

# Sacral Neuromodulation for Fecal Incontinence

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**Fecal incontinence has a negative effect on quality of life for all who experience it. First-line treatment is conservative. For patients who do not improve, sacral neuromodulation may be an option to consider.**

**F**ecal incontinence (FI) is defined as involuntary loss of liquid or solid stool. FI can have devastating implications from a social standpoint and can lead individuals to confining themselves to home. A study of community-dwelling individuals reported an FI prevalence of 2.2%, although 30% with FI were older than 65.<sup>1</sup> It is nearly twice as common in women, likely due to the strong association between FI and internal and external anal sphincter deficits occurring with vaginal delivery ( $P < .001$ ).<sup>2</sup>

## CONSERVATIVE THERAPY

Conservative therapy is the first-line treatment for FI. The use of fiber supplements, avoiding bowel stimulants such as caffeine, and taking antitmotility agents such as loperamide can all increase stool firmness so that patients can have better defecatory control. Biofeedback has also shown promise in

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retraining pelvic floor muscles for better coordinated stool storage with subsequent controlled defecation.<sup>3</sup> Ultimately, 50% will have improved continence with conservative therapy, with one-third being completely continent.<sup>4</sup> If these initial measures are successful, further evaluation can be avoided.

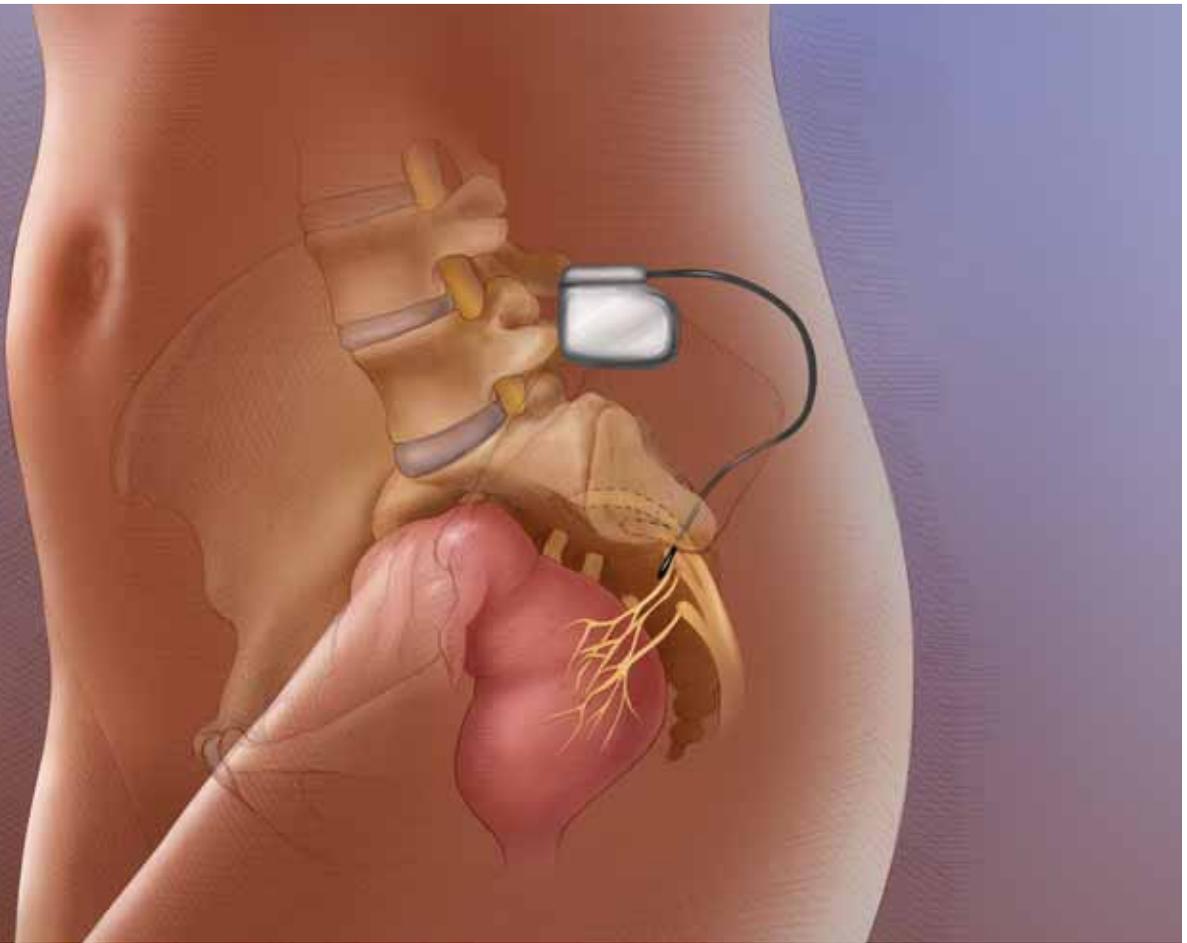
## WORK-UP WHEN CONSERVATIVE TREATMENT FAILS

