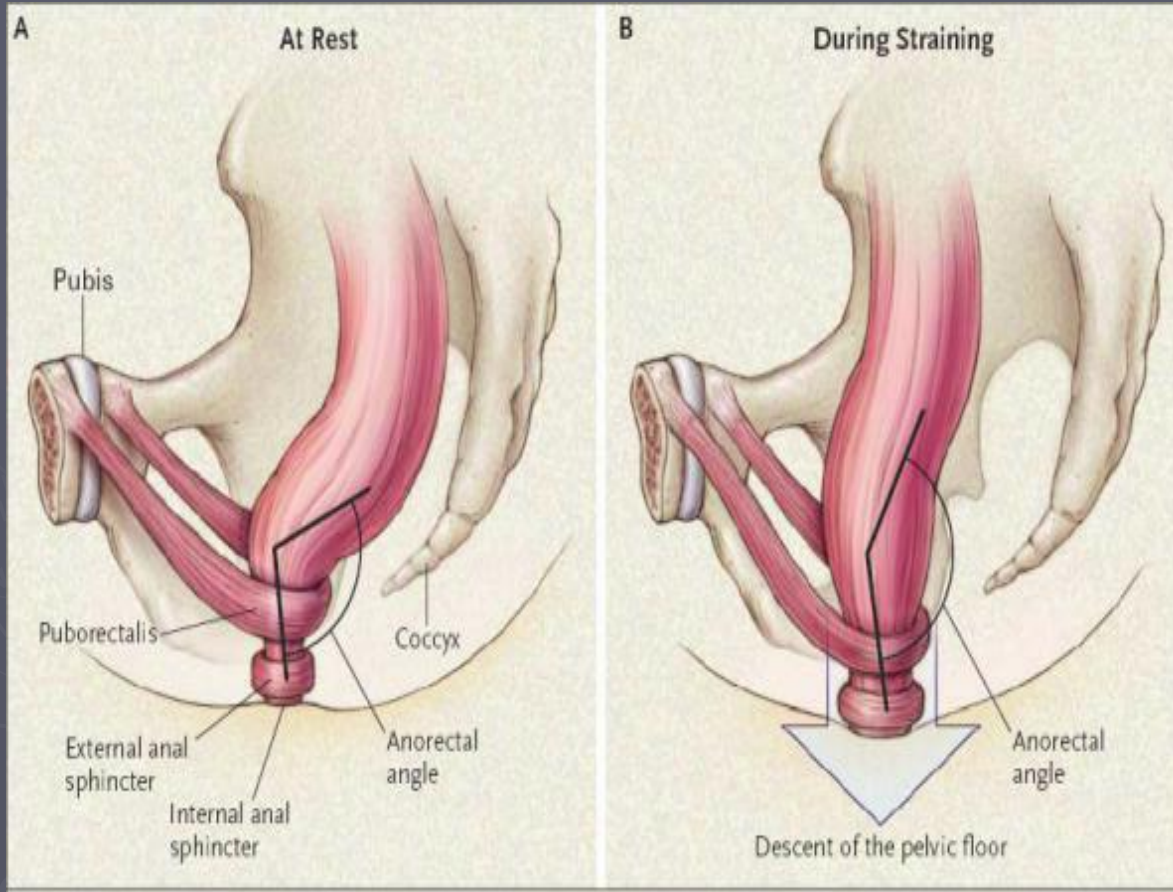
- striated muscle
- somatic innervation (pudendal, S3-4)
- squeeze pressure → double MRAP
- VOLUNTARY CONTINENCE, reflex contraction during cough or lifting

Anatomic Factors

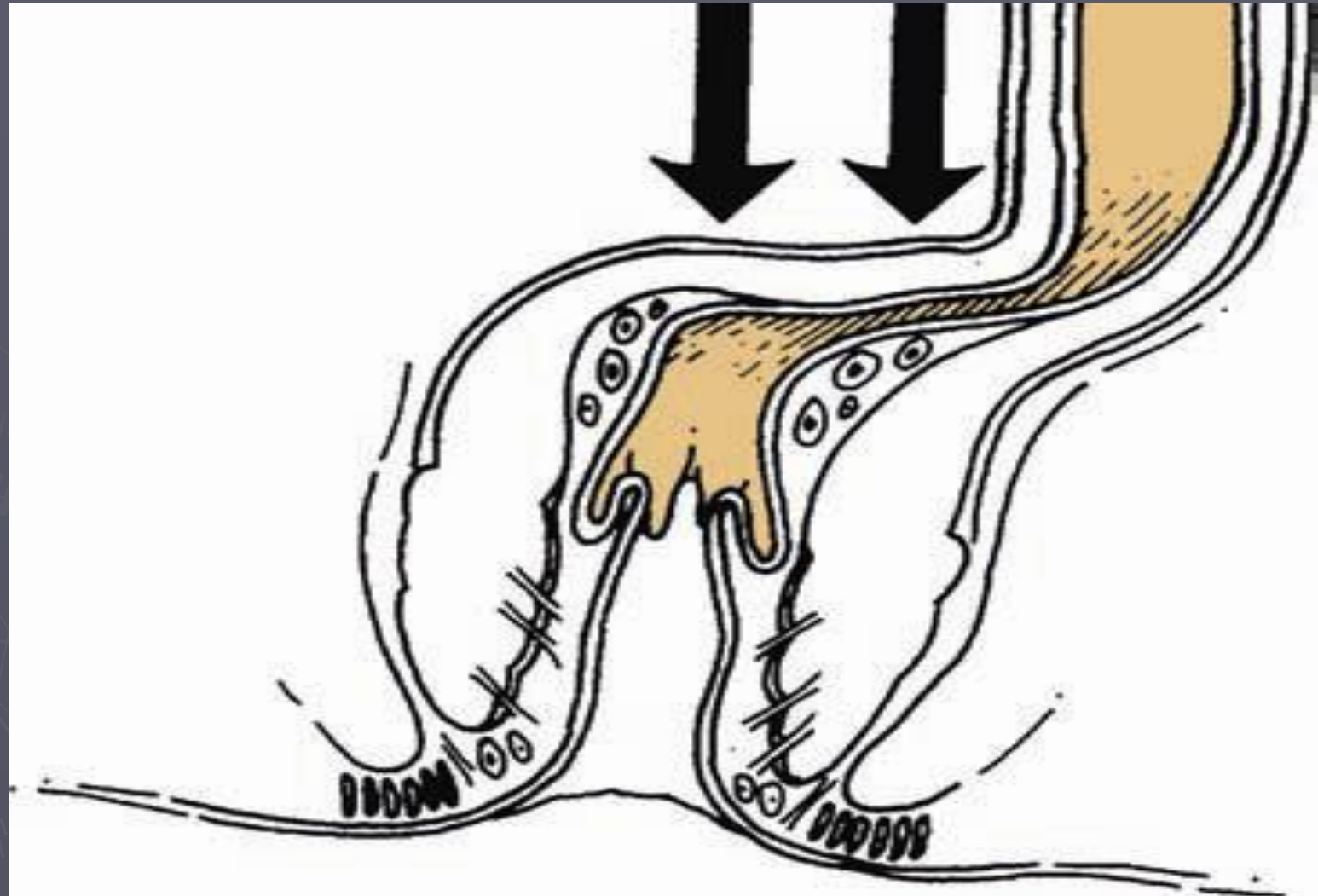
► Pelvic Diaphragm



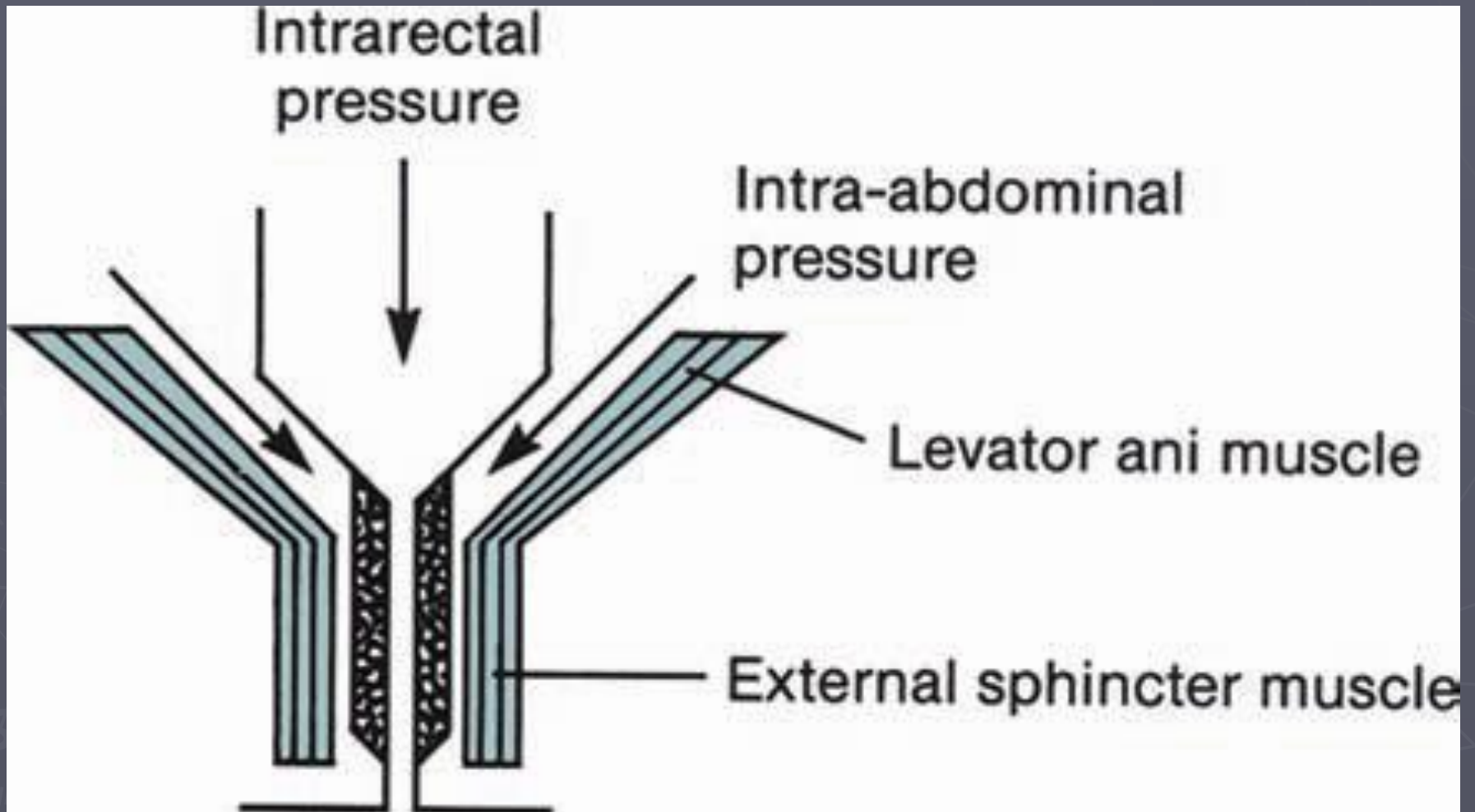
Anorectal Angle



Flap Valve Mechanism

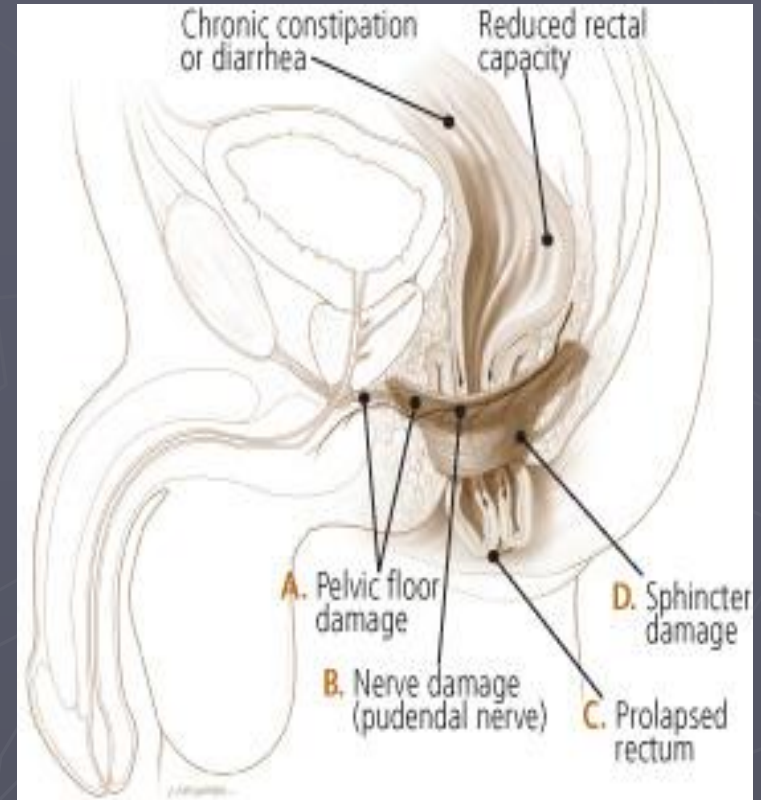


Flutter Valve



Loss of Continence

- ▶ abnormal stool consistency, overflow
- ▶ reduced storage capacity or compliance
- ▶ abnormal sensation
- ▶ abnormal pelvic floor or sphincter mechanism



MOSTLY MULTIFACTORIAL

Overflow Incontinence

▶ Diarrhea

- IBD, infection, radiation enteritis, short gut
- laxative abuse, dementia

▶ Constipation or Impaction

- IBS, childhood encopresis
- constipating medications
- dementia, psychosis
- immobility, reduced fiber intake
- **mainly ELDERLY**

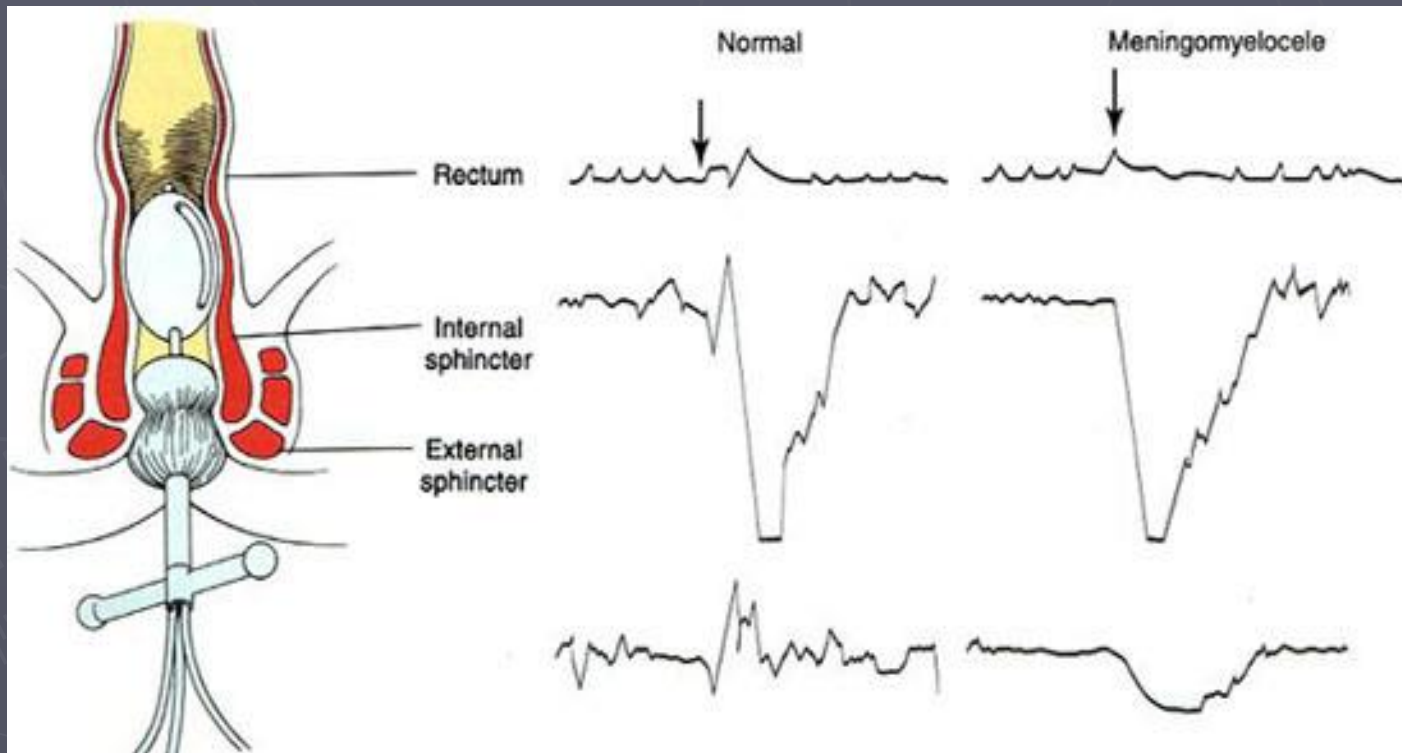
Reduced Storage Capacity

(decreased compliance)

- ▶ inflammatory bowel disease
- ▶ rectal ischemia
 - radiation proctitis
 - colitis
- ▶ collagen vascular disease
- ▶ rectal neoplasms
- ▶ absent rectal reservoir
 - ileoanal, LAR

Impaired Rectal Sensation

- ▶ diabetes mellitus → multifactorial; megarectum
- ▶ CVA, MS, spinal cord or brain lesion



Abnormal Pelvic Floor

Sphincter Defects

► **Obstetrical Injury**

- defects in 35% primiparous & 40% multiparous
- only 1/3 to 1/2 symptomatic → **immediate or years later**
- RISK FACTORS → *3rd-4th degree lacs, prolonged labor, forceps, complications of episiotomy, high birth weight, OP presentation, prior injury or postpartum symptoms*

► **Anorectal Surgery**

- *fistula operations most common culprit*
- also hemorrhoid surgery, tx of fissures

Abnormal Pelvic Floor

Denervation

- ▶ **Primary**—“idiopathic neurogenic incontinence”
 - pubendal neuropathy in 80%→ puborectalis & EAS denervated, no voluntary control, no anorectal angle
 - **descending perineal syndrome**→traction neuropathy due to chronic straining, prolonged vaginal delivery
 - *irreversible injury when nerves stretched as little as 12%*
- ▶ **Secondary**
 - spinal cord or cauda equina injuries
 - diabetic neuropathy

Diagnosis



History

- ▶ *etiologic factors*
- ▶ *onset, duration, amount, and frequency*
- ▶ *type of incontinence*
- ▶ *urgency & frequency*

- ▶ **SEVERITY**

- Wexner Score
- Williams Score

- ▶ **QUALITY OF LIFE** (FIQOL scale)



See more funny photos at FUNNYBOX.COM

Wexner Scale

Type of Incontinence	Never	Rarely (<1/month)	Sometimes (<1/week)	Usually (<1/day)	Always (>1/day)
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Requires pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

20 points = complete incontinence

0 points = perfect continence

FIQOL Scale

Scale 1: Lifestyle

I cannot do many of the things I want to do (agreement, 4 points)

I am afraid to go out (frequency, 4 points)

It is important to plan my schedule (daily activities) around my bowel pattern (frequency, 4 points)

I cut down on how much I eat before I go out (frequency, 4 points)

It is difficult for me to get out and do things like going to a movie or church (frequency, 4 points)

I avoid traveling by plane or train (agreement, 4 points)

I avoid traveling (frequency, 4 points)

I avoid visiting friends (frequency, 4 points)

I avoid going out to eat (agreement, 4 points)

I avoid staying overnight away from home (frequency, 4 points)

Scale 2: Coping behavior

I have sex less often than I would like to (agreement, 4 points)

The possibility of bowel accidents is always on my mind (agreement, 4 points)

I feel I have no control over my bowels (frequency, 4 points)

Whenever I go somewhere new, I specifically locate where the bathrooms are (agreement, 4 pts)

I worry about not being able to get to the toilet in time (frequency, 4 points)

I worry about the bowel accidents (agreement, 4 points)

I try to prevent bowel accidents by staying very near a bathroom (agreement, 4 points)

I can't hold my bowel movement long enough to get to the bathroom (frequency, 4 points)

Whenever I am away from home I try to stay near a restroom as much as possible (frequency, 4 pts)

FIQOL Scale

Scale 3: Depression

In general, would you say your health is (excellent–poor 5 points)

I am afraid to have sex (agreement, 4 points)

I feel different from other people (agreement, 4 points)

I enjoy life less (agreement, 4 points)

I feel like I am not a healthy person (agreement, 4 points)

I feel depressed (agreement, 4 points)

During the past month, have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile? (extremely so–not at all, 6 points)

Scale 4: Embarrassment

I leak stool without even knowing it (frequency, 4 points)

I worry about others smelling stool on me (agreement, 4 points)

I feel ashamed (agreement, 4 points)

Physical Exam

▶ External assessment

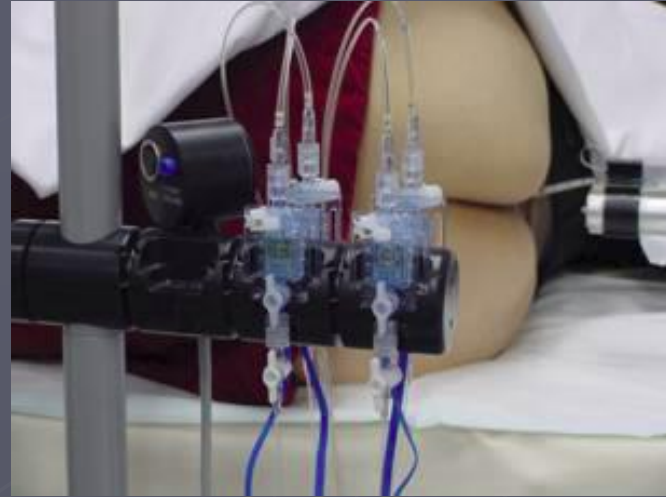
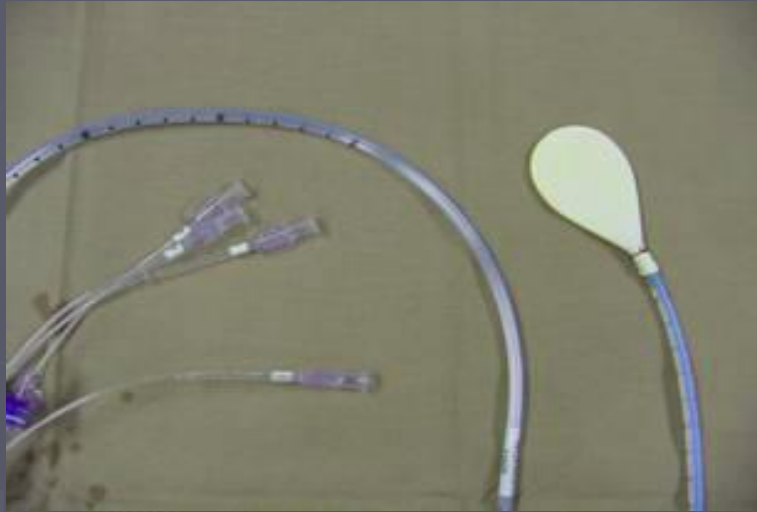
- odour, use of pad, undergarment soiling
- dermatitis, surgical scars
- hemorrhoids, fistulas, prolapse
- “anal wink”

▶ Digital exam

- mass or fecal impaction
- resting & squeeze pressure
- anovaginal septum, perineal body

