# Treatments for Fecal Incontinence: Current State of the Evidence

## Focus of This Summary

This is a summary of a systematic review evaluating the evidence regarding the potential benefits and adverse effects of surgical and nonsurgical treatments for fecal incontinence in adults. The systematic review included 63 unique studies plus 53 surgical case series published from 1980 to June 2015. The full report, listing all eligible studies, is available at *www.effectivehealthcare.ahrq.gov/fecal-incontinence*. While this summary is provided to assist in informed clinical decisionmaking, evidence reviews should not be construed to represent clinical recommendations or guidelines.

## Background

Fecal incontinence is the recurrent involuntary loss of feces, which is defined by the frequency of episodes (such as daily or weekly episode counts) and by the consistency of the feces (solid, liquid, or mucus). The causes of fecal incontinence may be neurological or non-neurological. However, multiple causes of fecal incontinence in individuals are common and a dominant etiology may not be determinable. The negative psychological effects, social stigma, and reduced quality of life surrounding fecal incontinence can be devastating. Severe skin breakdown and ulceration can result from fecal incontinence, particularly in nursing home residents and immobile adults.

Treatment goals are to decrease the frequency and severity of fecal incontinence episodes. Treatments for fecal incontinence are often delivered in combination. Treatments typically follow a progression from less invasive nonsurgical interventions (dietary fiber, drugs, pelvic floor muscle training with biofeedback [PFMT-BF]) to more invasive nonsurgical (anal sphincter tissue-bulking injections) or surgical interventions.

Nonsurgical treatments include dietary fiber supplementation, bowel schedules, stool-modifying drugs, PFMT-BF, anal plugs, rectal irrigation, or combinations thereof. The U.S. Food and Drug Administration (FDA) approved a vaginal bowel-control device in February 2015. Injection of biocompatible tissue-bulking agents into the anal canal walls is a newer, nonsurgical procedure.

Surgical procedures used to treat fecal incontinence in the United States include implanted sacral nerve stimulation, radiofrequency anal sphincter remodeling, antegrade colonic enema, anal sphincter repair (sphincteroplasty), sphincter replacement (artificial anal sphincter), surgical correction of conditions that can result in fecal incontinence (rectal prolapse, hemorrhoids, or rectocele), or colostomy when all other treatments fail.

## Conclusions

Evidence to support any fecal incontinence treatments in adults beyond 3 to 6 months is limited. There was low-level evidence that current nonsurgical interventions, such as psyllium dietary fiber supplementation and dextranomer tissue-bulking injections, showed modest improvements in fecal incontinence outcomes that met minimal important differences* in the short term. Durasphere® tissue-bulking injections (FDA-approved for another condition; unapproved by the FDA for fecal incontinence treatment) reduced fecal incontinence severity up to 6 months, but gains diminished thereafter. The evidence for the effectiveness of all surgical treatments was insufficient to permit meaningful conclusions.

It is difficult to compare the effectiveness of surgical to nonsurgical fecal incontinence treatments because nonsurgical approaches generally precede surgery or can be used after surgery. In addition, although multiple etiologies may contribute to fecal incontinence, the literature lacks information about which treatments work best for which fecal incontinence etiologies.

Noninvasive nonsurgical fecal incontinence treatments had few minor adverse effects. Surgical fecal incontinence treatments were associated with more frequent and more severe complications than nonsurgical interventions. Major surgical complications often required reoperation; fewer required permanent colostomy.

* The smallest benefit of a given treatment that is of value to patients.

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## Overview of Clinical Research Evidence

Table 1: Summary of Key Findings and Strength of Evidence for the Benefits of Treatments for Fecal Incontinence