When conservative FI treatment efforts are unsuccessful, more extensive evaluation is required. Endoanal ultrasound can assess both the internal and external sphincter so injuries can be more easily diagnosed. Anorectal manometry may also provide more detailed information on anorectal function with resting and squeeze pressures, anal canal length as defined by the high pressure zone, pressure at sensory and fecal urgency thresholds, maximal capacity, and rectal compliance.

Pudendal nerve terminal motor latency (PNTML) testing may be used to neurologically assess the continence mechanism. Increased amplitude, longer signal duration, or polyphasia suggest a physiologic attempt at reinnervation after neurologic injury. Defecography and 3-D dynamic pelvic floor MRI may be of further consideration.<sup>3</sup>

## SACRAL NEUROMODULATION

When sphincter defects are identified, sphincteroplasty is the most common ther-



apy, but long-term effectiveness is 50% to 60%.<sup>5</sup> Artificial bowel sphincter, fecal diversion, and dynamic graciloplasty have significant surgical morbidity, which has sparked interest in sacral neuromodulation (SNM) for treating FI. Currently, InterStim™ (Medtronic, Minneapolis, MN) is the only commercially available device for SNM. It was first described for use in FI in 1995.<sup>6</sup> Although considerable European data have suggested SNM is both safe and effective, it only recently received FDA approval for treating fecal incontinence in the United States in March 2011.<sup>7</sup>

In 2009, experts from 18 gastrointestinal centers published a position paper on the use of SNM for FI. Consensus is that SNM should be reserved for those who have at least one episode of FI per week on bowel diary or have significant changes to their quality of life due to incontinence. They should have failed conservative management with bowel regimens and biofeed-

back. They should have FI to liquid or solid stool and not just flatal incontinence.<sup>8</sup>

Historically, SNM has used greater than 50% improvement in symptoms as the definition of successful implantation. The criteria or measurement used to define improvement for FI has not been proscribed.

Whether being used for FI or for urinary indications, the implantation of an SNM remains a multistep process. In all cases, a test phase is performed prior to the implantation of the internal pulse generator (IPG), which contains a power source and the hardware to control the settings of stimulation.

#### **Mechanism of Action**

In general, the mechanism of action is poorly understood. Multiple studies failed to show an effect on anal manometry or intrarectal pressures. Whereas sphincteroplasty results in increased PNTML, SNM does not show a difference between preoperative and postoperative values.<sup>9</sup>

**TABLE 1. Sacral Neuromodulation Symptom Reduction Compared to Baseline — Outcome Measures From 30 Studies\***

Outcome	Median % Reduction	Lowest % Reduction	Highest % Reduction
Cleveland Clinic Continence Score	50.0	25.0	93.1
Number of incontinent episodes	80.4	53.0	100
Days with incontinence	71.1	58.5	97.1
Number of soiling episodes	67.5	40.0	78.6
Number of fecal urgency episodes	88.9	88.9	88.9
Number of defecations	56.0	40.4	68.9

\* References available as Appendix with online article at [www.femalepatient.com](http://www.femalepatient.com).

**FOCUS POINT**  
**SNM should be reserved for those with significant quality-of-life changes due to incontinence.**

One study showed that rectal filling and the urge to defecate were perceived at higher volumes with the device activated, demonstrating an effect on rectal perception.<sup>10</sup> This reduced urgency also suggests that contractile function of the large bowel is affected.<sup>11</sup>

Endoanal ultrasound demonstrated decreased diameter of both the internal and external anal sphincters as well as decreased distance from the rectum to the pubic symphysis, all indicative of contraction of the pelvic floor.<sup>10</sup> Ultimately, the third sacral nerve root contains afferent and efferent autonomic nerves, as well as voluntary somatic fibers, all of which are thought to be involved.