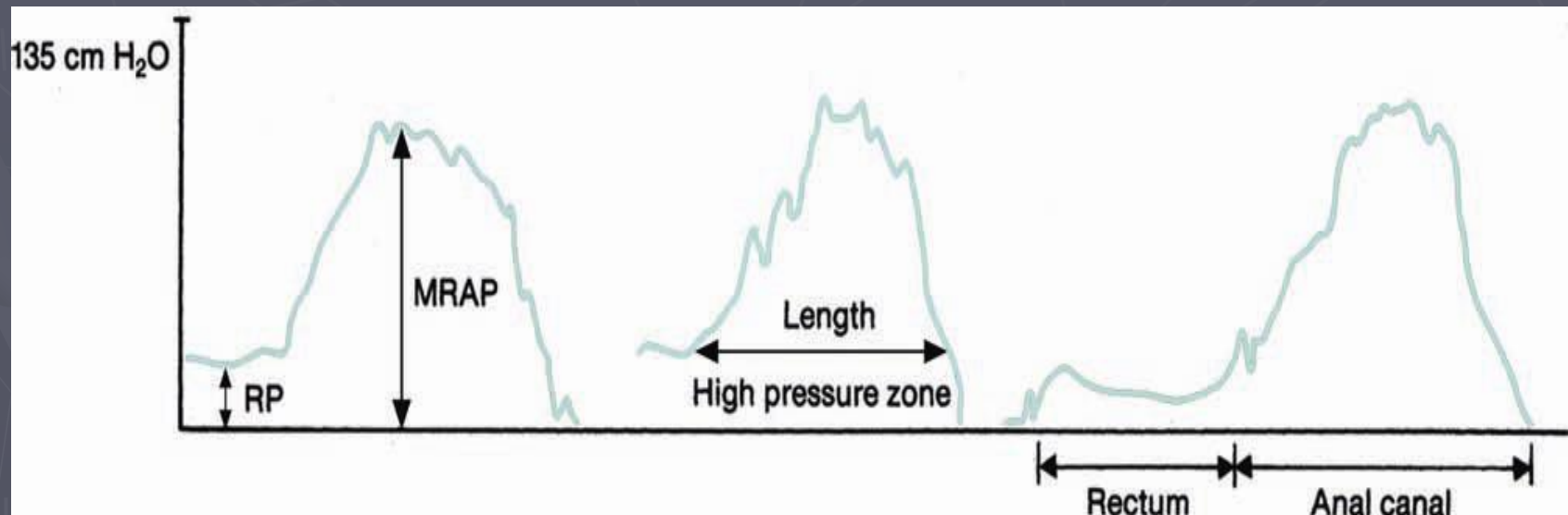


Anorectal Manometry



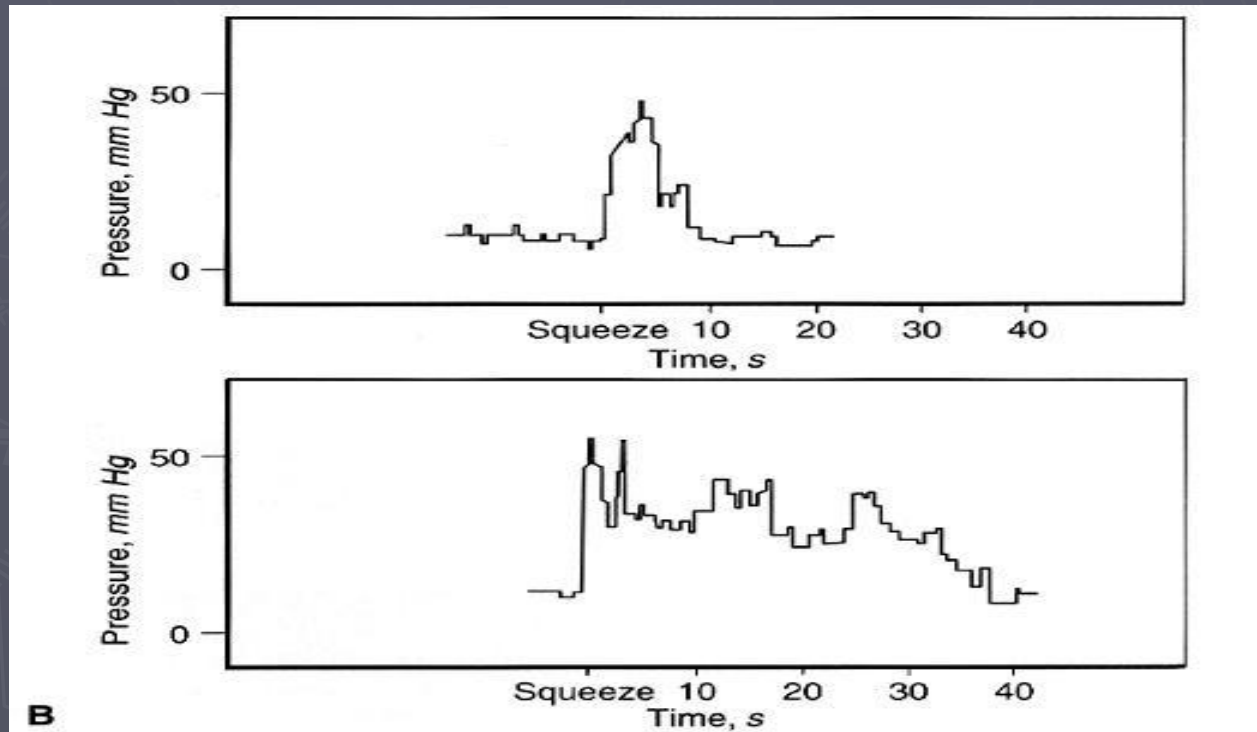
Anorectal Manometry

- ▶ length of anal canal
- ▶ maximal resting anal pressure



Anorectal Manometry

- ▶ voluntary function
- ▶ amplitude & duration of squeeze pressure



Anorectal Manometry

▶ rectal sensation & compliance

- rectal sensory threshold
- first sensation of urgency (20cc)
- maximum tolerable volume (sensation of pain)
- *biofeedback not helpful if sensory threshold poor..*

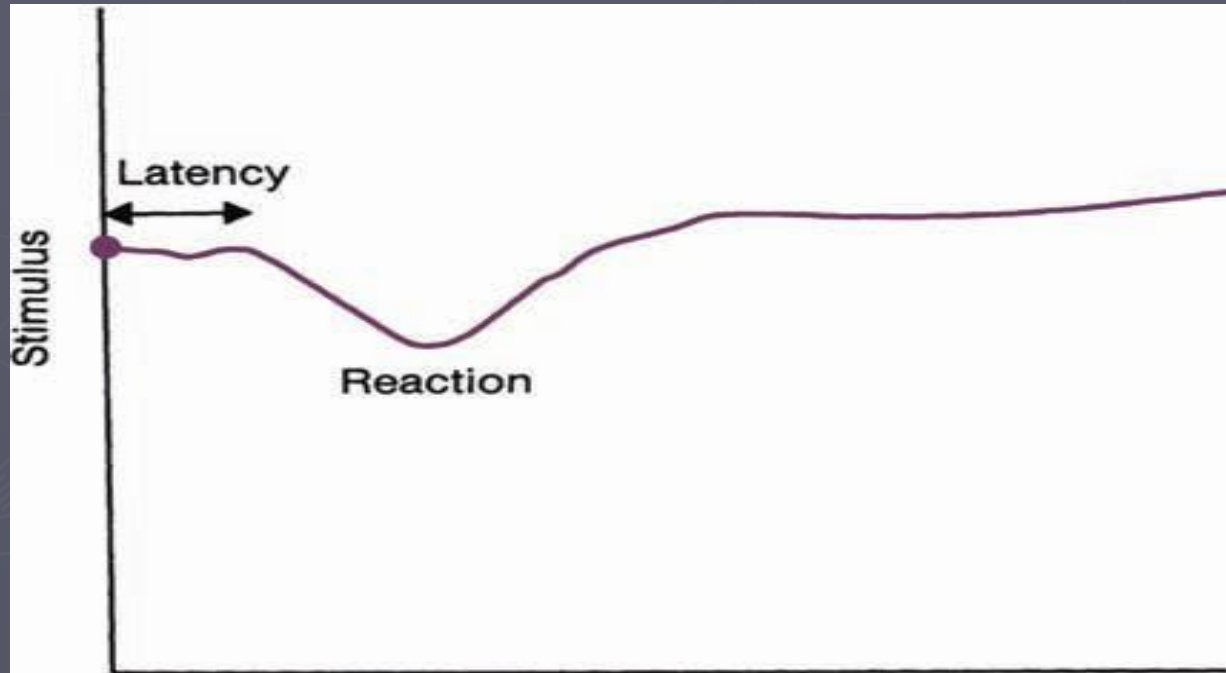
▶ cannot discriminate between anatomic & neurologic defects

Pudendal Nerve Terminal Latency

- ▶ evaluates pelvic floor innervation
- ▶ measures time from pudendal stimulation to EAS contraction (normal \rightarrow 2.0 msec)



Pudendal Nerve Terminal Latency



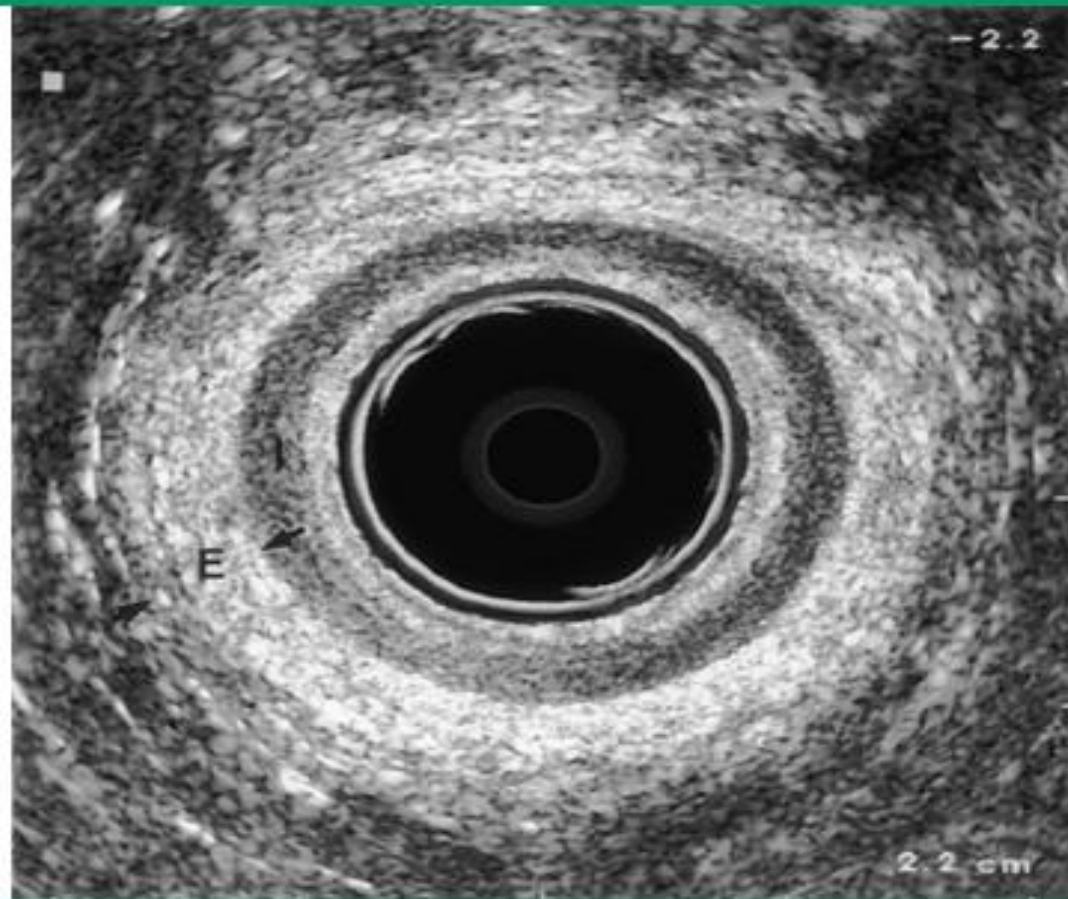
- ▶ painless but operator dependent
- ▶ poor correlation with symptoms & histology

Endoanal Ultrasound

- ▶ anatomic defects
 - sphincters
 - puborectalis
 - rectal wall
- ▶ correlates well with manometry
- ▶ simple, reliable, non-invasive

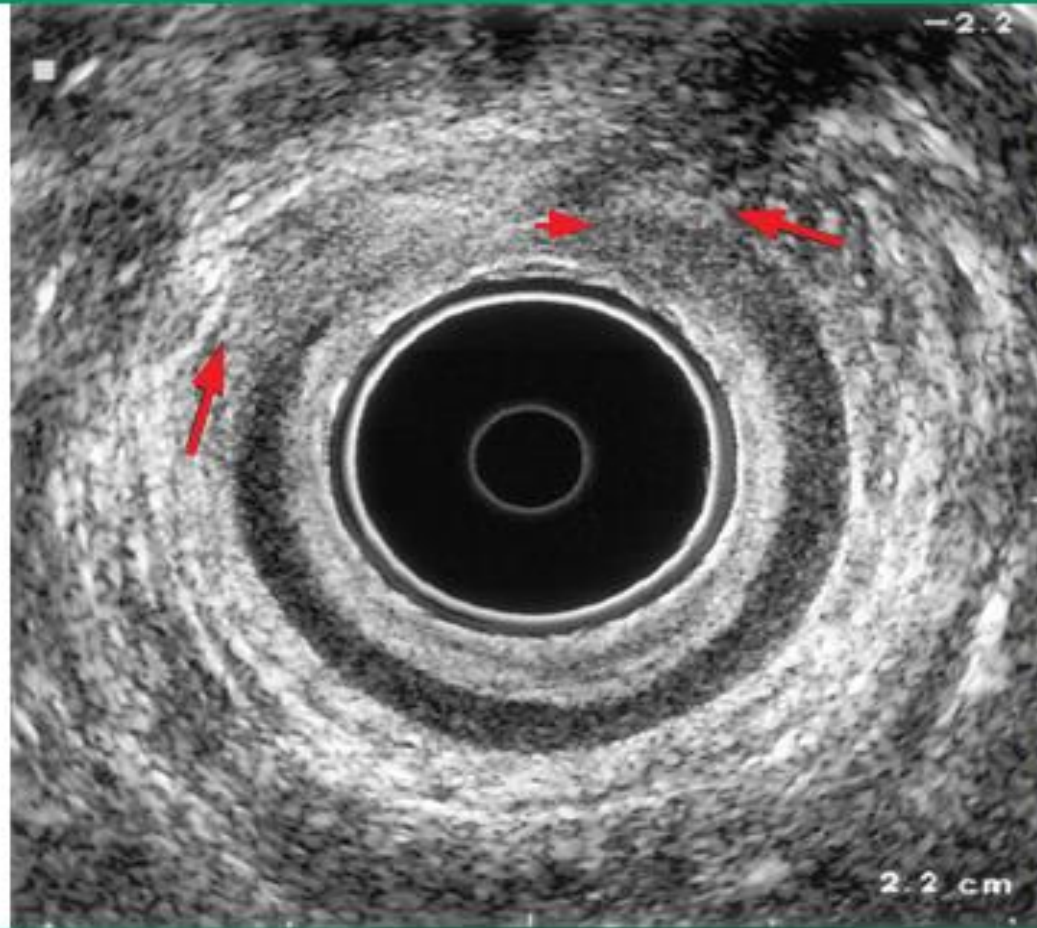


Normal anal ultrasound



Anal ultrasound showing the anal sphincter muscles in cross section through the mid anal canal. The darker homogenous ring is the internal anal sphincter smooth muscle (i). The white heterogeneous ring surrounding this is the external anal sphincter (arrows; E). The top of the figure is anterior.

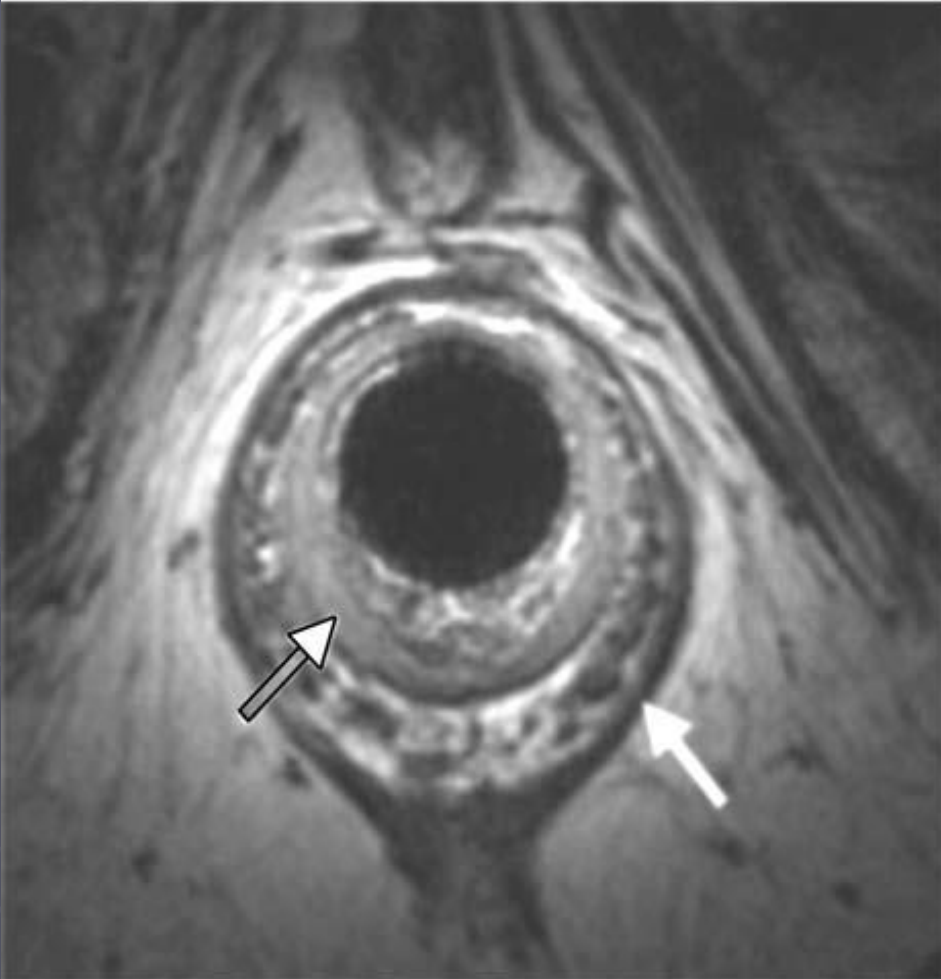
Anterior sphincter damage



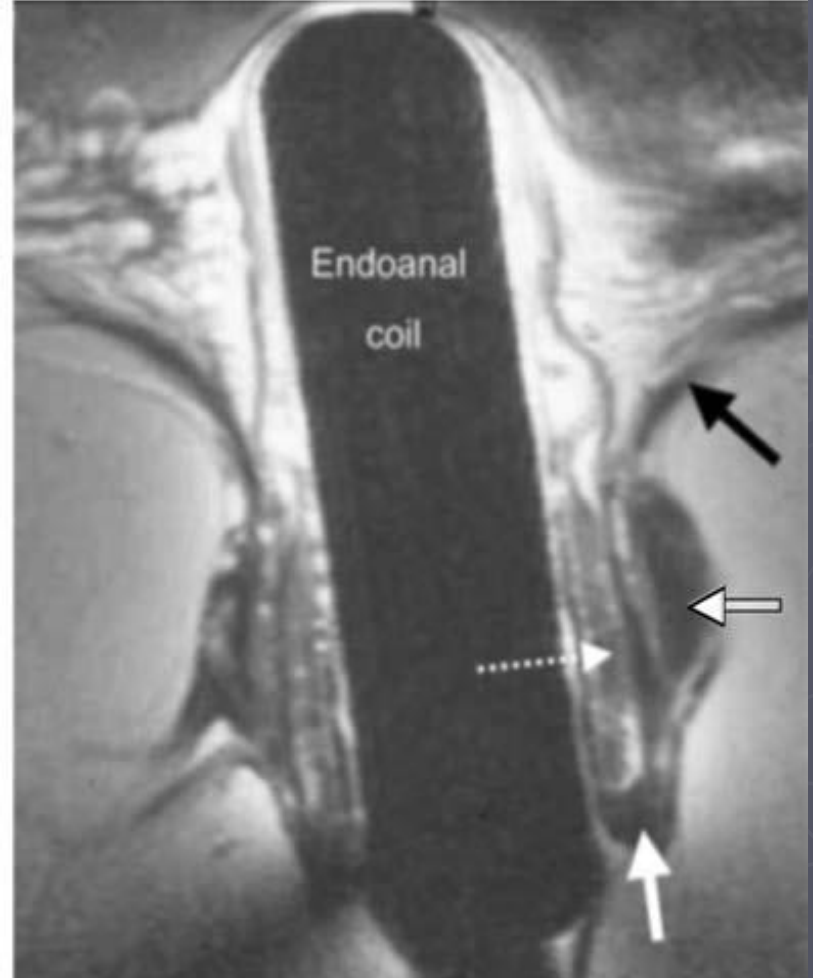
Anal ultrasound scan of a woman with anterior sphincter damage due to obstetrical complications. The top of the figure is anterior. There is disruption of the muscles of both the internal anal sphincter (small arrows) and the external anal sphincter (large arrows).

MRI *(endoanal or surface coil)*

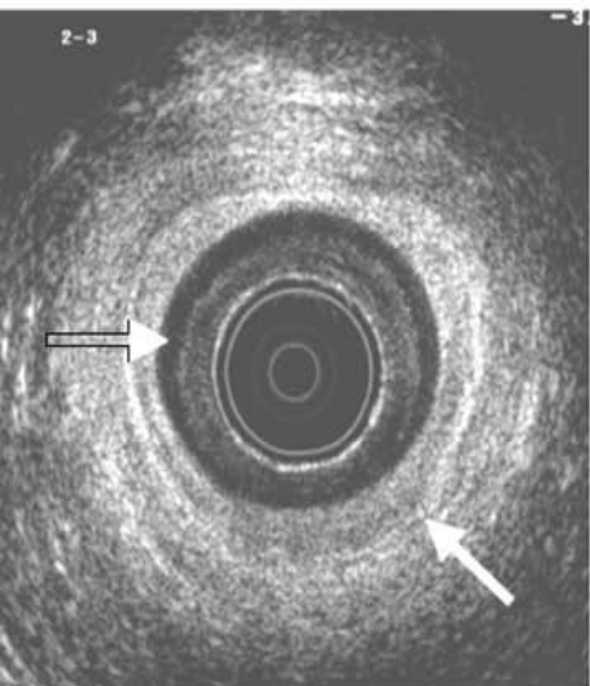
A



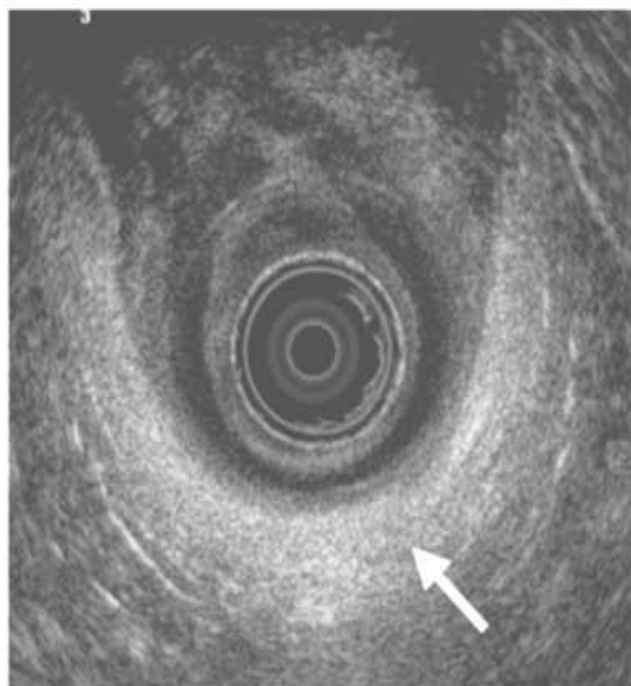
B



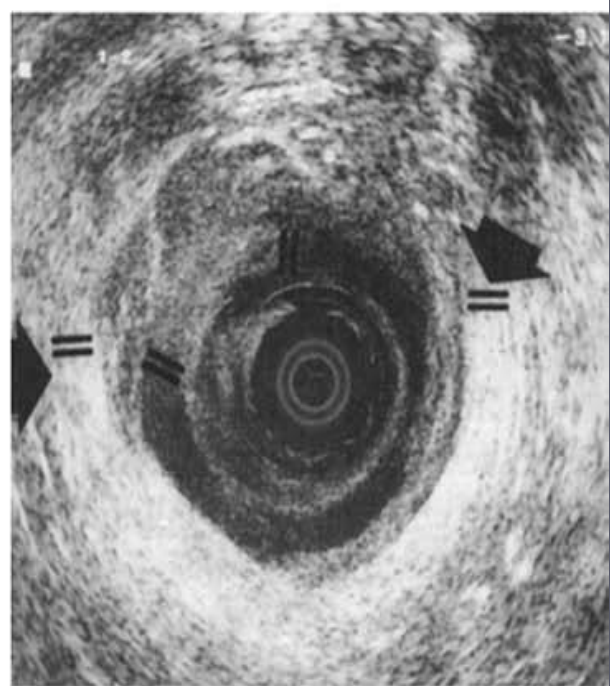
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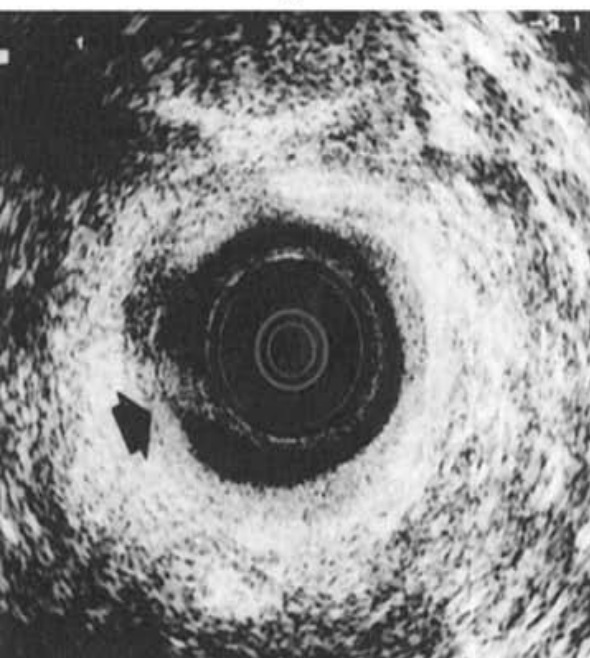
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C