| Intervention and Comparator | N Studies | N Subjects | Outcome Measured | Findings | SOE |
|---|---|---|---|---|---|
| **Nonsurgical Interventions** | | | | | |
| **Dietary fiber supplementation with psyllium vs. placebo** | 1 | 206 | Severity | Psyllium significantly decreased FI by 2.5 episodes per week versus placebo (0.7 fewer episodes per week) after 1 month of use. | ●○○ |
| **PFMT-BF plus electrostimulation vs. PFMT-BF alone*** | 2 | 109 | Severity | No significant difference was found between groups in improvement in the mean CCFIS score at 3 months. | ●○○ |
| | | | Quality of life | No significant difference in FIQL score was found between groups at 2 to 3 months; neither group improved (0.0- to 0.3-point change from baseline per FIQL subscale). | ●○○ |
| **Dextranomer tissue-bulking injections vs. sham injections** | 1 | 206 | Severity | The mean increase in number of FI-free days was greater in the treated group (3.1 days, SD 4.1) when compared with the sham group (1.7 days, SD 3.5). | ●○○ |
| | | | Severity | There was no significant difference in improvement in the CCFIS score for the treated versus the sham groups at 3 months (-2.6 points for dextranomer vs. -2.0 points for sham) and at 6 months (-2.5 points for dextranomer vs. -1.7 points for sham). | ●○○ |
| | | | Severity | There was a significant difference in the percentage of patients with a 50-percent or greater reduction in FI episodes at 6 months (52% of dextranomer-treated patients vs. 31% of sham-treated patients).<br>However, the median decrease in the number of FI episodes over 2 weeks was not significantly different between groups at 3 months or 6 months (treated group: 6.0 episode reduction [IQR 0.0–12.5] vs. sham group: 3.0 episode reduction [IQR 0.0–8.9]). | ●○○ |
| | | | Quality of life | Percent change (improvement) from baseline in the FIQL coping-behavior subscale favored dextranomer at 6 months (27%, CI 21% to 24%) versus sham (11%, CI 3% to 18%). Percent change in scores for three other subscales did not differ. | ●○○ |
| **Durasphere® tissue-bulking injections vs. PTQ™ injections (both unapproved by the FDA for FI)** | 2 | 75 | Severity | Durasphere® tissue-bulking injections reduced FI severity up to 6 months (-4 to -5 points on the CCFIS), but gains diminished thereafter. | ●●○ |
| **Dextranomer tissue-bulking injections vs. PFMT-BF with or without electrostimulation** | 1 | 126 | Severity | No significant difference was found between groups in Vaizey score** improvement at 6 months (-4.6 points for the dextranomer group vs. -5.4 points for the PFMT-BF control). | ●○○ |
| | | | Quality of life | No significant difference was found between groups in FIQL score at 6 months. | ●○○ |
| **Pharmacological interventions: oral clonidine (0.2 mg/day) vs. placebo** | 1 | 44 | Severity | No significant difference was found between groups in FICA score improvement at 1 month (1.6 points for clonidine vs. 1.5 for placebo). | ●○○ |
| **All other pharmacological interventions** | – | – | – | The evidence was insufficient for all other pharmacological interventions, including loperamide, topical phenylephrine, zinc-aluminum ointment, estrogen cream, and valproate sodium. | ○○○ |
| **All other nonsurgical interventions** | – | – | – | The evidence was insufficient for all other nonsurgical interventions, including anal electrostimulation, rectal irrigation, transanal irrigation, and bowel management programs. | ○○○ |
| **Surgical Interventions** | | | | | |
| **Surgical interventions** | – | – | – | The evidence for FI treatment benefits was insufficient for all surgical interventions. | ○○○ |

* Further research is needed to establish whether PFMT-BF works for FI. Intervention specifics are lacking in the included studies. Long-term exercise compliance with PFMT-BF for FI is unknown.

** Patients are scored on seven items to assess the severity of FI (including stool frequency, stool consistency, urgency, pad use, and lifestyle alterations).

CCFIS = Cleveland Clinic Fecal Incontinence Score; CI = confidence interval; FDA = U.S. Food and Drug Administration; FI = fecal incontinence; FICA = Fecal Incontinence and Continence Assessment; FIQL = Fecal Incontinence Quality of Life scale; IQR = interquartile range; N = number; PFMT-BF = pelvic floor muscle training with biofeedback; PTQ™ = an injectable silicone biomaterial; SD = standard deviation; SOE = strength of evidence

**Strength of Evidence Scale**†

- High: ●●● High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- Moderate: ●●○ Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- Low: ●○○ Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.
- Insufficient: ○○○ Evidence either is unavailable or does not permit a conclusion.

† The overall evidence grade was assessed based on the ratings for the following domains: study limitations, directness, consistency, precision, and reporting bias. Other domains that were considered, as appropriate, included dose-response association, plausible confounding, and strength of association (i.e., magnitude of effect). For additional details on the methodology used to assess strength of evidence, please refer to: Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions—Agency for Healthcare Research and Quality and the Effective Health-Care Program. J Clin Epidemiol. 2010 May;63(5):513-23. PMID: 19595577.