#### Efficacy of SNM

We reviewed 30 different studies on SNM, encompassing a total of 1,597 subjects, to look at the efficacy of this therapy for FI. These studies are included as supplemental information in the Appendix (available in online article at [www.femalepatient.com](http://www.femalepatient.com)). Of the 1,456 patients who ultimately underwent implantation of an IPG after a successful test phase, 1,176 (80.8%) had greater than 50% improvement from baseline symptoms and were classified as SNM success.

Within individual studies, success ranged from 45.5% to 100%.<sup>12,13</sup> This variation is possibly due to the heterogeneity of outcome variables used, so we have summarized the efficacy of different outcome variables in Table 1 as the percentage reduction compared to preimplantation.

It is important to remember that SNM success is defined as greater than 50% reduction in symptoms, but which symptom should be used as an outcome variable is not defined. It is also important to note that the values in Table 1 are the global improvement of all study participants and should not be confused with the greater than 50% improvement required within an individual to be classified as a success.

#### Complications From SNM

Complications related to device implantation are similar to those seen when SNM is used for other indications. These include infections both superficial and deep, seromas, pain at implantation site, lead migration, battery failure, and loss of efficacy. These can lead to device removal or revision of the IPG or SNM leads. The major complications are summarized in Table 2, based on data from 5 studies.<sup>14-18</sup> Approximately 1 in 8 participants (12.7%) underwent a revision, and an additional 1 in 8 (11.9%) underwent explantation of the device. Pain was the most frequent complication and was more commonly seen in thinner patients.<sup>14</sup>

#### Cost-Effectiveness of SNM

Three studies have tried to address whether SNM is a cost-effective strategy for FI. The goal of the first study was to determine costs for various treatments for incontinence, which have been converted to relative costs in Table 3.<sup>19</sup> A second report demonstrated that the cost-effectiveness of SNM over a

**TABLE 2. Sacral Neuromodulation Complications From 5 Studies<sup>14-18</sup>**

Author	Revision	Explantation	Infection	Pain	Seroma/Hematoma
Tjandra <sup>13</sup>	—	—	—	5.7%	1.9%
Gallas <sup>14</sup>	—	—	1.5%	21.5%	—
Hetzer <sup>15</sup>	—	—	5.4%	16.2%	2.7%
Michelsen <sup>16</sup>	12.7%	11.9%	1.6%	—	—
Wexner <sup>17</sup>	—	—	10.8%	5.8%	1.7%

Note: Not all studies had data on all complications. A study lacking data is denoted with (—).

5-year time period was only 54% of the accepted threshold value. Notably, 85% of the costs were encountered during permanent implantation.<sup>5</sup> A final study found that SNM costs £3.63 (approximately \$5.55) per every episode of FI that is avoided.<sup>20</sup>

## CONCLUSION

Sacral neuromodulation is a minimally invasive treatment for FI. It is reserved for those whose incontinence is more frequent than once per week and who have failed conservative therapies. While it has shown efficacy and safety in Europe since 1995, it was only recently approved by the FDA for use in the United States. Still, the mechanism of action is not fully understood. It is successful in greater than 80% of those who pass the testing phase. However, a significant proportion will eventually have the device revised or explanted due to complications such as pain and infection. It has been shown to be cost-effective, with cost-effectiveness ratios less than accepted threshold

values. Ongoing research on the efficacy, safety, and cost-effectiveness of SNM may continue to show it is a viable second-line therapy for treating refractory FI.

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**TABLE 3. Relative Costs of Treatment of Fecal Incontinence<sup>19</sup>**

Procedure	Relative Total 5-Year Costs
Conservative therapy	0.15
Sphincteroplasty	0.24
Sacral neuromodulation	1.00 (reference cost)
Dynamic graciloplasty	1.43
Colostomy	1.53

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Appendix: available with the online article at [www.femalepatient.com](http://www.femalepatient.com).

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## Appendix for Table 1 of Sacral Neuromodulation for Fecal Incontinence, The Female Patient, 2011;36(6):14.

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