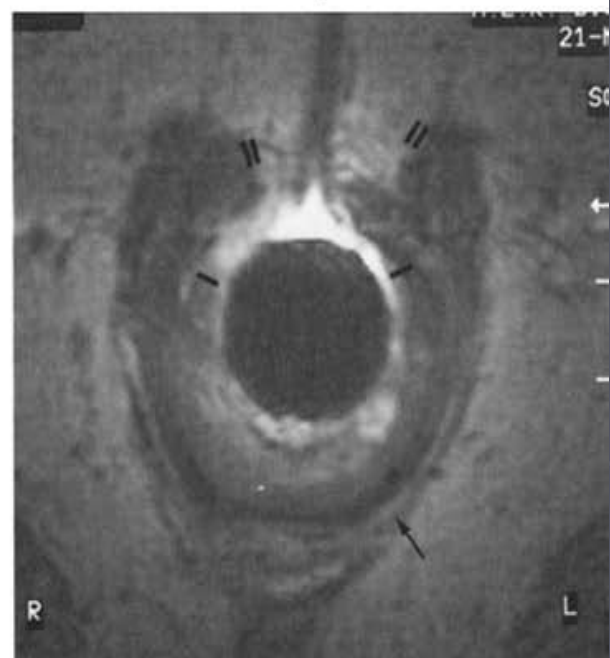
D



E



F



Defecography

- ▶ **radiologic visualization of defecation**
 - shows pelvic floor activity in each stage → *rest, straining, defecation, closing*
 - changes in anorectal angle
 - degree of evacuation
 - evaluates pelvic descent
 - detects occult or overt prolapse
- ▶ limited use for incontinence
- ▶ wide inter-observer variability

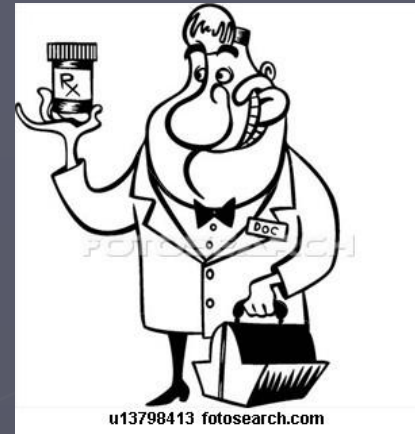




Management

Medical Therapy

- ▶ improve stool consistency
 - treat underlying cause
 - dietary modifications
 - bulking agents
 - constipating medication →
loperamide >> diphenoxylate, anticholinergics, codeine, bile acid binders, TCAs, topical neo
- ▶ perineal hygiene, scheduled toileting
- ▶ enemas, colonic irrigation +/- anal plug
- ▶ ***mainly helpful for minor incontinence***

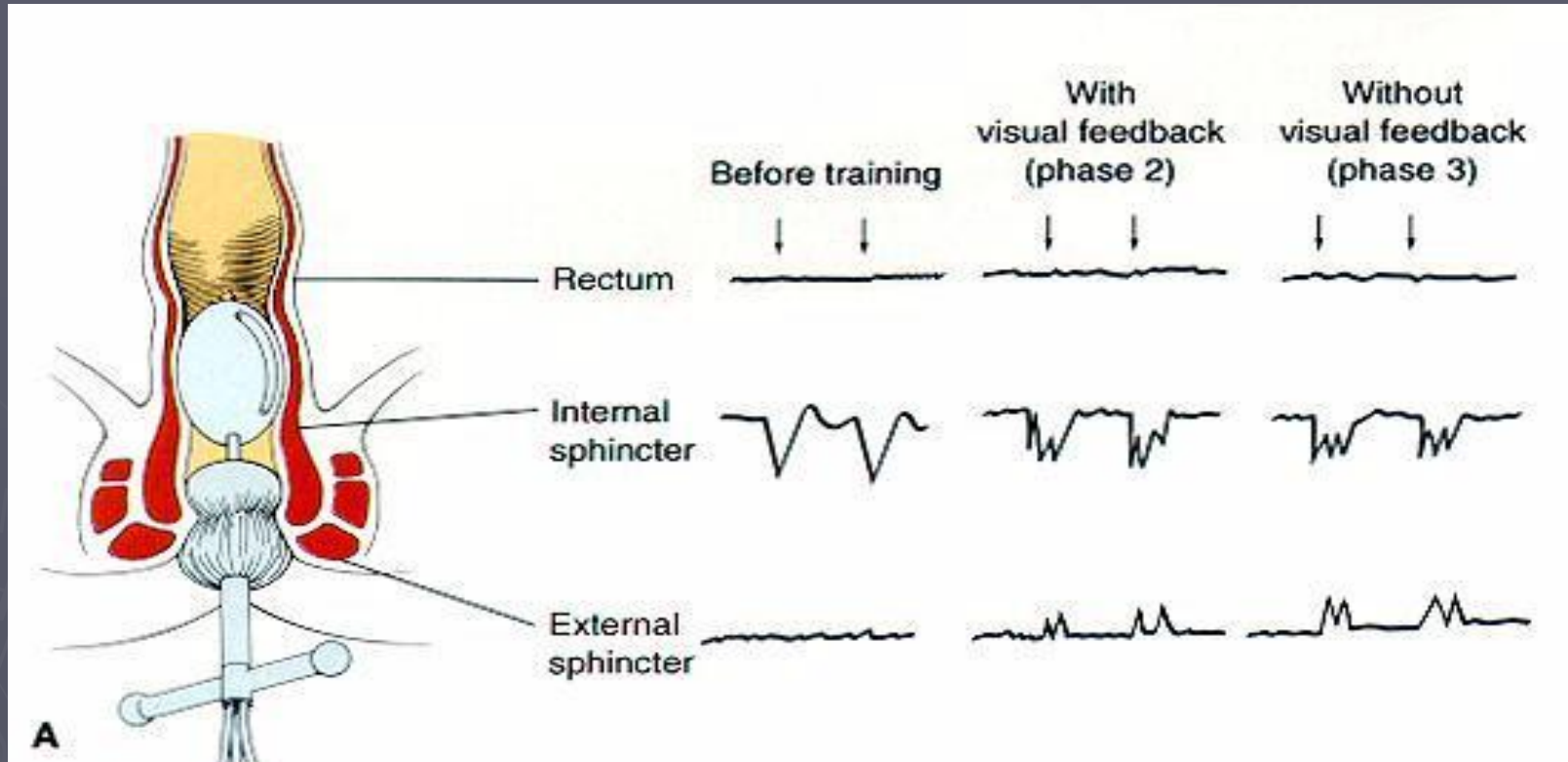


Biofeedback

- ▶ cognitively retraining pelvic floor & abdominal wall musculature using electrodes on an anal plug and abd wall surface
 - improve striated muscle contraction
 - enhance ability to perceive rectal distension
 - coordinate pelvic floor contraction with rectal distention
- ▶ best for partial denervation
- ▶ minor structural defects
- ▶ *non-invasive & cheap*
- ▶ *time-consuming & labor intensive*



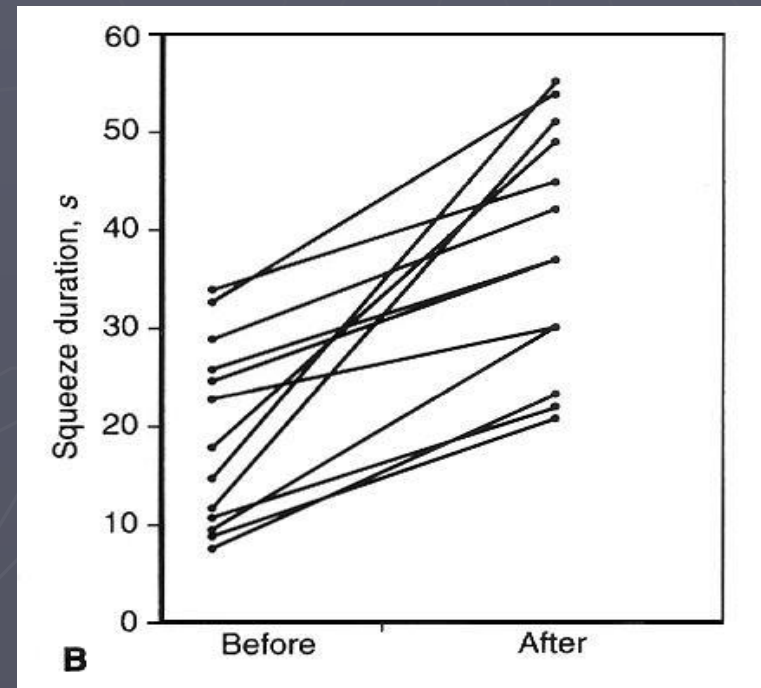
Biofeedback



- ▶ results are mixed (*38-100% success rates*)
 - benefits 75%, cures 50%
 - best after anorectal surgery, worst → spinal cord injury

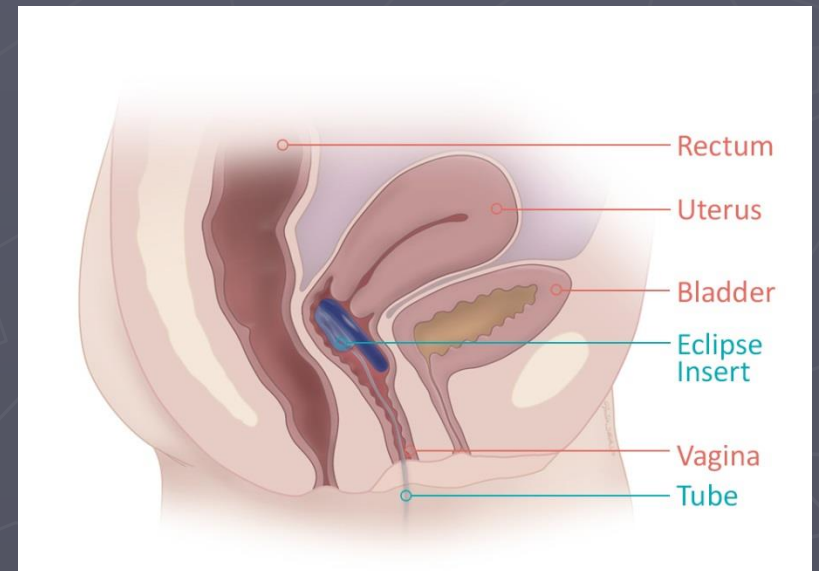
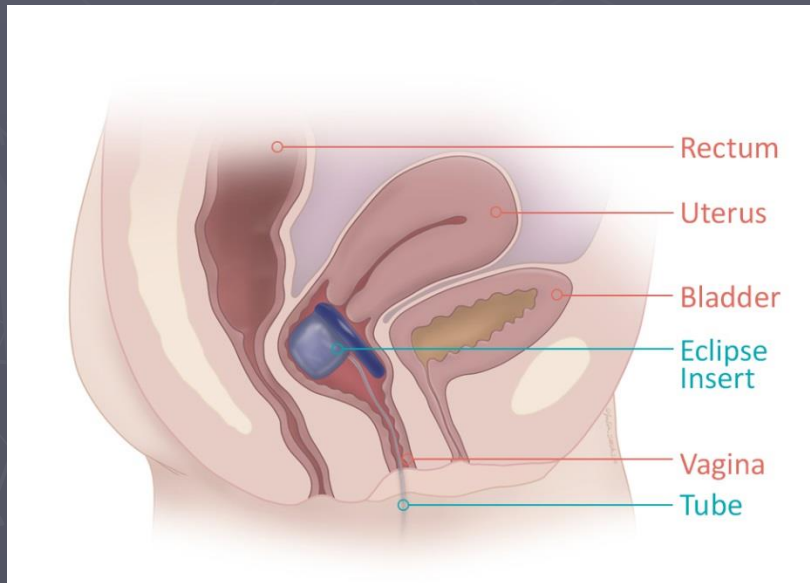
Biofeedback

- ▶ superior to pelvic floor strengthening exercises
- ▶ deterioration with time
- ▶ may need refresher sessions
- ▶ **CLINICIAN EXPERTISE**
- ▶ **PATIENT MOTIVATION**
- ▶ Not helpful for—
 - dementia
 - complete denervation
 - decreased rectal capacity 2° proctitis or resection



Vaginal Insert

- ▶ approved by FDA in 2015
- ▶ dynamic, patient-controlled, reversible



Vaginal Insert

LIFE Study



- ▶ Multicenter, open-label
- ▶ 110 patients entered study
 - *Vaginal atrophy was relative contraindication*
 - **Only 55% properly fitted & continued on**
- ▶ *Successful symptom reduction at 1 & 3 mos.*
 - *86% per protocol, 79% intention to treat*
- ▶ *Improved FIQOL, 96% comfortable*
- ▶ **LIBERATE** (larger, long-term f/u)

Vaginal Insert

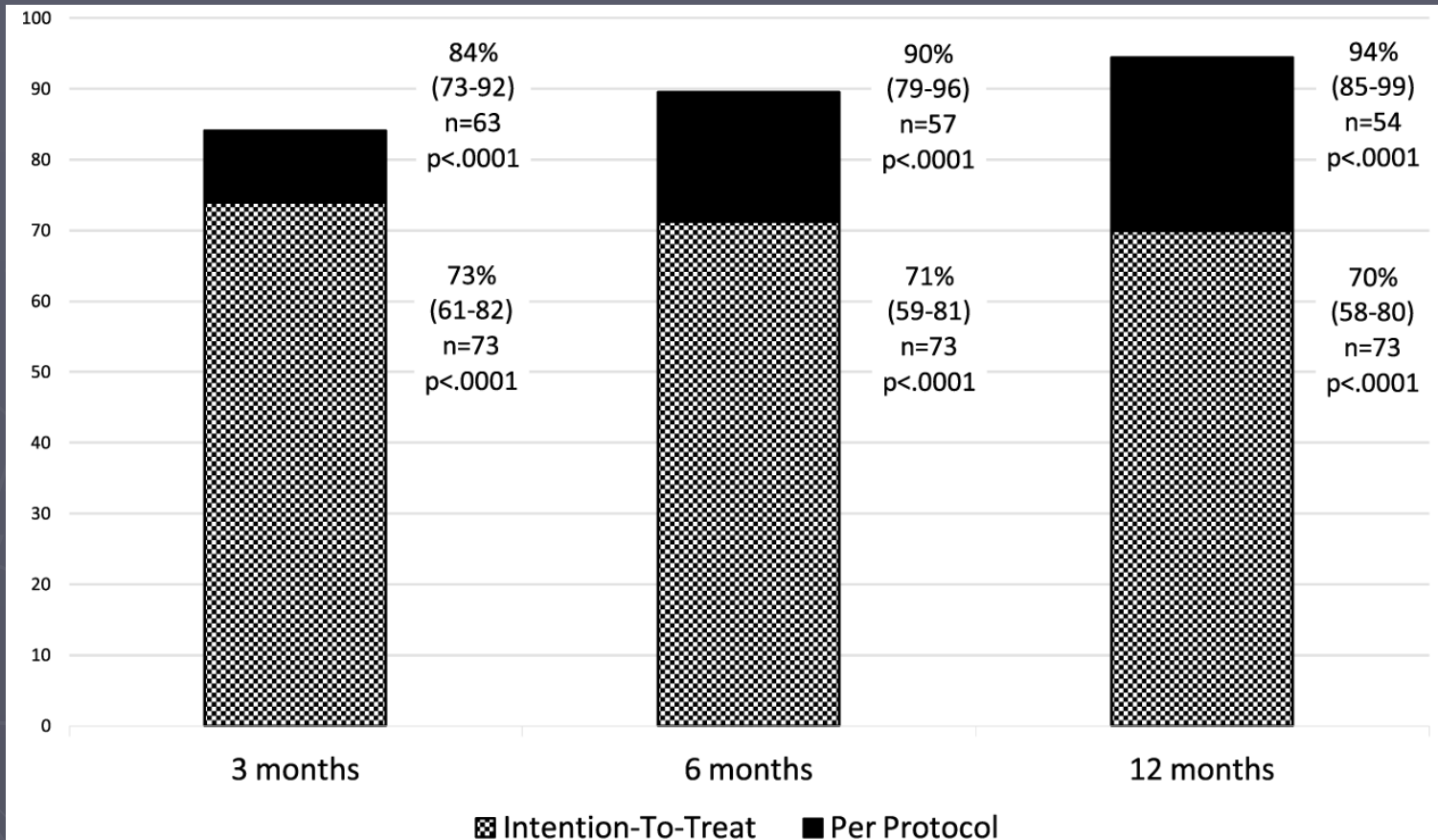
LIBERATE Study



- ▶ Multicenter, open-label
- ▶ 73 patients eligible to enroll
 - *Successful fit required*
 - *Successful 2 wk trial*
 - *Baseline mean of 14.1 \pm 12.15 FI episodes over 2 wks*
- ▶ Primary outcome → success at 3, 6, 12 mos
- ▶ Secondary outcomes → FIQL, St. Mark's score, other satisfaction measures

Vaginal Insert

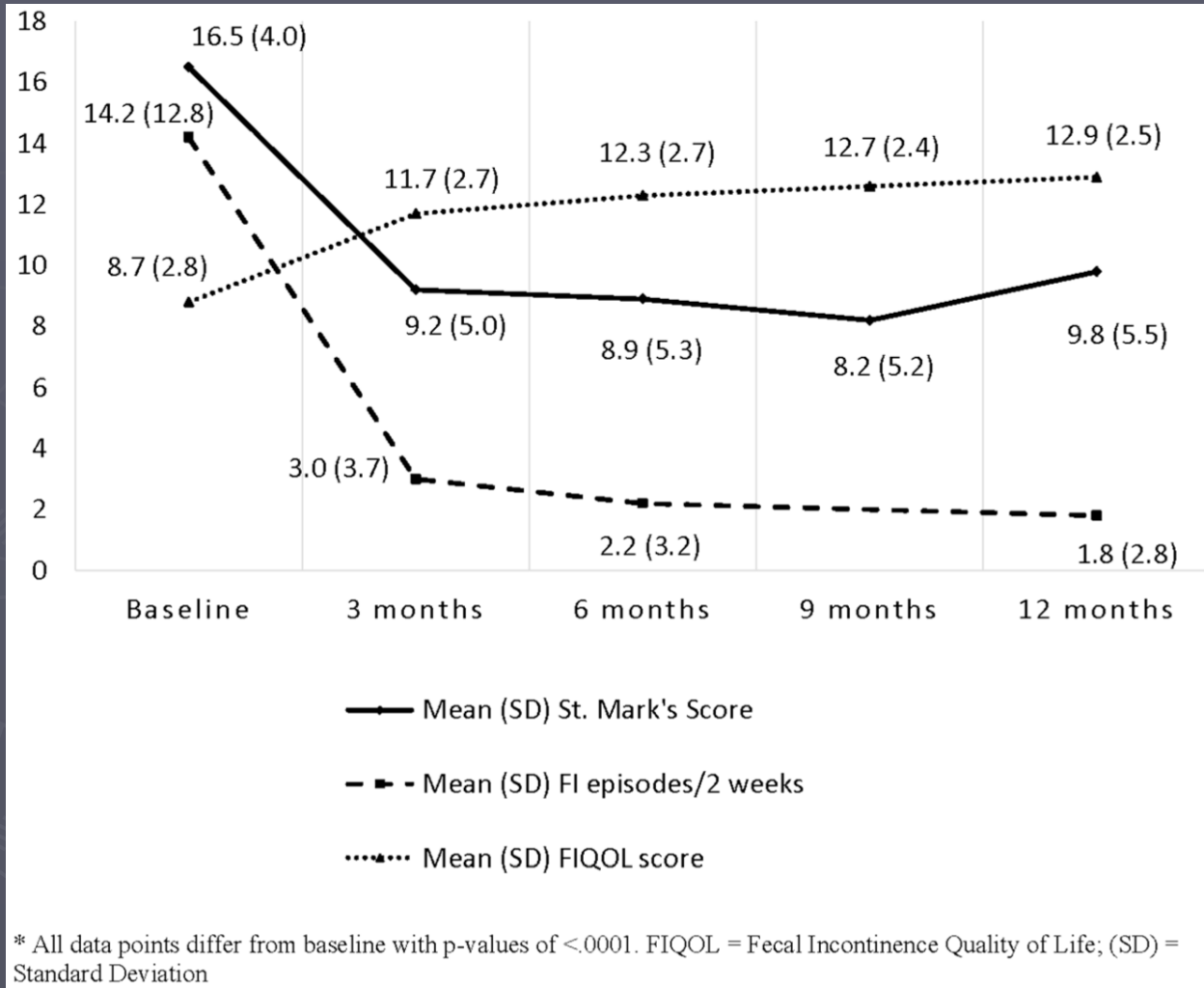
LIBERATE Study



Legend: Values displayed are percentages of participants in each group with at least 50% reduction in frequency of FI episodes per 2 week period with 95% Clopper-Pearson confidence intervals; p-values reflect exact binomial test comparing these percentages to 40%.