## Overview of Clinical Research Evidence *(Continued)*

Table 2: Adverse Effects Associated With Interventions for Fecal Incontinence

| Intervention | Most Common Adverse Effects |
|---|---|
| **Nonsurgical Interventions** | |
| **Dietary fiber supplementation** | Gastrointestinal symptoms |
| **PFMT-BF** | None |
| **PFMT-BF with electrostimulation** | Local pain if low-frequency stimulation was used |
| **Electrostimluation (without PFMT)** | Local discomfort |
| **Dextranomer tissue-bulking injections** | Leakage of injected agent, infection, prolonged defecation, proctalgia, rectal hemorrhage, diarrhea, constipation, injection site bleeding, rectal discharge, anal pruritus, proctitis, painful defecation, fever |
| **Durasphere® tissue-bulking injections (unapproved by the FDA for FI)** | Bruising, erosion through rectal mucosa |
| **Oral medications** | Abdominal pain, nausea, headache, constipation, vomiting |
| **Surgical Interventions** | |
| **Radiofrequency anal sphincter remodeling** | Pain, bleeding, swelling, mucosal ulceration |
| **Antegrade colonic enema** | Wound infection, stenosis of stoma, bowel issues (impaction, large bowel obstruction) |
| **Sacral nerve stimulation** | Infection, pain, electrode or lead problems (e.g., fractured leads, other), device malfunction; 3 to 24 percent of patients had the device surgically removed (explanted) |
| **Anal sphincter repair** | Wound infection, anal stenosis, bowel obstruction, sepsis, fistula |
| **Anal sphincter replacement (artificial bowel sphincter)** | Serious complications were common, including infection, perianal wound problems (leakage, perforation, erosion), pain, and sepsis.<br>Reoperations were common for these problems; 14 to 81 percent of recipients had the device explanted and either had it replaced (most often) or were treated with colostomy (less often). |

FDA = U.S. Food and Drug Administration; FI = fecal incontinence; PFMT-BF = pelvic floor muscle training with biofeedback

## Gaps in Knowledge and Limitations of the Evidence Base

- The strength of evidence for most treatments for fecal incontinence in adults was low or insufficient, suggesting that future studies of higher quality that comply better with standards for study conduct could change the conclusions of this review.
- Careful descriptions of patients in clinical studies—including contributing fecal incontinence etiologies, baseline characteristics, and comorbid conditions—are needed to improve the applicability of results from individual studies.
- Although fecal incontinence is a chronic problem, most evidence examined interventions over the short or intermediate term. Longer term information on benefits and adverse effects would better inform clinical decisions for managing chronic fecal incontinence.
- Patient-centered outcomes—such as issues with urgency—have been underexamined in research studies.
- Few, if any, treatments can completely cure fecal incontinence; therefore, information on treatment combinations would benefit the evidence base.
- Better comparisons of the benefit-to-harm ratios of fecal incontinence treatments are needed, especially for more invasive surgical interventions. Substantial and life-altering adverse events sometimes occur after surgery for fecal incontinence, and these events were underidentified in randomized controlled trials (RCTs) alone.
- Addressing the variability in definitions for fecal incontience episodes and outcome measures in RCTs would improve comparability across studies.

## What To Discuss With Your Patients and Their Caregivers

- The treatment options available for fecal incontinence and that more than one treatment approach might be needed
- Patient preferences in treatment selection, their outcome priorities, and the issues that affect the patient the most (e.g., urgency, frequency, avoidance of social interactions)
- That there is limited evidence to support the effectiveness of the currently available interventions or to support the superiority of one intervention when compared with another
- Potential adverse effects associated with the treatments

## Companion Resource for Patients


*Treatments for Fecal Incontinence: A Review of the Research for Adults* is a free companion to this clinician research summary. It can help patients and their caregivers talk with their health care professionals about the various options that are available for treating fecal incontinence.

## Ordering Information

For electronic copies of this clinician research summary, the companion patient summary, and the full systematic review, visit *www.effectivehealthcare.ahrq.gov/fecal-incontinence.*

## Source

The information in this summary is based on *Treatments for Fecal Incontinence*, Comparative Effectiveness Review No. 165, prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-2012-00016-I for the Agency for Healthcare Research and Quality, March 2016. Available at *www.effectivehealthcare.ahrq.gov/fecal-incontinence.* This summary was prepared by the John M. Eisenberg Center for Clinical Decisions and Communications Science at Baylor College of Medicine, Houston, TX.

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