Vaginal Insert

LIBERATE Study



Anal Insert Device



- ▶ Single use, soft silicone (*two upper disk sizes*)
- ▶ Expels spontaneously with BM

Anal Insert Device

Safety & Efficacy Data

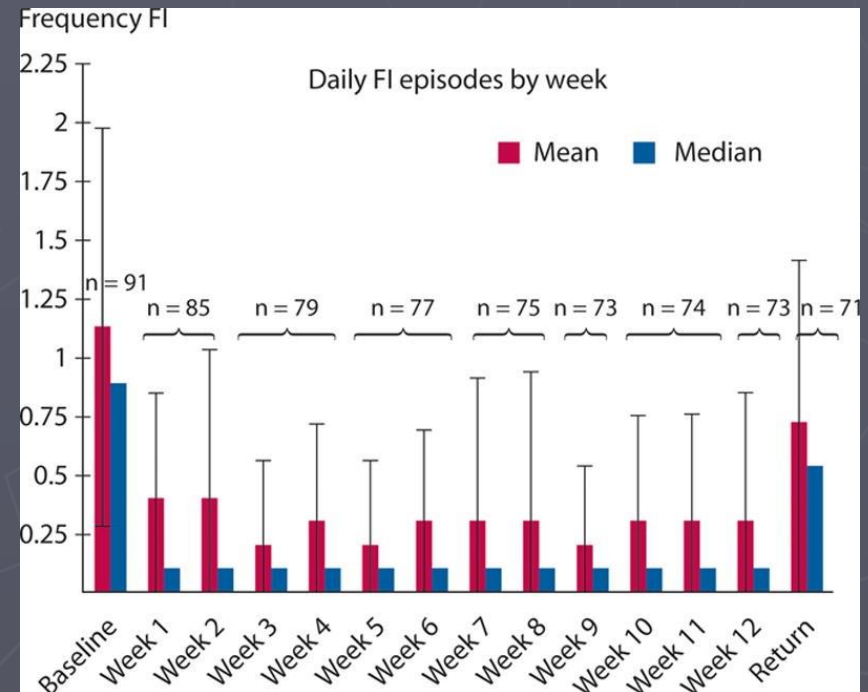
▶ 73 pts completed 12 weeks of treatment

▶ 62% success (ITT)

▶ QOL not evaluated

▶ AEs in 51%

- *Urgency*
- *Displacement*
- *Irritation, pain, soreness*



Surgical Options

- ▶ Repair
- ▶ Reinforce
- ▶ Replace
- ▶ Re-innervate

- ▶ Re-route



Repair

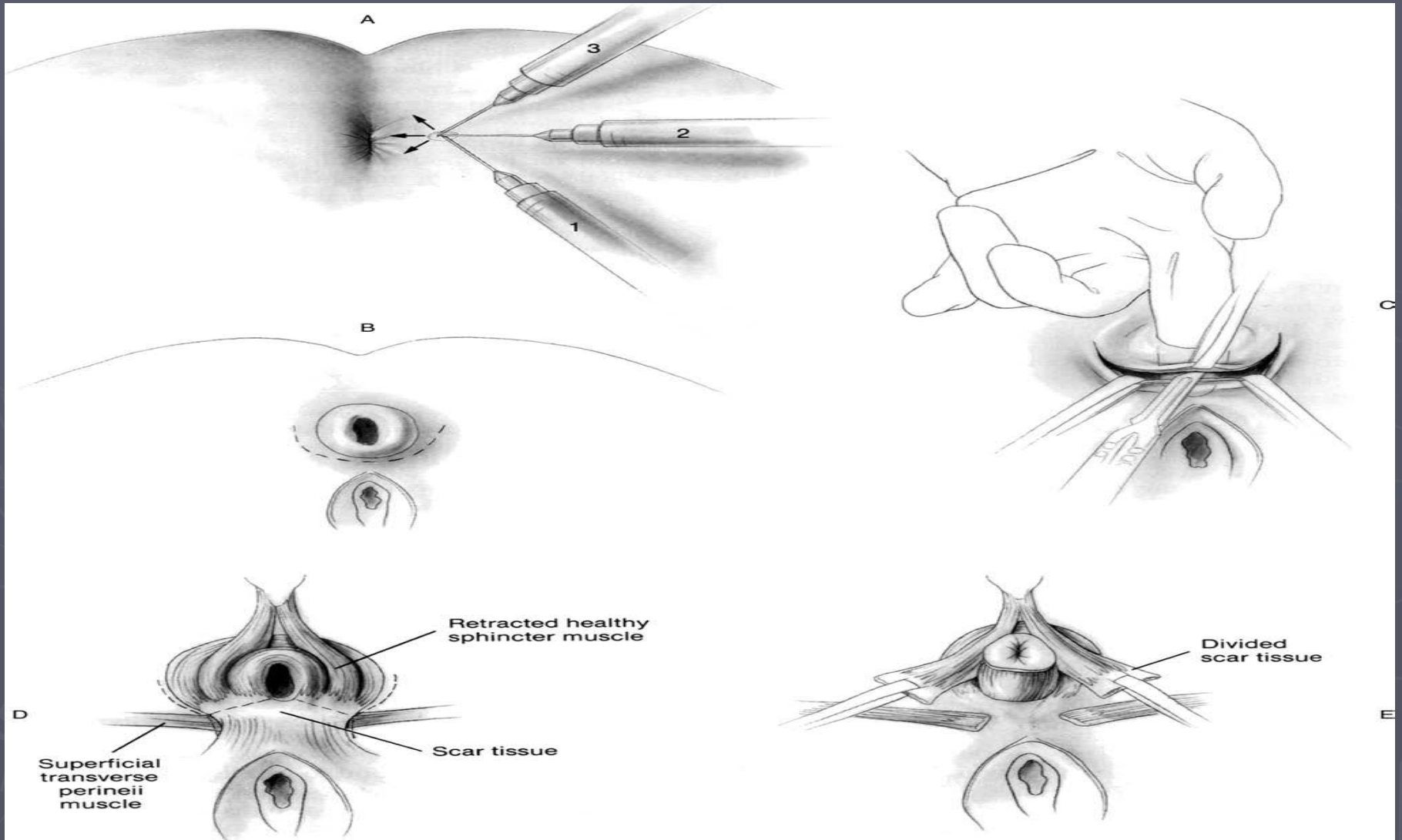
► Anterior Sphincteroplasty

- traumatic sphincter injury
- overlapping repair
- restores perineal body, corrects rectovag fistula

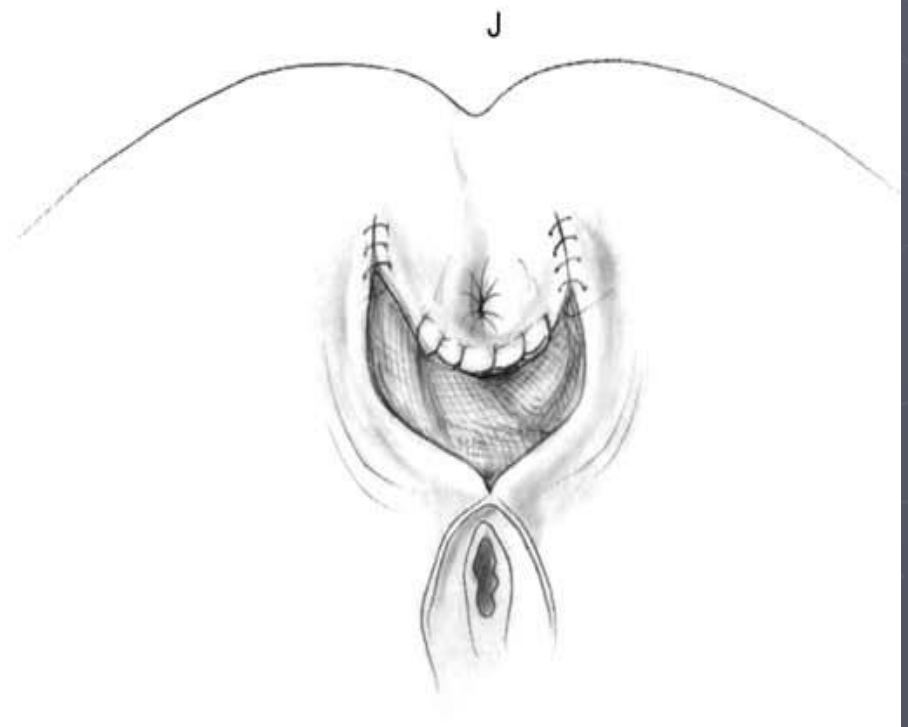
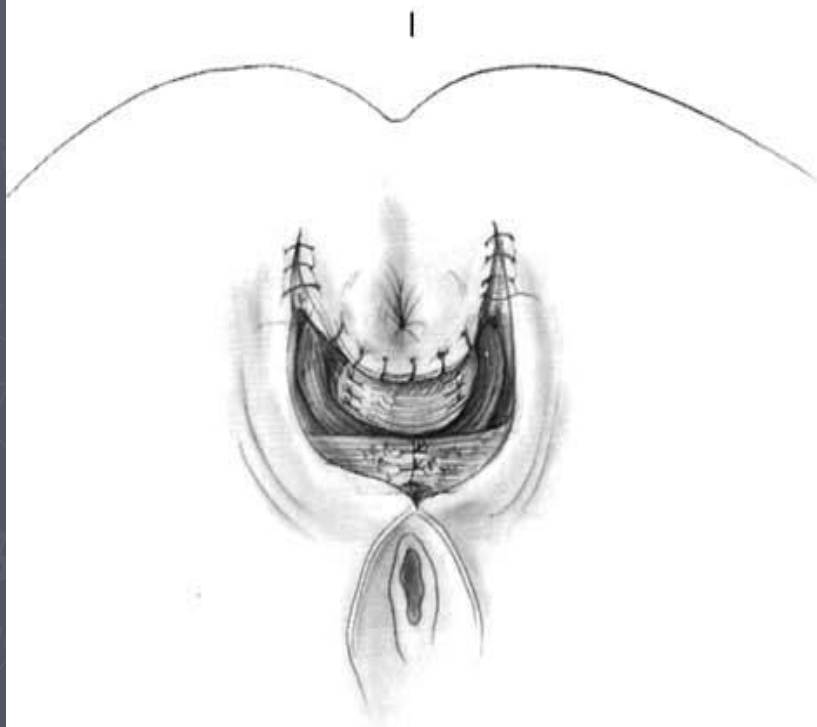
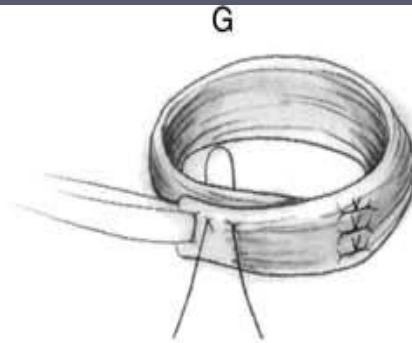
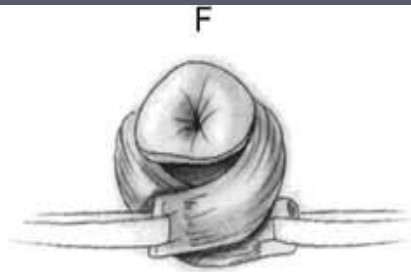
► Postanal Repair

- pelvic floor weakness or descent
- denervation damage
- restores anorectal angle & lengthens anal canal
- *Replaced by SNS*

Anterior Sphincteroplasty



Anterior Sphincteroplasty



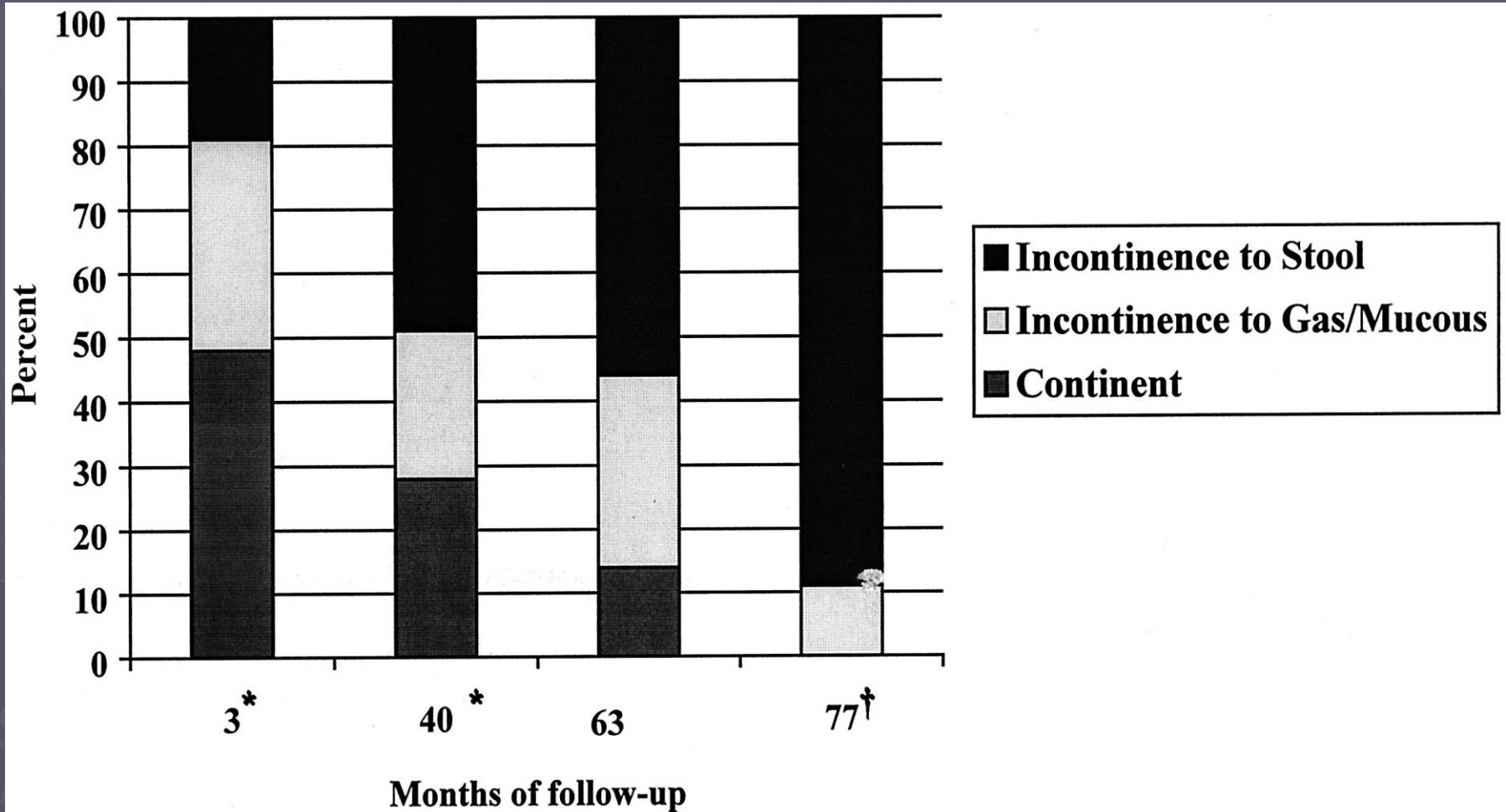
Anterior Sphincteroplasty

- ▶ functional improvement in 50-80%
- ▶ BUT deteriorates over time
- ▶ most have residual symptoms
- ▶ can repeat repair

- ▶ risk factors for poor outcome
 - *pelvic floor denervation*
 - *residual sphincter defect*
 - *lateral or posterior repairs*

Outcome vs. Length of F/u

Halverson & Hull DCR 2002



Reinforce

▶ Anal Encirclement

(Thiersch 1891)

now...Biologic Mesh??



▶ Muscle Transposition

- dynamic graciloplasty
- gluteus maximus transfer

▶ Injectable & Implantable Bulking Agents

▶ SECCA Procedure

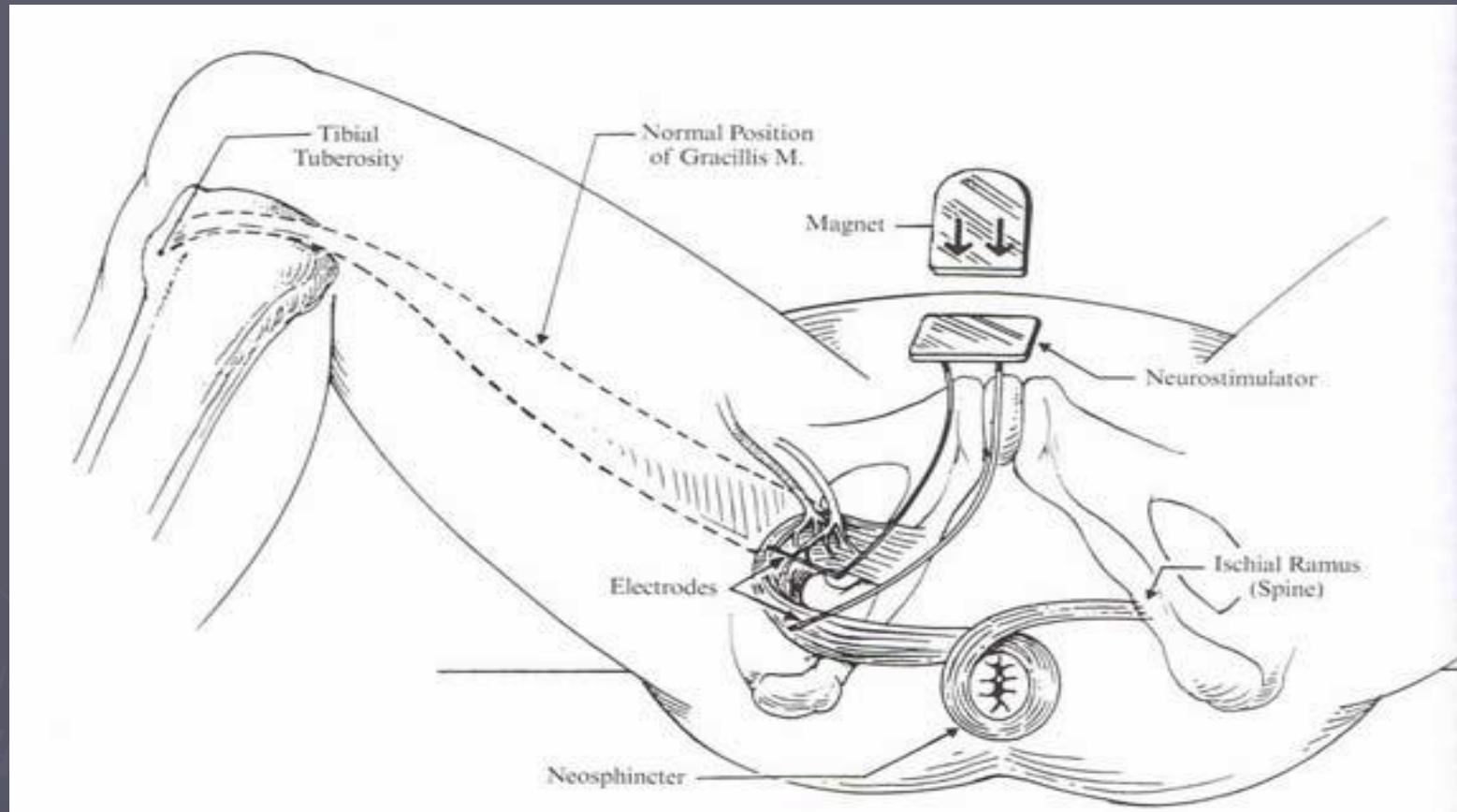
Dynamic Graciloplasty

► **Indications**

- completely destroyed sphincter
- defect too large for repair

► **Technical Issues**

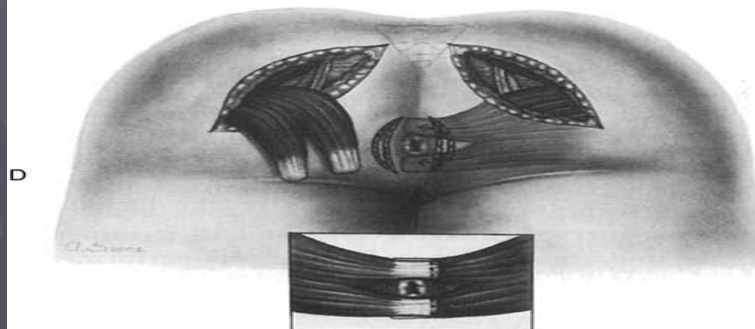
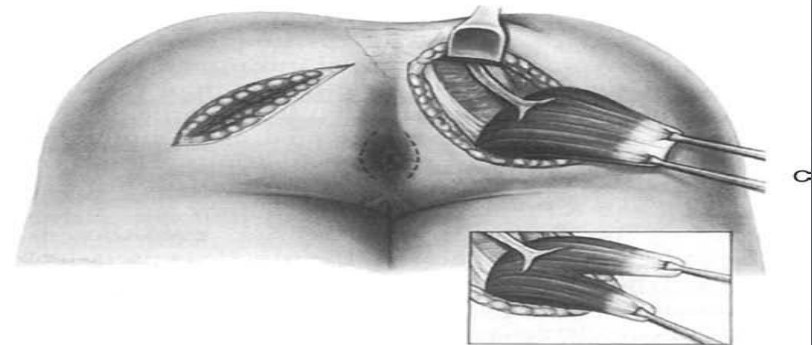
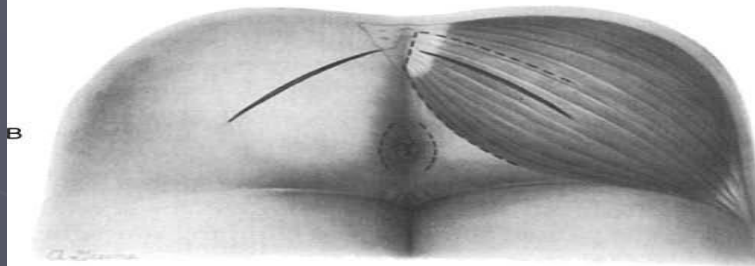
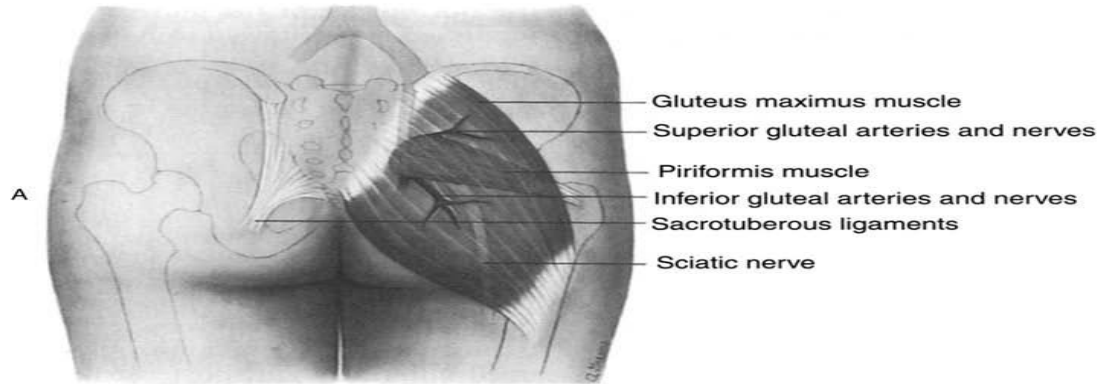
- anatomically suitable, expendable adductor function
- must be adapted to contain long-acting, automatic, non-fatiguable muscle fibers
- implanted stimulator device not available in US



► Results

- success rates vary 40-80% (*73% continence at 2yrs*)
- complication rates high but treatable (*39% wound infxn*)
- median survival of implanted battery → 405 weeks

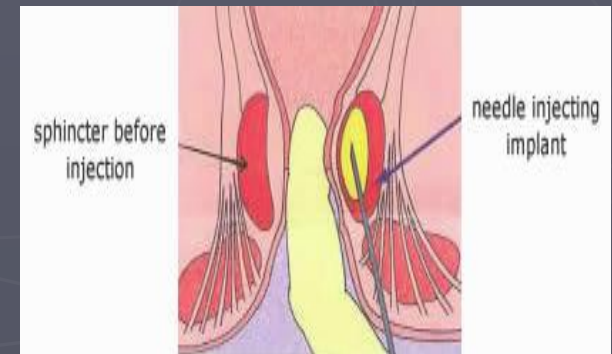
Gluteus Transposition



Injectable Bulking Agents

- ▶ facilitates closure of the anal canal
- ▶ no change in anal canal pressure
- ▶ submucosal or intersphincteric injection

- silicone, collagen
- biologic tissue
- carbon-coated microbeads

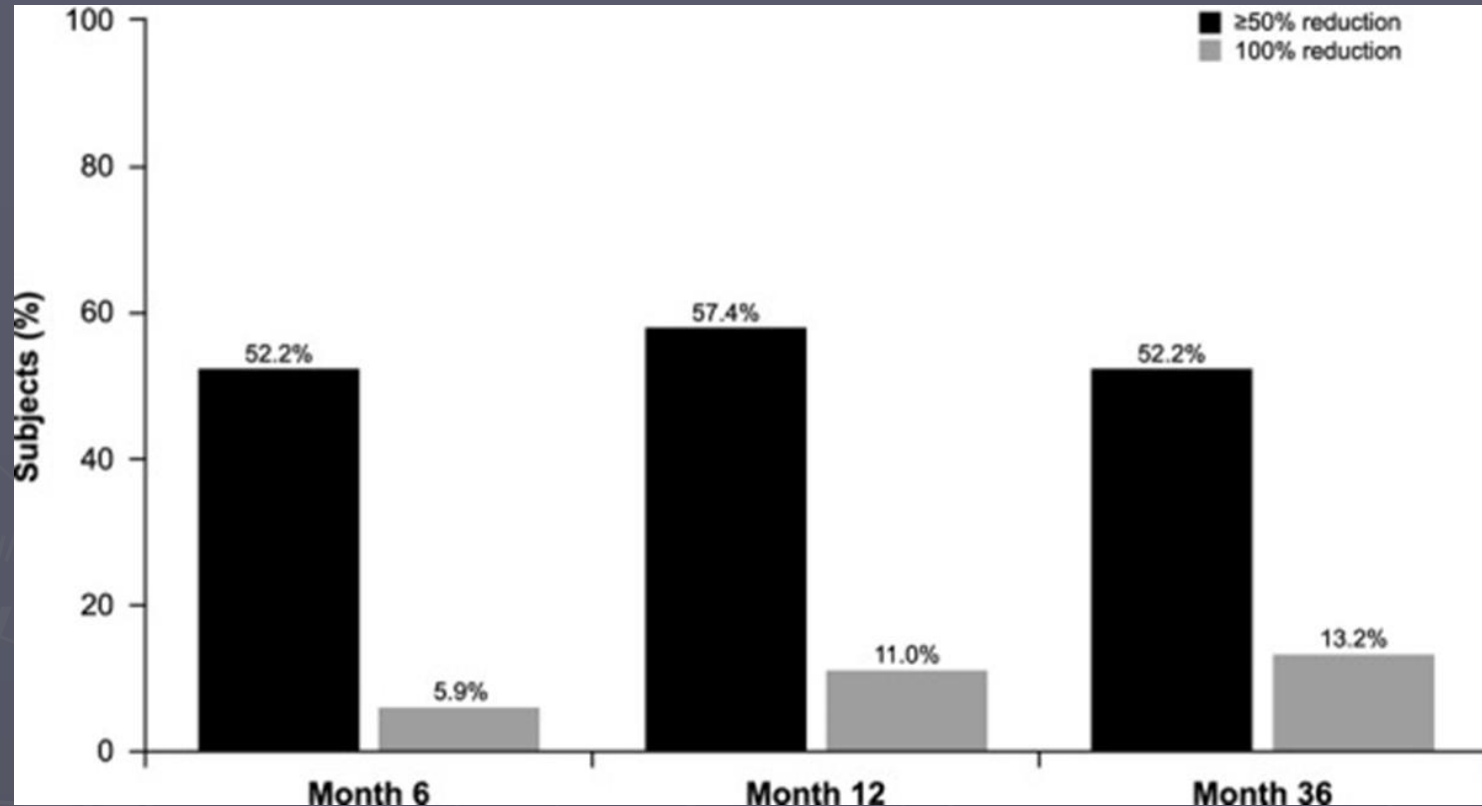


- ▶ some positive short-term results but variable effect on quality of life
- ▶ side effects → bleeding, discharge, pain, pruritis, BM changes, abscesses...

Injectable Bulking Agents

Material	Author, yr	n	f/u (mos.)	Morbidity	Results
PTFE	Shafik 1993	11	18-24	0	63% after 2 nd injection
Autologous fat	Shafik 1997	14	9-24	--	86% after 2 nd injection
Silicone	Malouf 2001	10	6	--	30%
Silicone	Tjandra 2004	42 (sono) 40 (RCT)	12	0	more improvement with sono guide
Silicone	Soerensen 2008	33	3-22	--	18% major improve, no manometry change
Hyaluronic Acid	Graf 2011	136/70 (RCT)	6	128 minor 2 serious	52% treated vs. 31% sham
Hyaluronic Acid	Danielson 2009	34	12	0	mean incontinence episodes reduced 22->10

Long-term Data

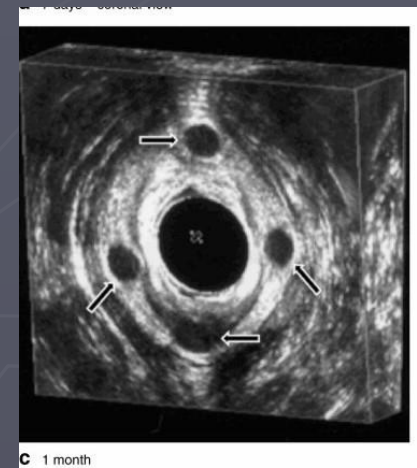
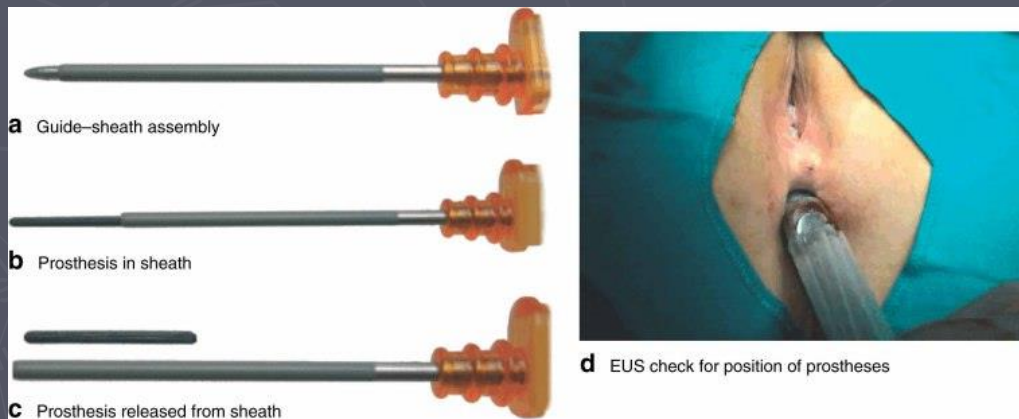
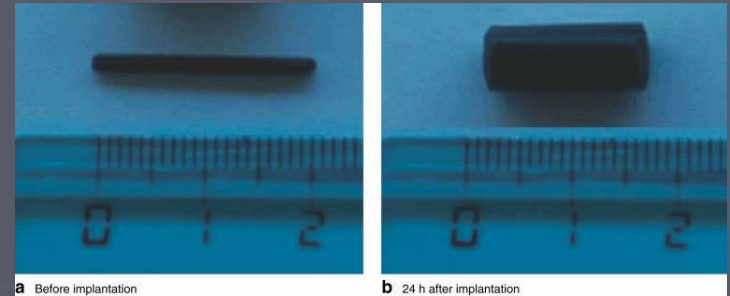


- ▶ 112 of the 136 patients with 36 month f/u
- ▶ *BUT...no specific selection criteria, only 6% complete continence at 6 months*

Implantable Bulking Agents

"Gatekeeper"

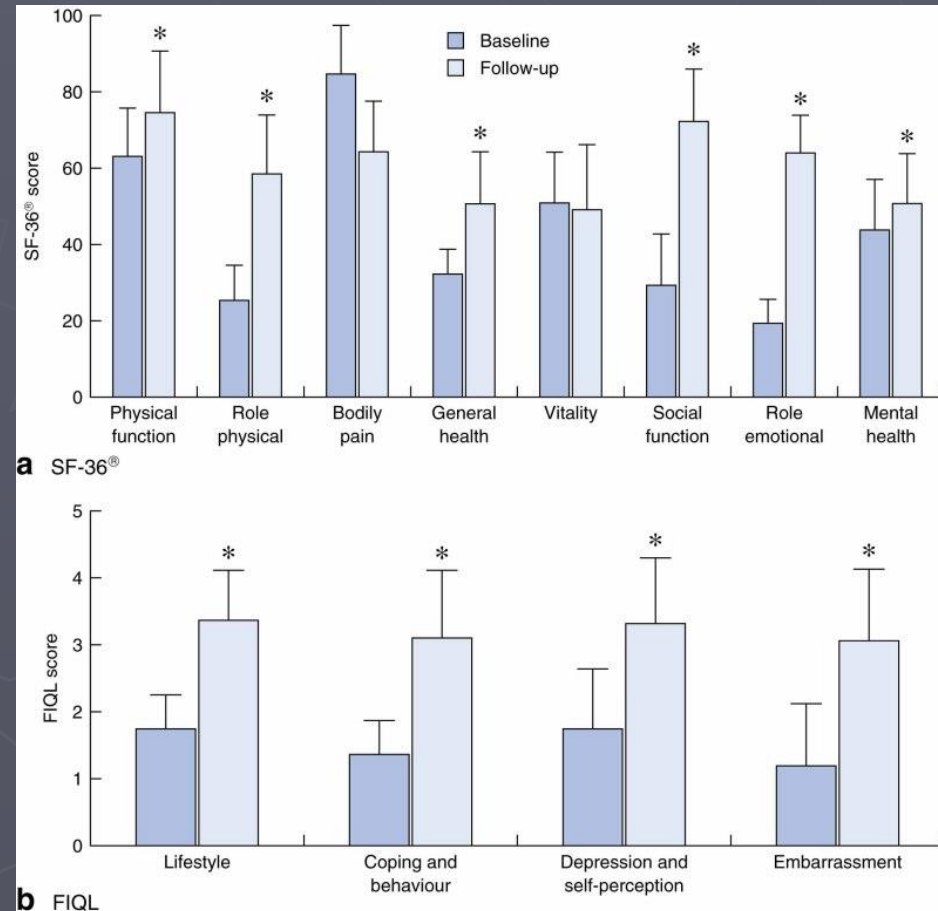
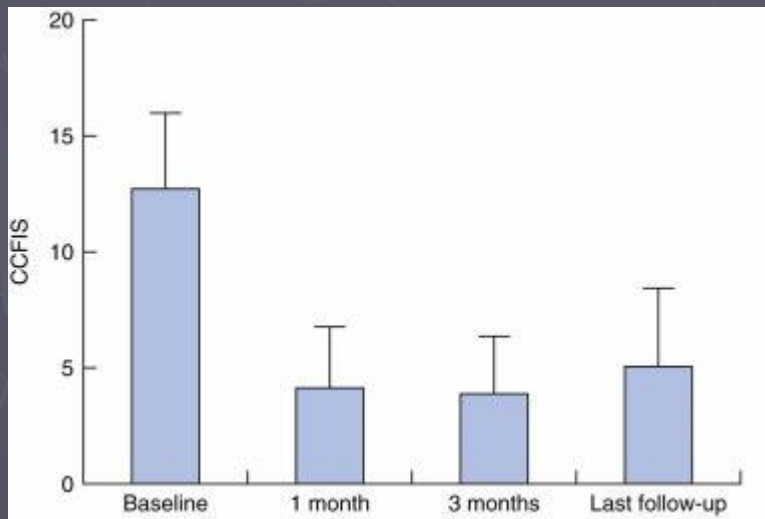
- ▶ Polyacrylonitrile cylinder
- ▶ Inserted into intersphincteric space
- ▶ Four quadrants



Implantable Bulking Agents

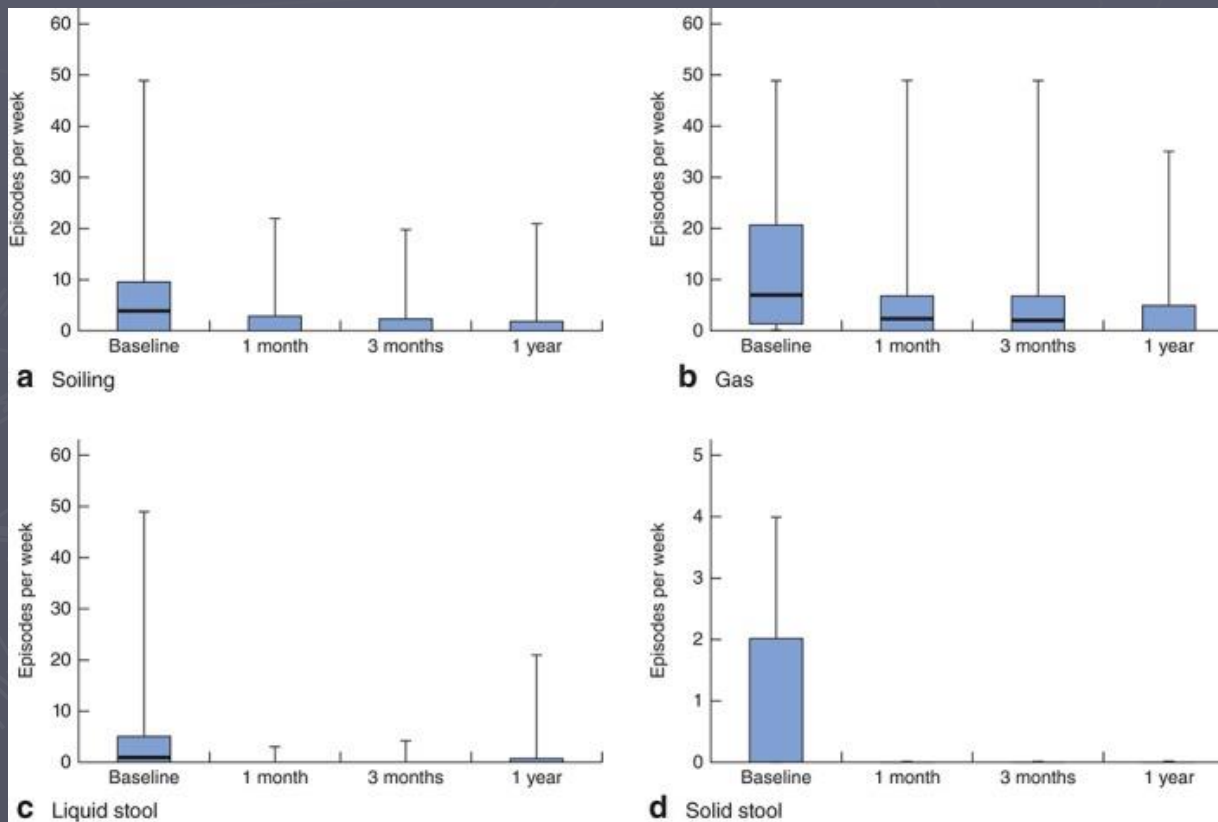
"Gatekeeper"

- ▶ pilot study (14 pts)
- ▶ 3 yr mean follow-up
- ▶ No major morbidity



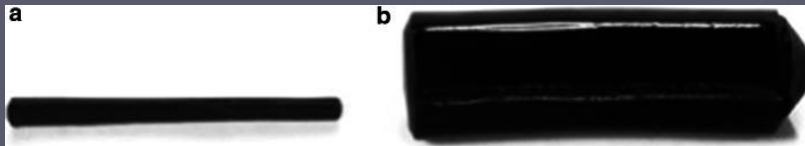
Implantable Bulking Agents "Gatekeeper"

- ▶ Prospective multicenter analysis of 54 pts
- ▶ Safe and sustained clinical efficacy to 1 yr

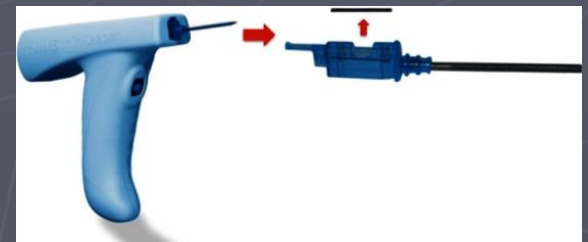
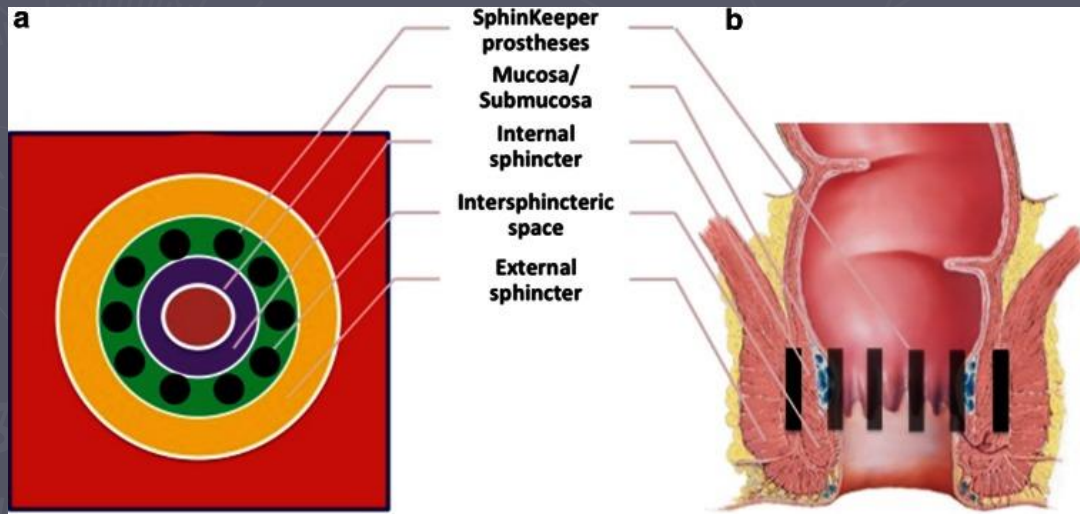


Implantable Bulking Agents

"SphinKeeper"



- ▶ 10 patients
- ▶ Local anesthetic
- ▶ EUS guided



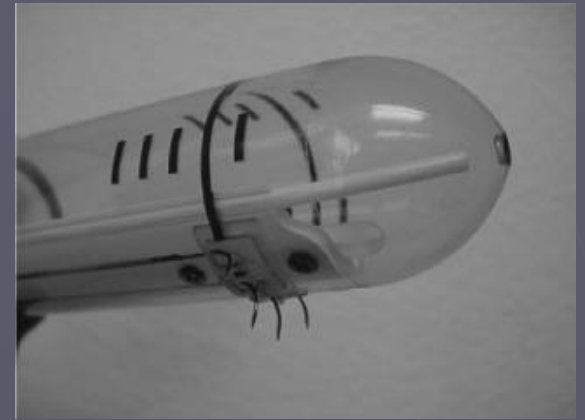
SECCA Procedure

- ▶ delivery of temperature-controlled RF energy to internal sphincter
- ▶ stimulate collagen deposition & scarring
- ▶ increase ability to recognize & retain stool
- ▶ *FDA approved in 2002*



SECCA

- ▶ requires sedation
- ▶ into internal sphincter
- ▶ 20 sets of lesions from 5mm below to 2cm above dentate line
- ▶ up to 84% have positive response

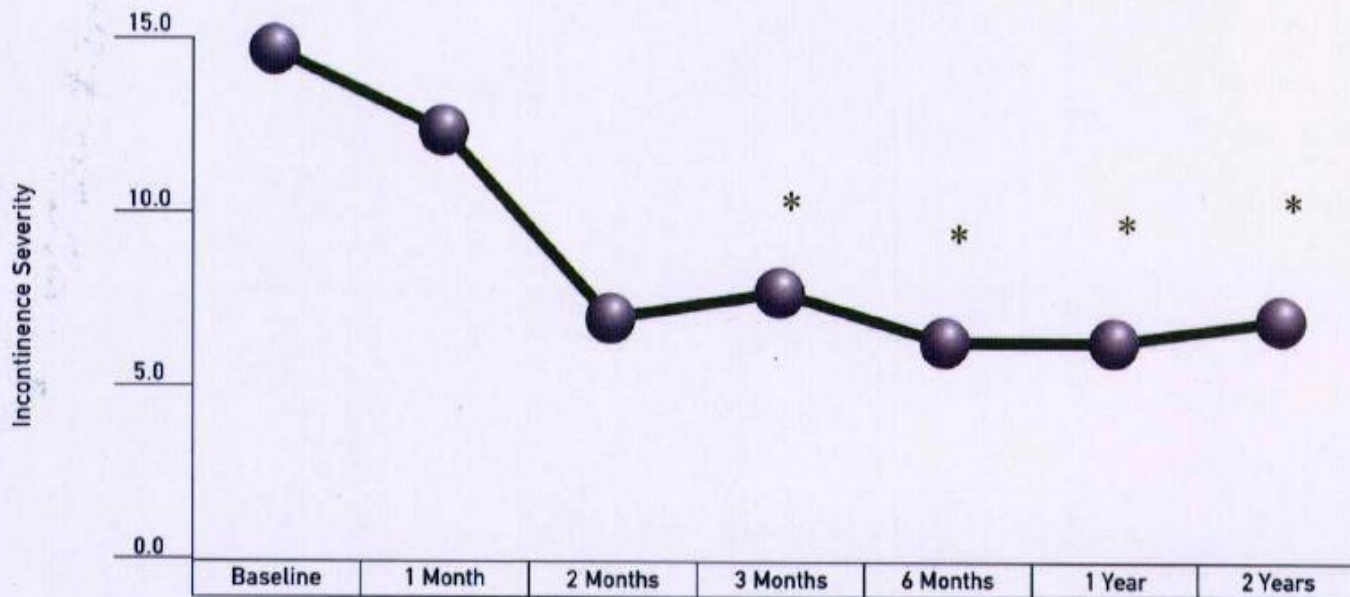


Pilot Study (2002)

Fecal Incontinence Severity Pilot Study – CCF- FI Score

Pilot Study

In a 10 patient pilot-study, incontinence severity was significantly improved at two year follow-up.

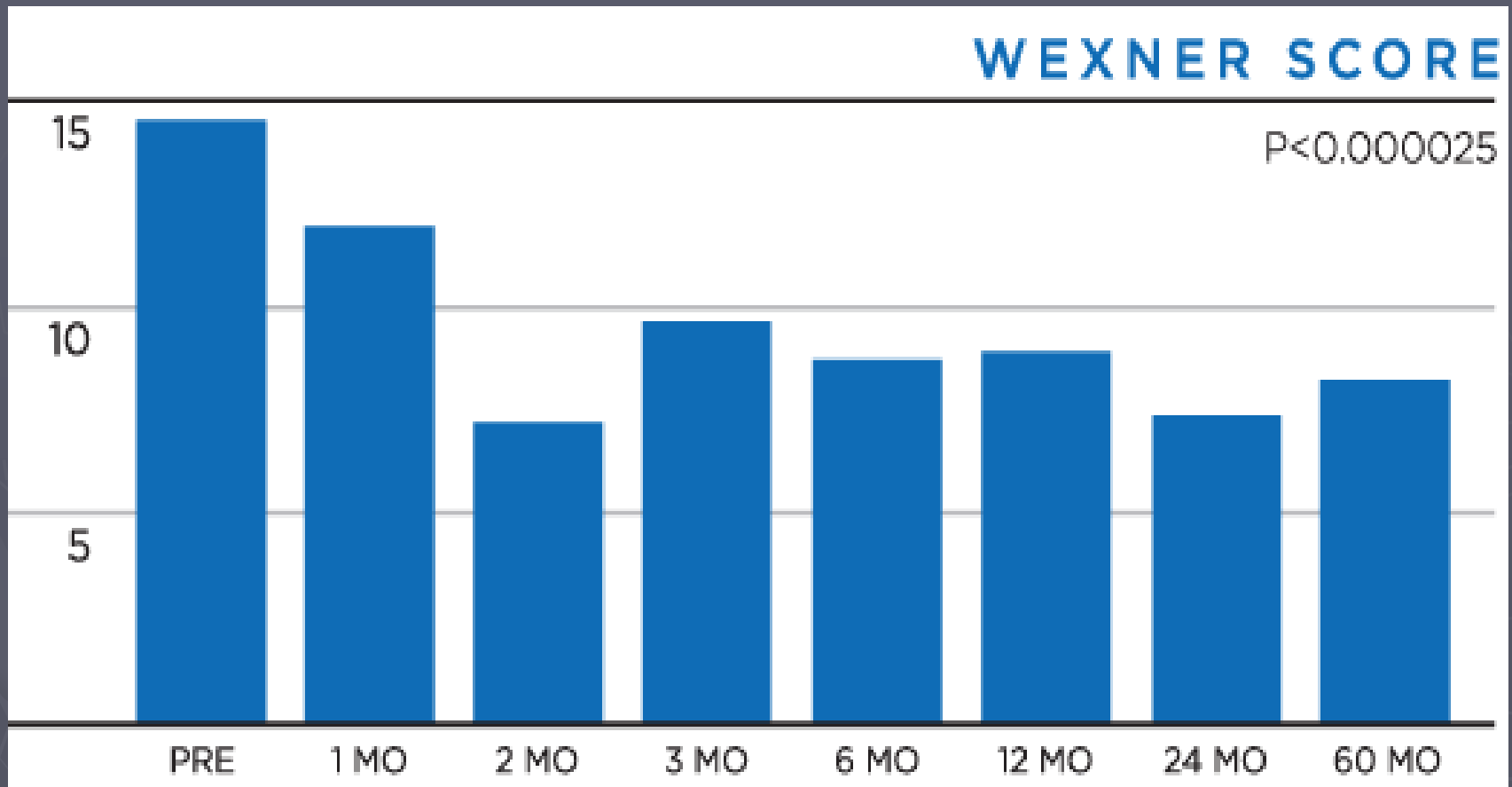


Indications for use: The Secca™ System is indicated for the treatment of fecal incontinence in those patients with incontinence to solid or liquid stool at least once per week and who have failed more conservative therapy.

* $p < 0.05$ vs. baseline.
Takahashi, et al. ASCRS 2002

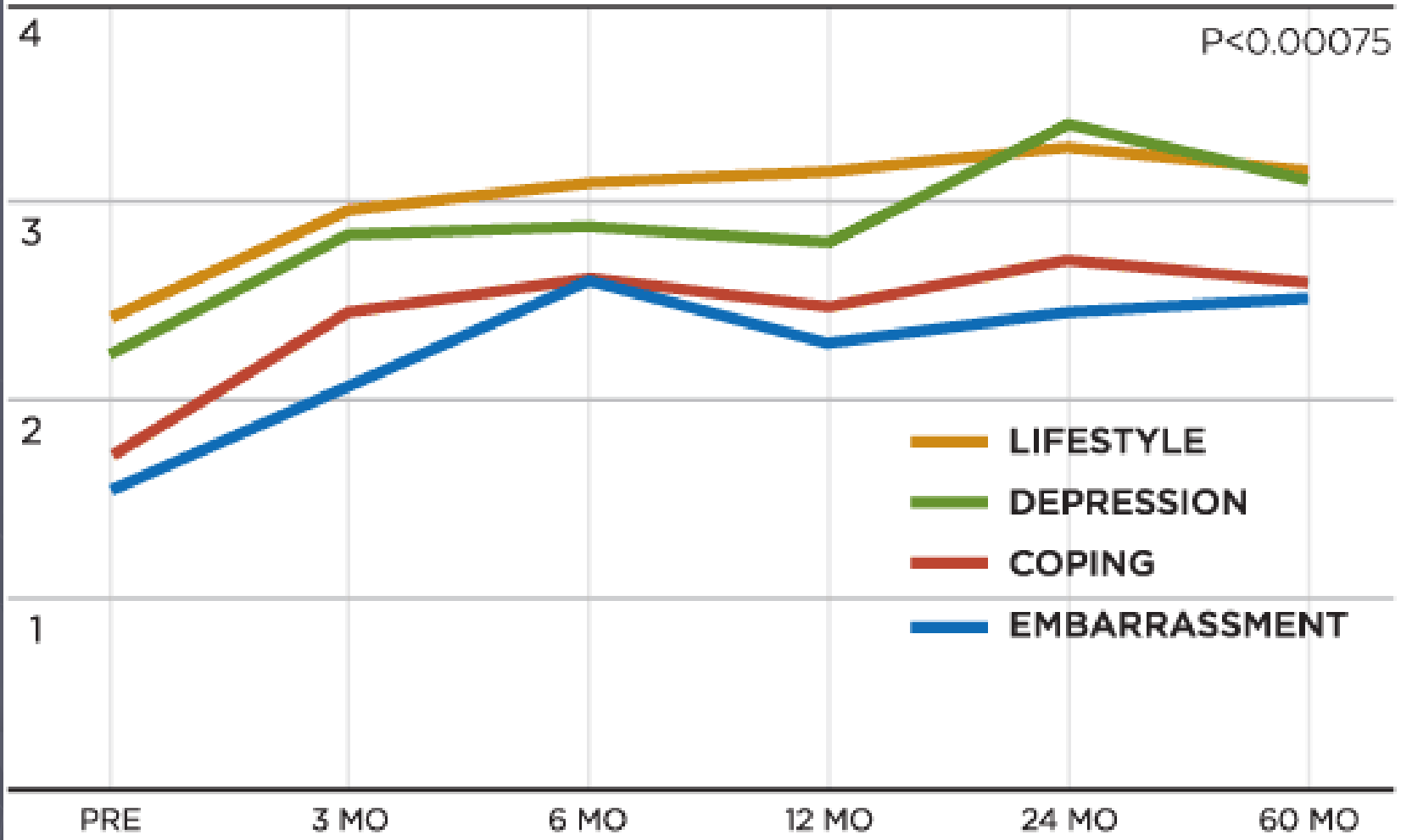
CCF-FI = Cleveland Clinic Florida - Fecal Incontinence

Follow-Up Report (2008)



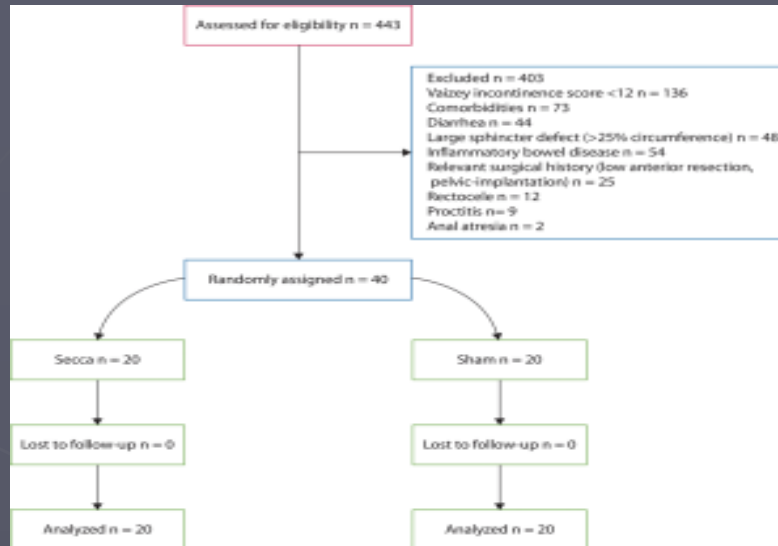
Diseases of the Colon
Takahashi-Monroy, et al. 2008

P<0.00075



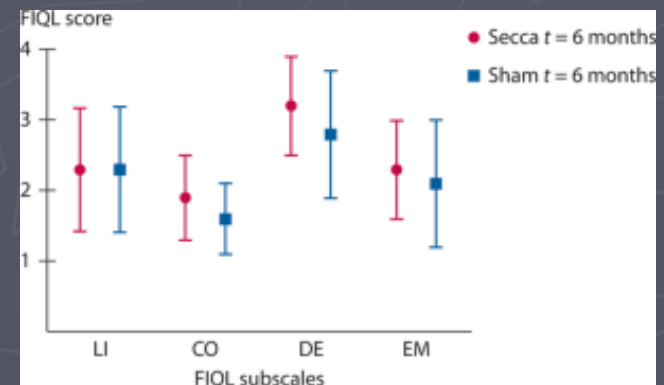
SECCA randomized data

- ▶ RCT 40 pts
- ▶ secca vs. sham
- ▶ 6 month f/u



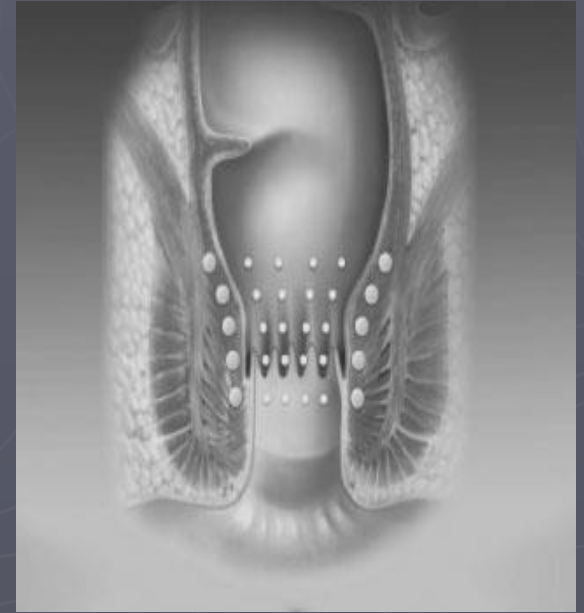
- ▶ Statistically but not clinically significant improvement in **incontinence episodes**

- ▶ No change in **QOL**
- ▶ No change in **anorectal function**



SECCA Summary

- ▶ safe & well-tolerated
- ▶ minimally invasive
- ▶ “no bridges burned”
- ▶ first-line?? before surgery
- ▶ non-surgical candidates
- ▶ after failed procedure
- ▶ last resort prior to colostomy
- ▶ *need better efficacy data to inform patient selection*



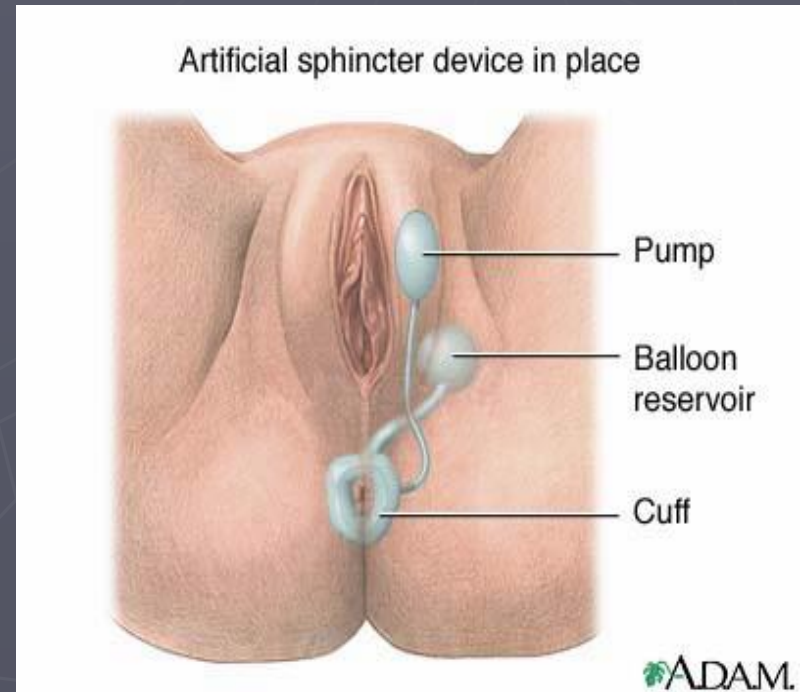
Replace

► Artificial Bowel Sphincter

- occlusive fluid-filled cuff encircles anal canal
- pressure-regulating balloon
- control pump in labia

► Results

- excellent when it works
- 85% complication rate
- 50% removal
- evacuation difficulty
- pain, infection, erosion into vagina



ABS: Safety & Efficacy

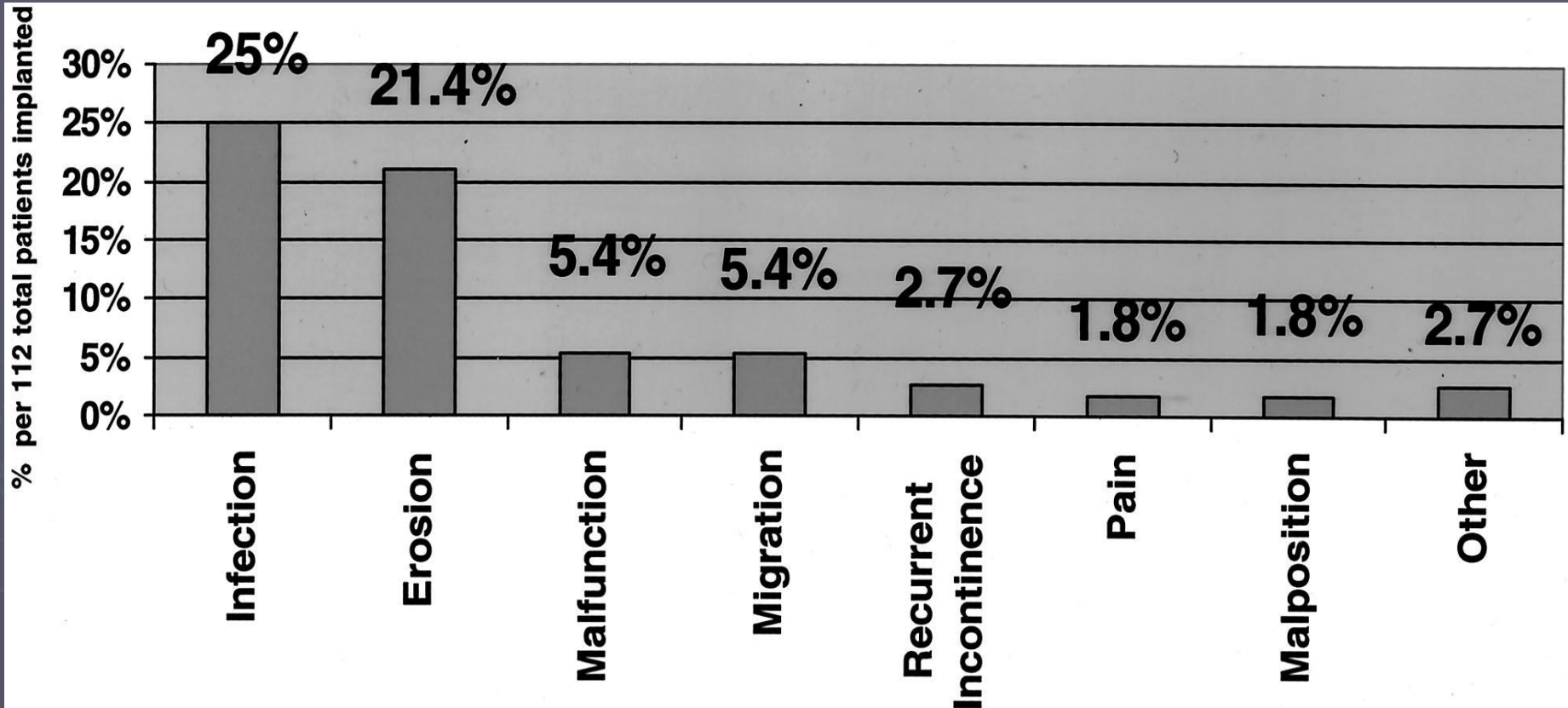
Wong et al, DCR 2002

- ▶ multicenter, prospective
- ▶ 112 patients implanted (age 18-81)
- ▶ 384 device-related adverse events in 99 pts
 - 246 required no or non-invasive intervention
 - 51 pts required 73 revisions (46%)
 - infection requiring revision in 25%
- ▶ 41 pts required explantation (37%), 7 reimplanted



Adverse Effects

Wong et al, DCR 2002



- ▶ "other" → *anourethral fistula, constipation, cuff too large*

ABS: Safety & Efficacy

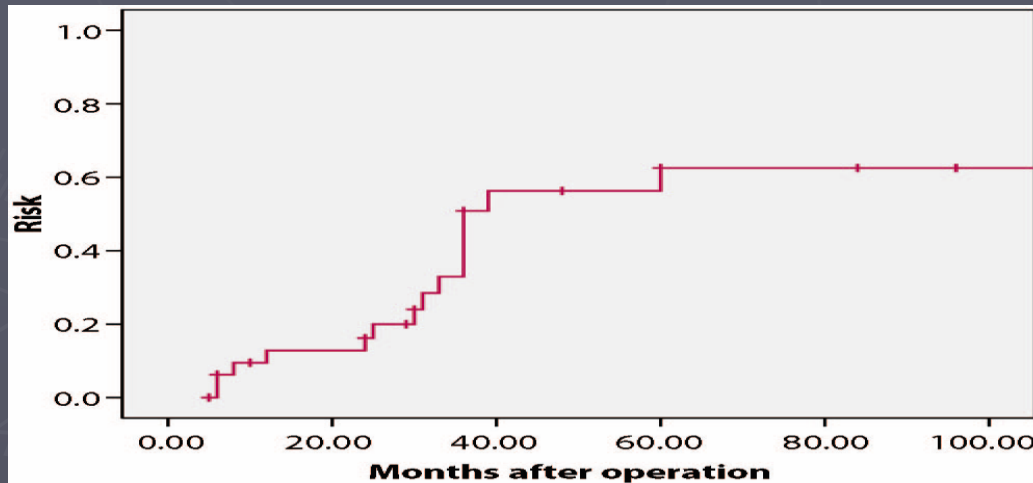
Wong et al, DCR 2002

- ▶ FI scores improved in 63 pts at 6 mos., 55 pts. at 12 mos.
- ▶ **Successful Outcomes**
 - 85% in pts with functioning device
 - 53% intention to treat
- ▶ *for severe FI with significant anatomic deformity and/or denervation*

Factors Associated with Failure

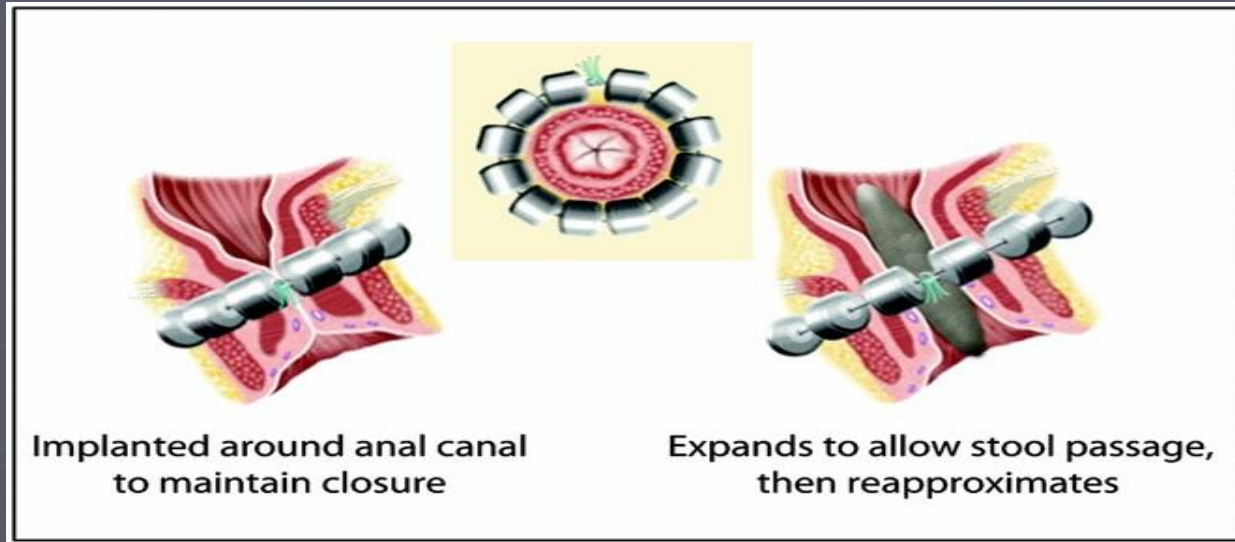
Wexner, et al., DCR, 2009

- ▶ 51 procedures in 47 pts → **infection in 23**
- ▶ Cumulative Risk of Explantation (**57% at 5 yrs**)



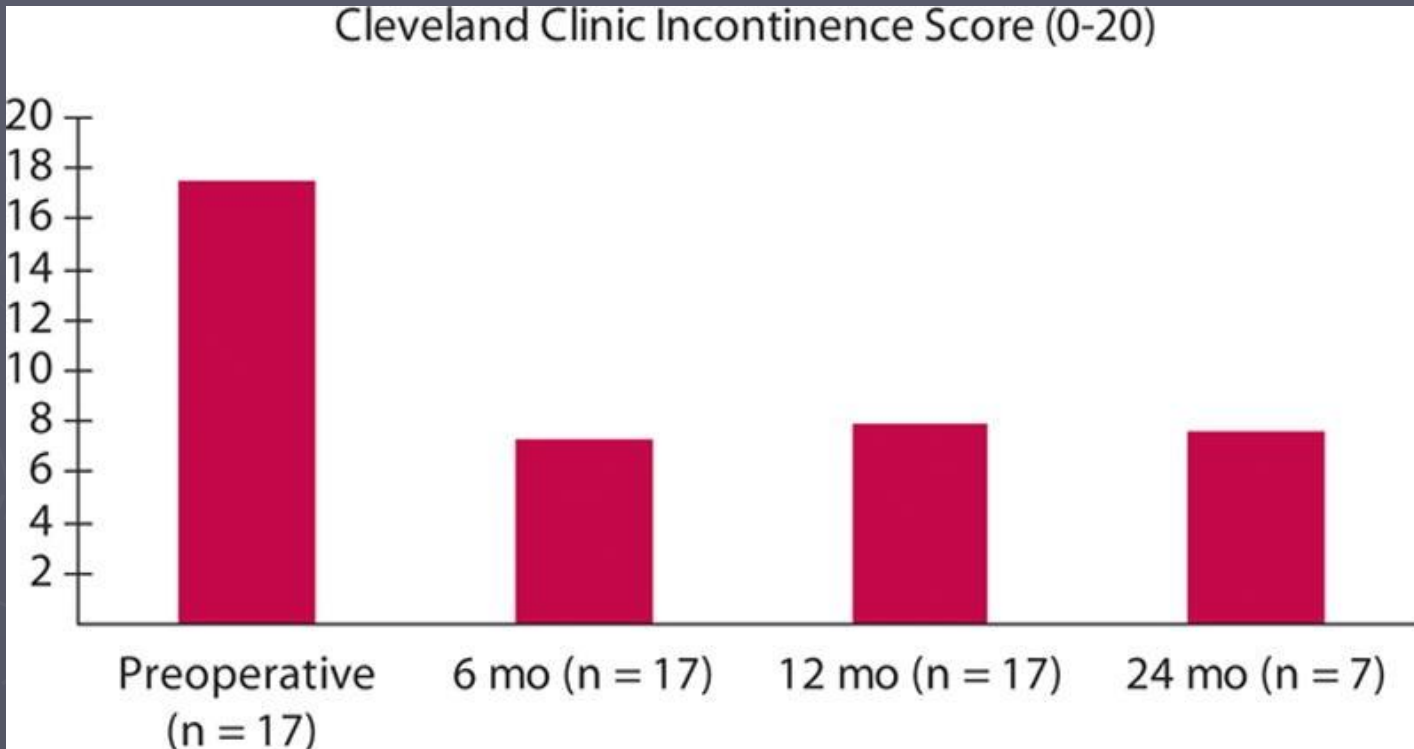
- ▶ *EARLY* → *h/o perineal sepsis*
- ▶ *LATE* → *device malfunction*

Magnetic Anal Sphincter



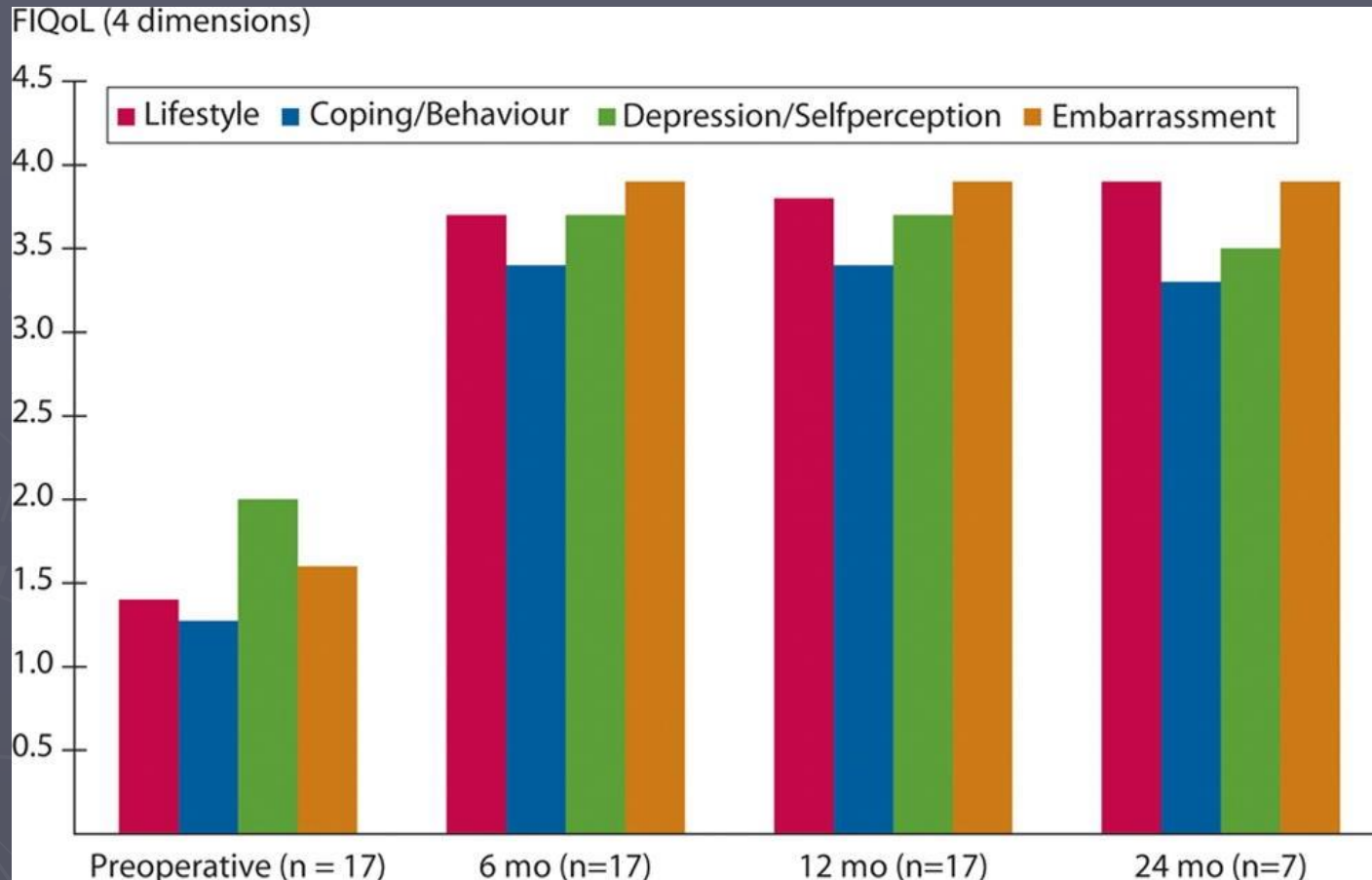
- ▶ first described in 2010 (14 pts; 5 pt with 6 mo f/u)
 - *reduction of weekly incontinence episodes from 7.2 to 0.7 (90.9%)*
 - *reduction in Wexner score from 17.2 to 7.8 (54.7%)*
- ▶ 2 pts at 1 yr f/u with perfect continence

Magnetic Anal Sphincter



- ▶ successful implantation in 94%
- ▶ clinical improvement in 76%

Magnetic Anal Sphincter

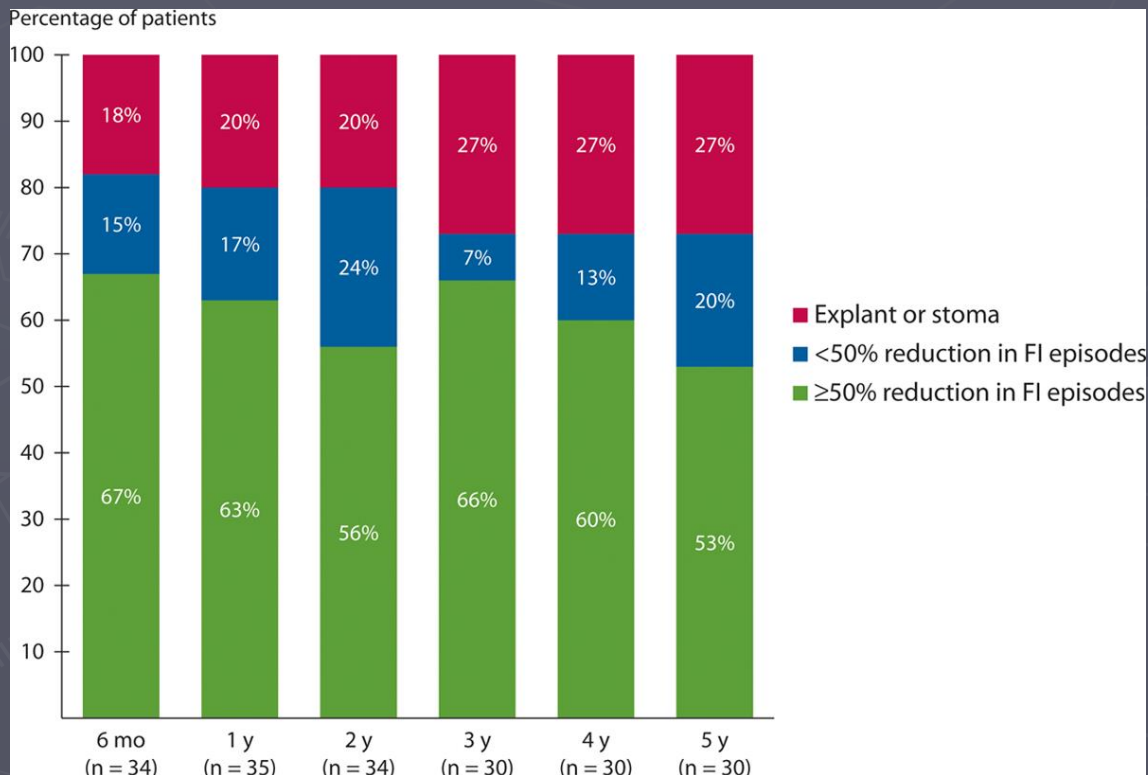


► increased resting tone & squeeze

Magnetic Anal Sphincter

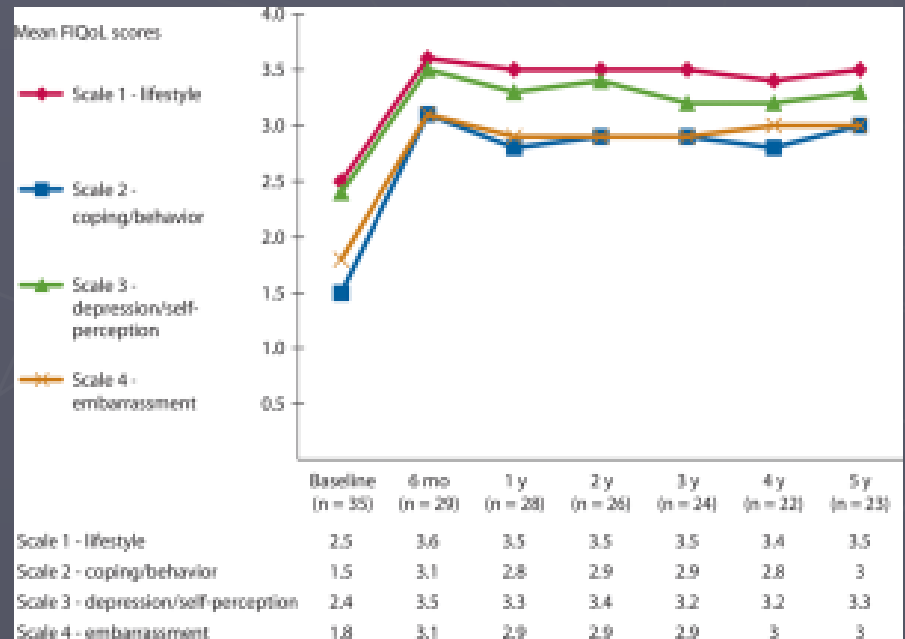
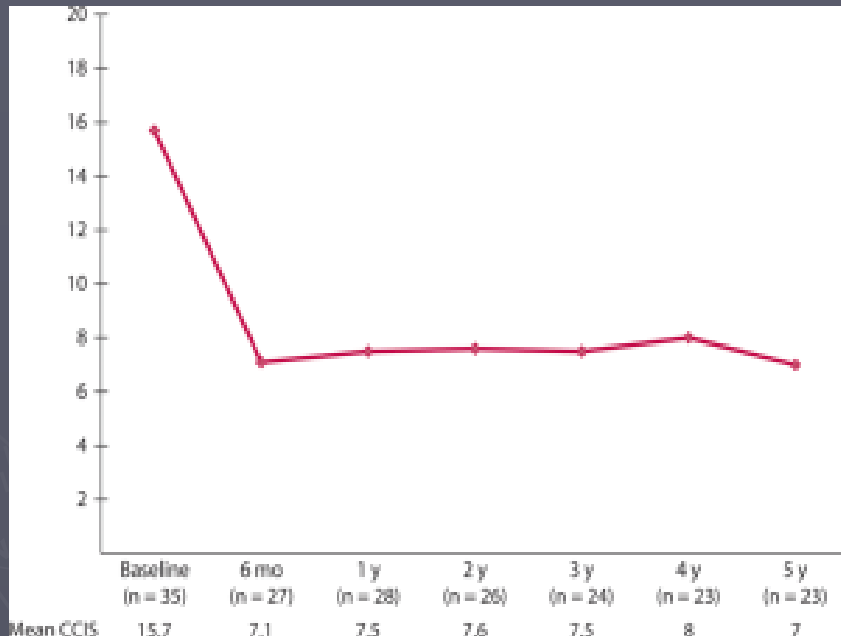
Long-Term Data

- ▶ prospective multicenter pilot study
- ▶ 35 pts with severe FI, median follow-up 5 yrs



Magnetic Anal Sphincter

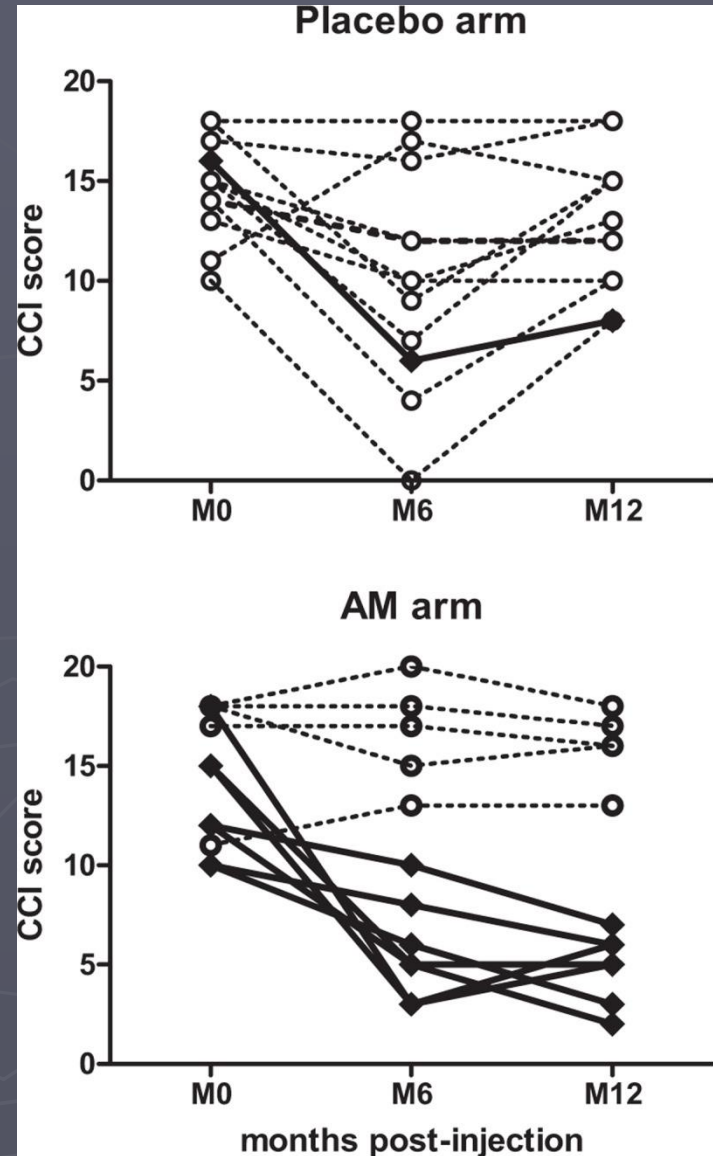
Long-Term Data



- ▶ Compared to SNS? *two RCTs...*
- ▶ SaFaRI (350 pts, UK) + MOS STIC (156 pts, France)

What about Stem Cells?

- ▶ placebo-controlled DB RCT
- ▶ 24 pts, 6 & 12 mos f/u
- ▶ intersphincteric injection of autologous myoblasts
- ▶ **6 mos** → significant improvement in both groups
- ▶ **12 mos** → placebo returned to baseline, AM continued to improve
- ▶ overall response rate--
58% vs. 8% (p=0.03)



Re-innervate

► Sacral Nerve Stimulation

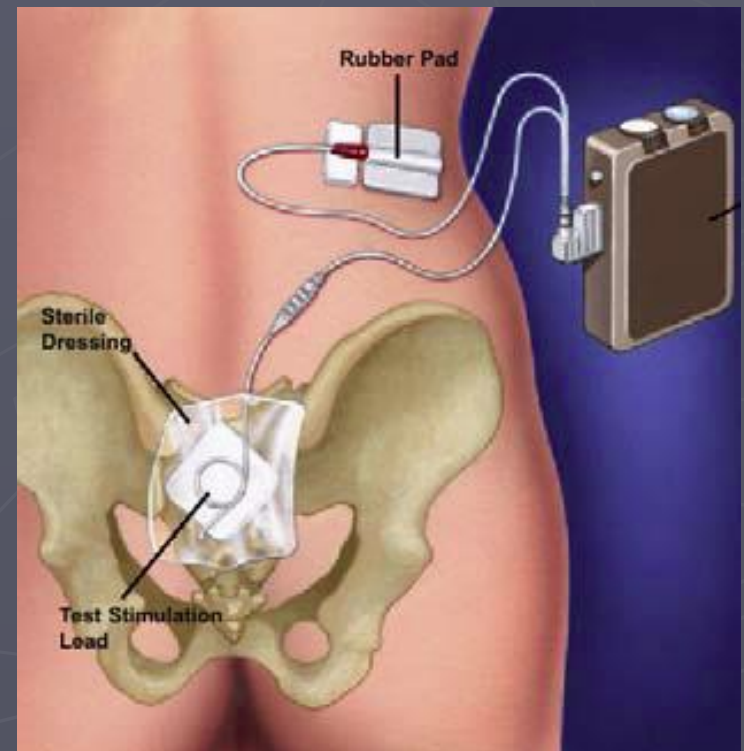
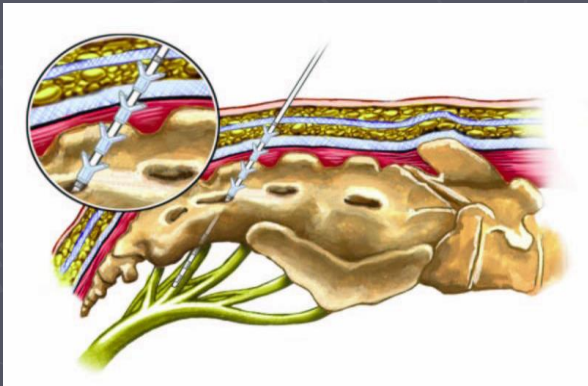
- effective for urinary incontinence → also improved fecal incontinence in those pts
- for pelvic floor denervation with structural integrity

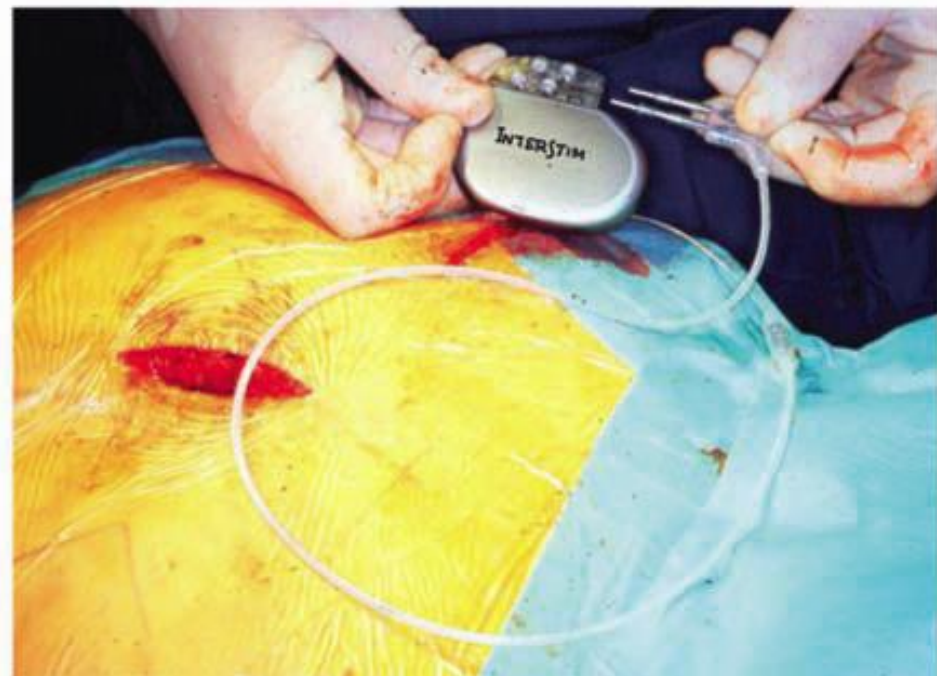
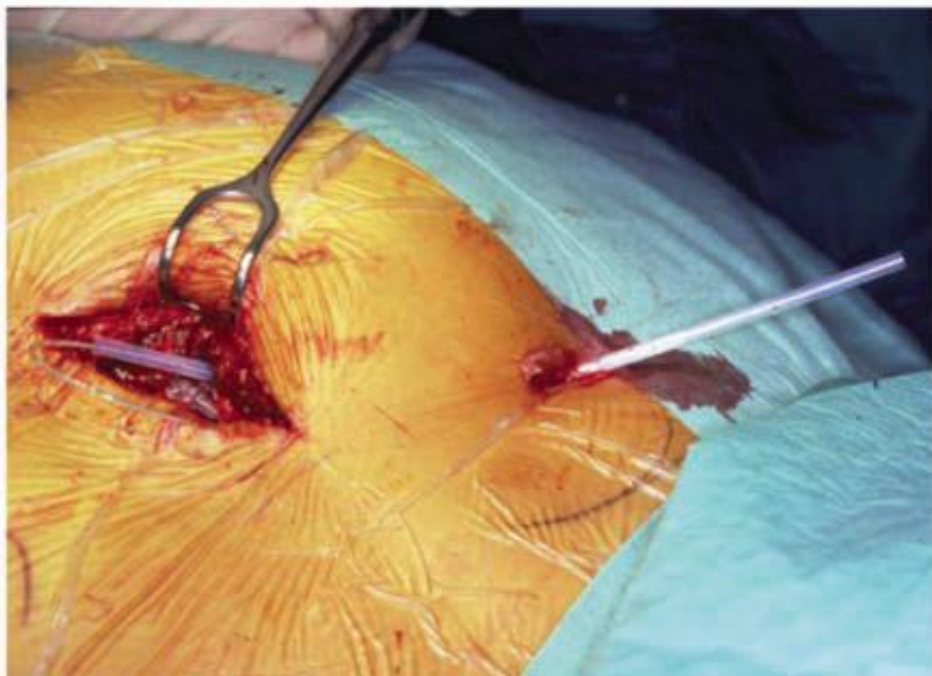
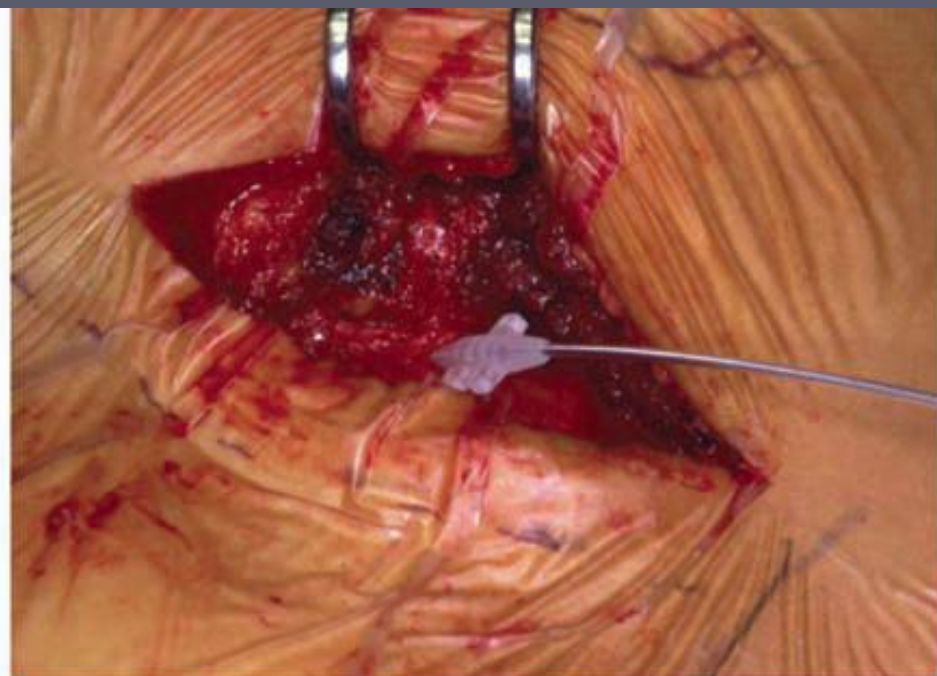
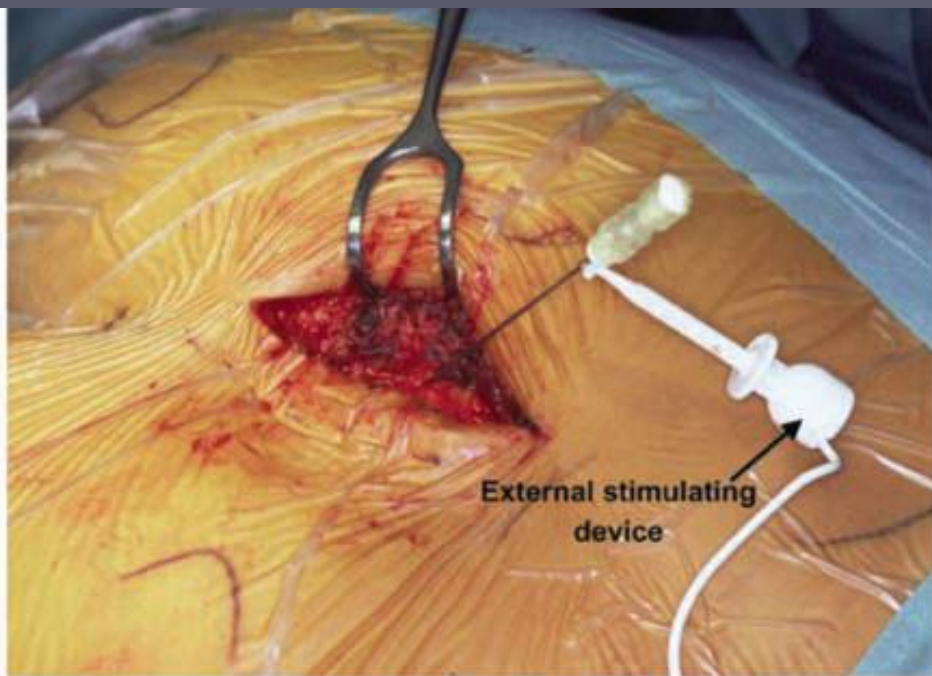
- *first studies in 1995*
- *popular in Europe*
- *approved in US*
April 2011



Sacral Nerve Stimulation

- ▶ electrode inserted into S3 foramen
- ▶ low grade stimulation via implanted stimulator
- ▶ can do 2-3 wk operative trial
- ▶ or...3 day office-based test
- ▶ permanent → up to 8 yrs





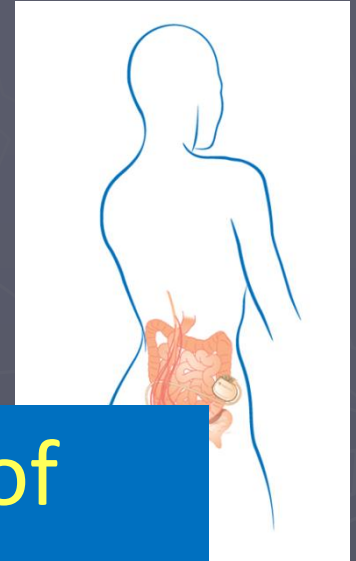
SNS Technique



Sacral Nerve Stimulation

How Does It Work?

- ▶ “Focuses mild electrical pulses on the nerves that control the pelvic floor muscles, anal sphincters,

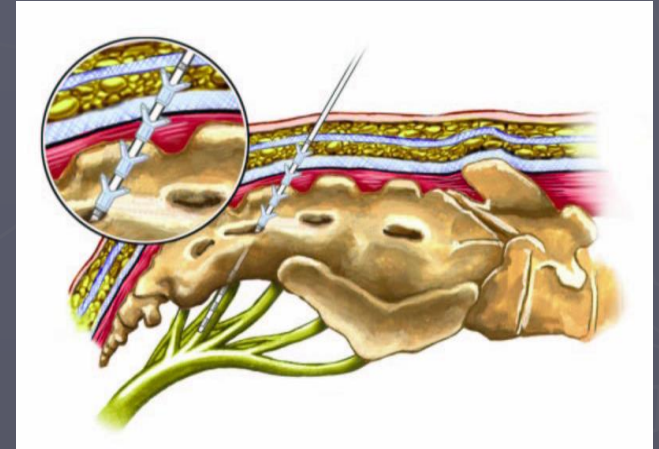


a * While the **precise mechanism of action for InterStim Therapy has not been fully established**, efficacy has been proven in clinical studies...

Sacral Nerve Stimulation

- ▶ 80% success rate overall

- increased rest & squeeze pressure (*sometimes*)
- improved rectal sensation)
- about 40% achieve complete continence



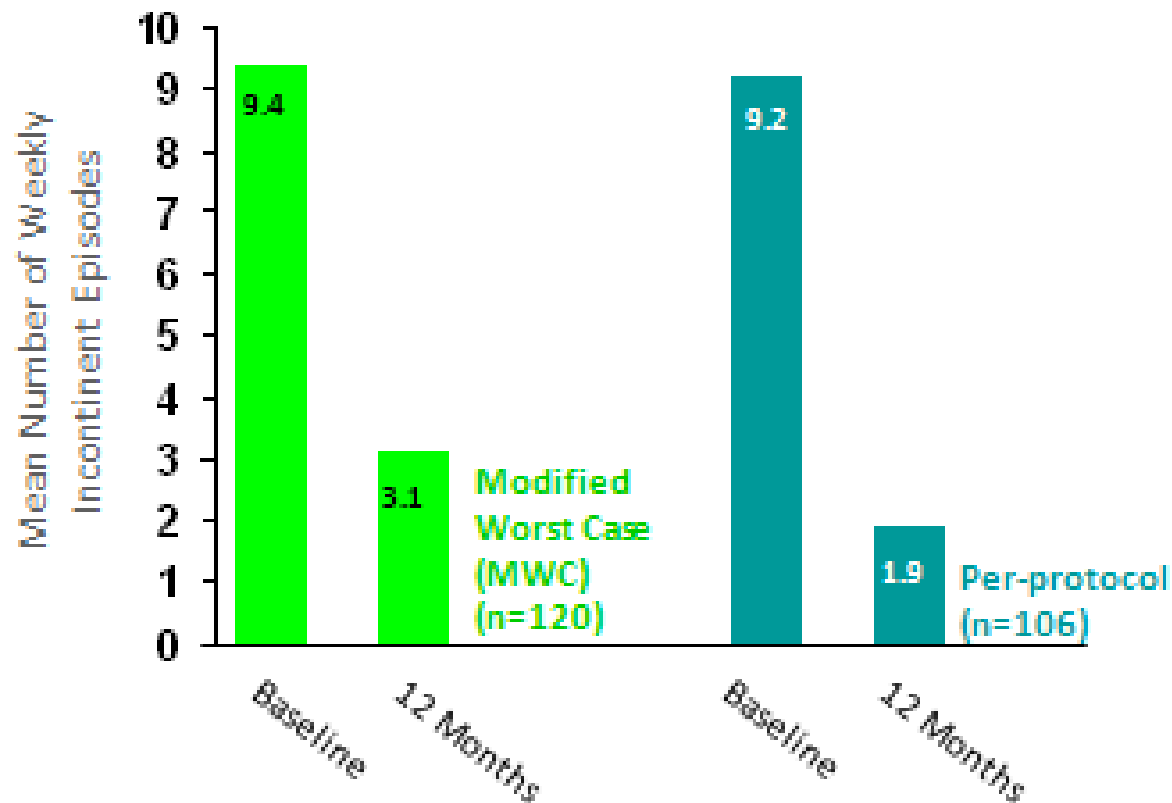
- ▶ More and more long-term data >10 yrs

- ▶ adverse events include...

- *pain, seroma, infection, vaginal tingling, GI/GU upset*
- *rarely explantation needed*

Clinical Efficacy: Reduction in Episodes

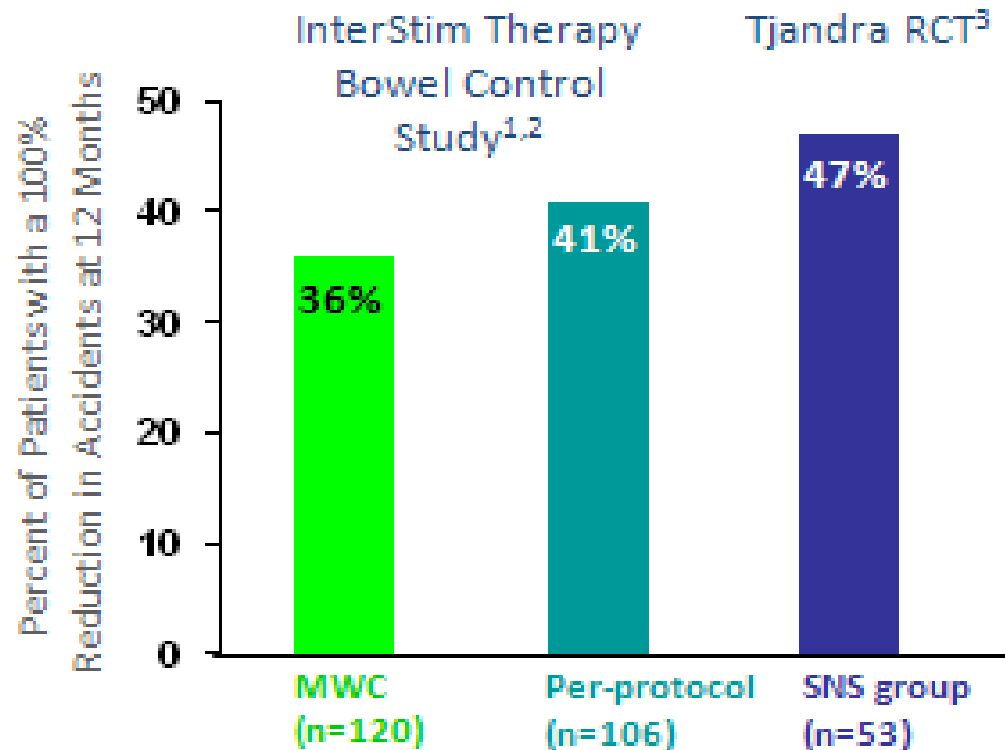
InterStim Therapy Bowel Control Study



1. Werner SD, Celler JA, et al. *Ann Surg*. 2010 Mar;251(3):443-9.

2. Medtronic-sponsored research. InterStim Therapy Clinical Summary Incof, 2011.

Clinical Efficacy: Complete Continence

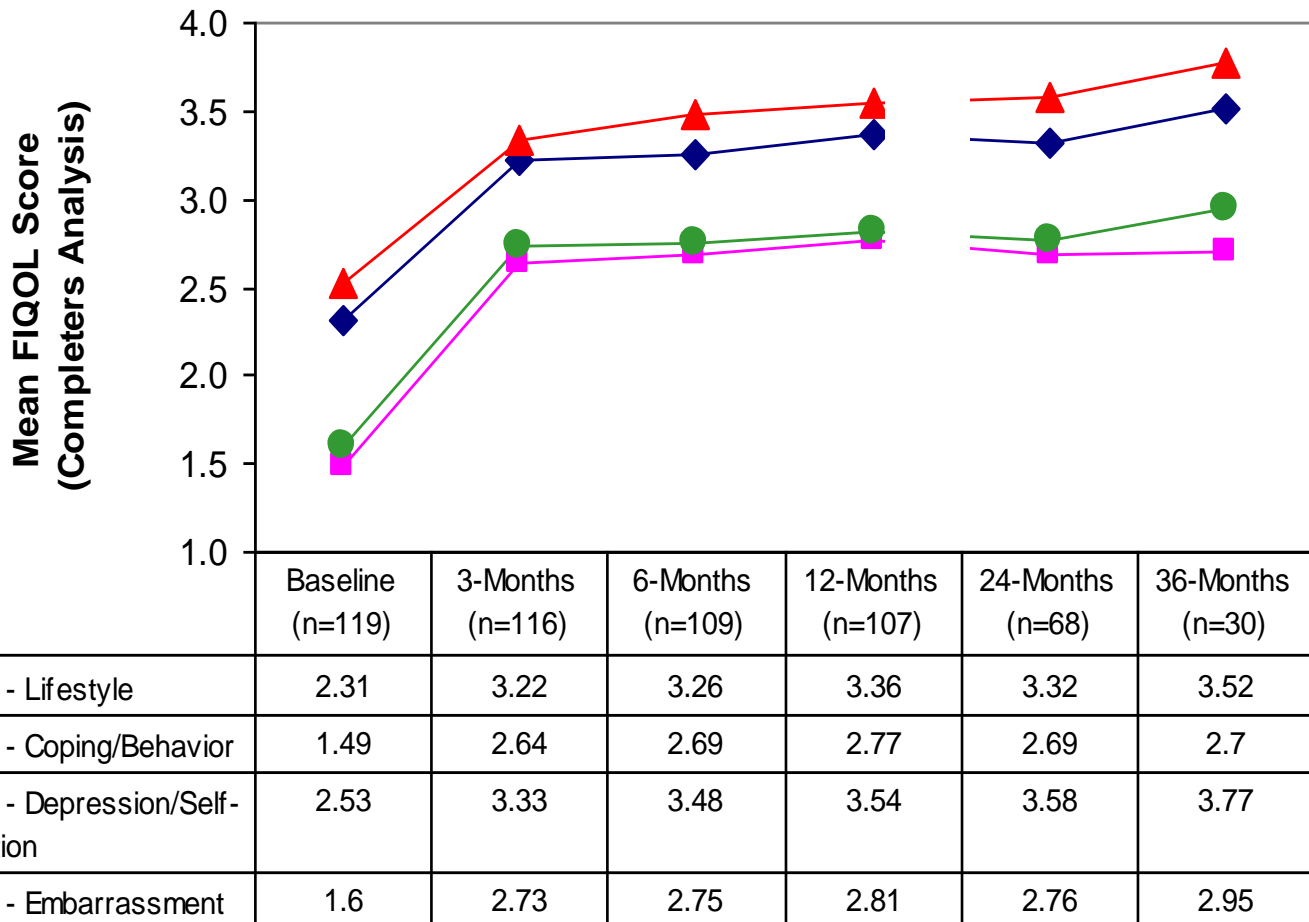


1. Wexner SD, Celler JA, et al. Ann Surg. 2010 Mar;251(3):443-9.

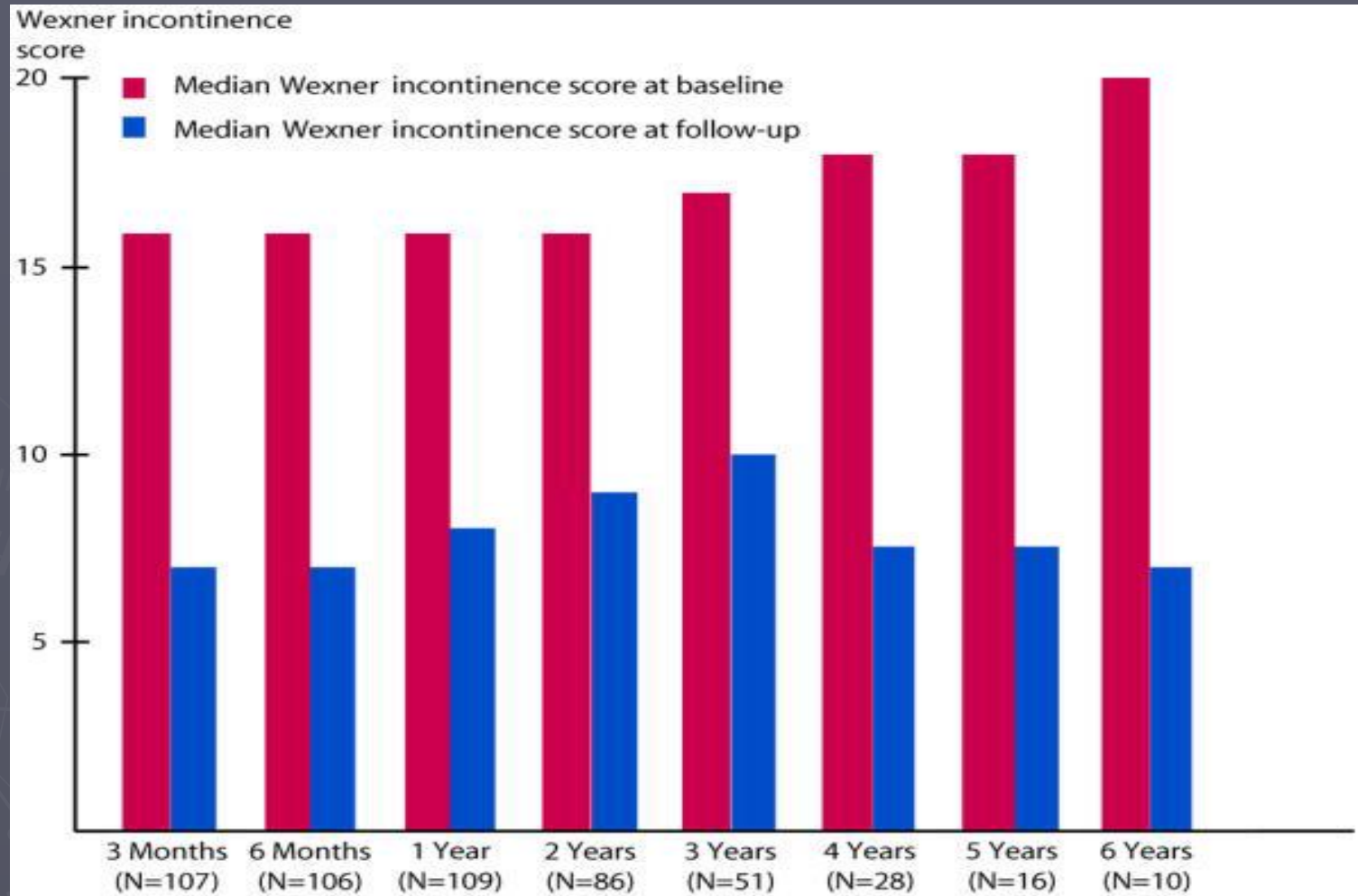
2. Medtronic-sponsored research. InterStim Therapy Clinical Summary Inset, 2011.

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.

Clinical Efficacy: Quality of Life

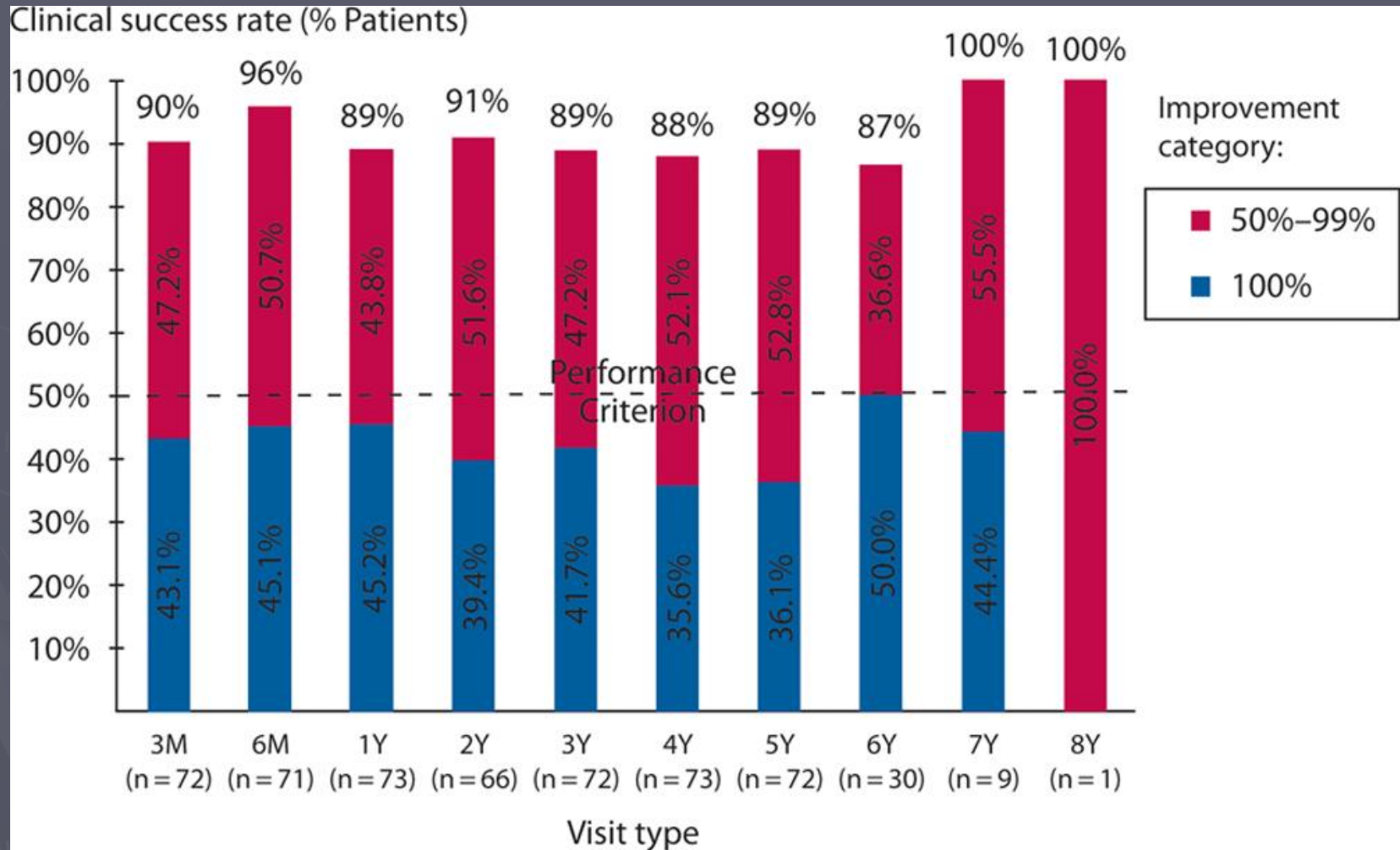


Six Year Experience

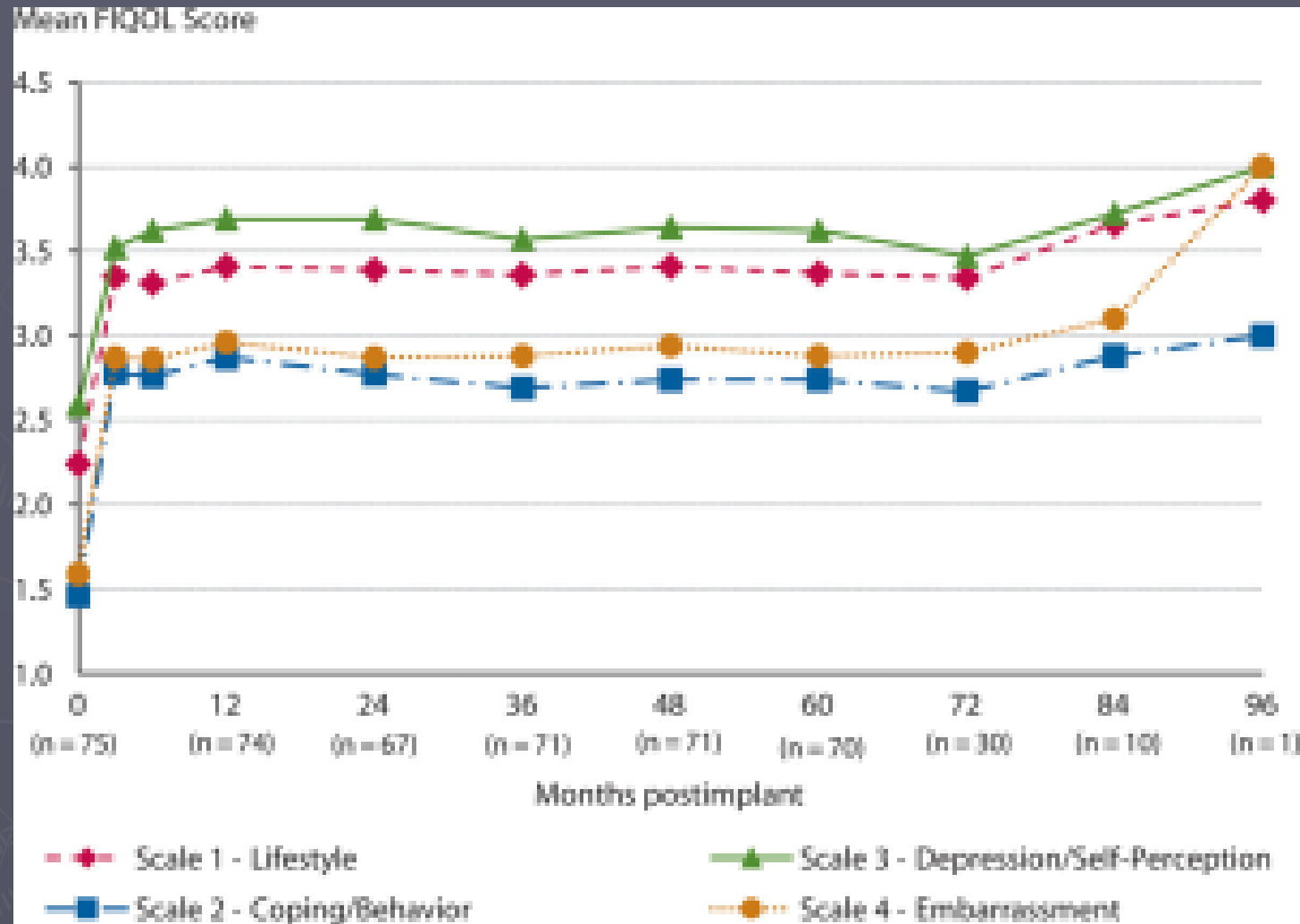


p < 0.001 for 3 and 6 months, and 1, 2, 3, 4 and 6 years. *p* = 0.001 for 5 years

More Long-term Data



More Long-term Data



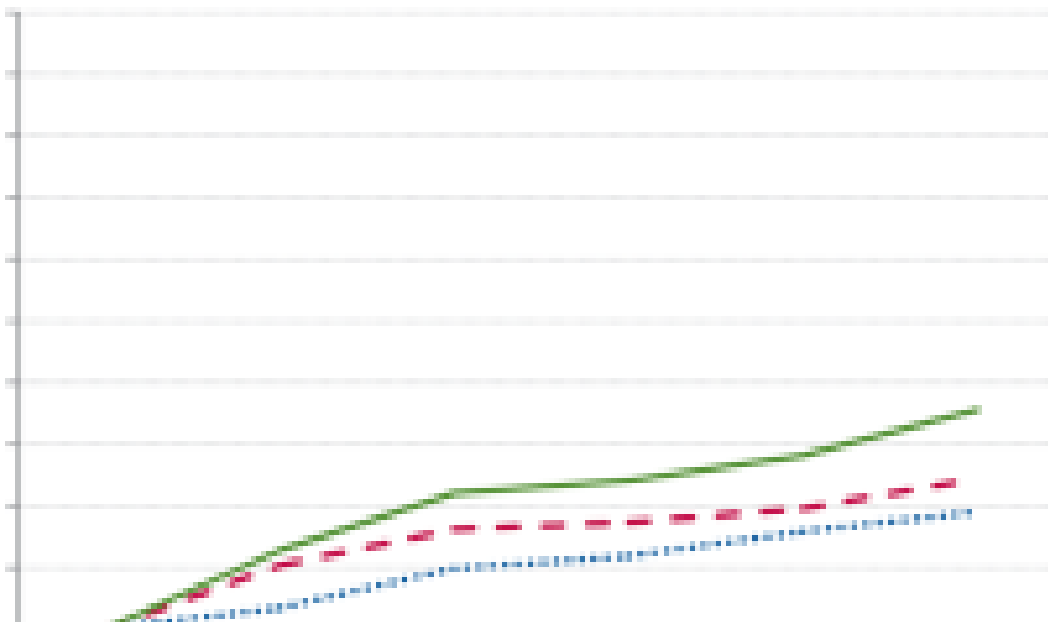
Adverse Events

- ▶ Test Stimulation Phase (n=132)
 - implant site pain (3.8%), lead fracture (1.5%)
- ▶ Implant Phase (n=120)
 - implant site pain (25.8%), implant site infection (10.5%)
 - parasthesias (10.8%), change in sensation of stimulation (5.8%)
 - diarrhea (5.8%), pain (5%), urinary incontinence (5%)
- ▶ *Lower rate of infection overall compared to other treatments*
- ▶ **Early → abx...LATE → requires explantation**
(about 19% at 5 yrs)¹

Rates of re-intervention

Cumulative probability of surgical intervention

100.0%
90.0%
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%



	0	1	2	3	4	5
--- Revision/replacement	0.0%	10.3%	16.2%	17.3%	19.5%	24.4%
..... Permanent explant	0.0%	3.4%	9.8%	11.8%	15.8%	19.0%
— Any surgical intervention	0.0%	12.8%	22.1%	24.1%	28.1%	35.6%

Time from implant (in years)

What about the more typical FI pts?

- ▶ Retrospective analysis of all pts undergoing SNS in Finland from 1999-2017
 - 462 procedures done for FI → **432 pts for analysis**
 - 313 (72.5%) had successful test phase
 - ▶ 25% obstetrical injury
 - ▶ 23% iatrogenic injury (*LAR, STARR, hem/fistula sx*)
 - ▶ 16% neurologic etiologies
- ▶ **Long-term success in 59.3%**
 - Subjective pt reports & permanent functioning device
 - Mean follow-up 2.4 yrs
 - *Etiology impacted test success but not final outcome*

SNS Summary

- ▶ minimally invasive, broad applicability
- ▶ comparable or better efficacy with much lower morbidity than other surgical options
- ▶ Reproducible and durable results
- ▶ no burnt bridges....first step or last resort, combined approach?
- ▶ *BUT... expensive, MRI incompatibility, need for revision in about 25%*

Tibial Nerve Stimulation

- ▶ Percutaneous or transcutaneous
 - L4/5 & S1/2/3 fibers
 - motor, sensory, autonomic
- ▶ First described in 1980s for GU sx's
 - 60-80% success rates in case series
 - FDA approved in 2000
 - RCT of 220 pts (54.5% vs. 20.9% sham)
- ▶ FDA approved in 2000 (*not for FI*)

Tibial Nerve Stimulation

- ▶ In-office procedure
- ▶ Hand-held stimulator
- ▶ 30 minute sessions
- ▶ Weekly or biweekly for 6-12 wks
- ▶ Test mode to determine appropriate current for motor & sensory response
- ▶ *Well-tolerated, rare paresthesias/numbness*



Tibial Nerve Stimulation

Data for FI

- ▶ **Case series** report 59-77% success
- ▶ **Randomized, Placebo-controlled Trials**
 - 82% PTNS vs. 45% TTNS vs. 13% sham (*only 30 pts*)¹
 - CONFIDeNT (115/112 pts) → 38% PTNS vs. 31% sham²
- ▶ *Compared to SNS?*
 - Retrospective data showed no difference³
 - Randomized pilot → SNS better (67% vs. 47%)⁴

1. George, et al. BJS 2013; 100: 330-8.

2. Knowles, et al. Lancet 2015; 386: 1640-8.

3. Asari, et al. Colorectal Dis 2014; 16: O393-99.

4. Thin, et al. BJS 2015; 102: 349-58.

or finally...**Re-route**



- ▶ converts perineal colostomy to abdominal stoma
- ▶ when all other treatment fails, BUT address in initial consultation
- ▶ simplifies bowel care & improves quality of life
- ▶ combine with **rectosigmoid resection** to avoid persistent mucus discharge

In Summary

- ▶ devastating problem which is under-recognized and under-reported
- ▶ multifactorial etiology
- ▶ role of diagnostic testing?
- ▶ many new treatment options, no clear algorithm anymore
- ▶ minimalist approach over major reconstruction

*When 900 years old
you reach,*

have control, you will not."

