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Anal Incontinence Improvement After Silicone Injection May Be Related to Restoration of Sphincter Asymmetry

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Background. This study aimed to evaluate manometric parameters that may explain improvement in anal incontinence using a silicone bulking agent. *Methods*. Incontinent patients having internal sphincter defects were prospectively selected and injected with a silicone bulking agent. Manometry and endoanal ultrasound were performed before and 3 months after injections. Twenty continent healthy volunteers were used only for manometric comparison. *Results*. Thirty-five patients (28 females; mean age 60.3 years) and 20 controls entered this study. Patients had lower resting and squeeze pressures compared with controls ($P < .05$). Length of the high-pressure zone increased from 1 to 1.7 cm postinjection ($P = .002$). Asymmetry index showed a significant change postinjection ($P < .001$). *Conclusion*. Despite considerable clinical improvement, no significant increase in manometric pressures was noted posttreatment. There was significant improvement in both high-pressure zone and asymmetry index, and these findings may explain the mechanism of action of the bulking agent injected.

Keywords: silicone; fecal incontinence; asymmetry index; manometry

Anal incontinence is a complex condition with a wide range of available treatment modalities.[1,2] One of the new minimally invasive options is injection of bulking agents. Although there have been a number of substances described and used for this purpose, their exact mechanism of action remains unclear. The aim of this prospective study was to assess the results of transsphincteric silicone injection for the treatment of anal incontinence and to correlate anal manometric parameters that may explain the improvement in continence after injection of this bulking agent.

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Patients and Methods

After institutional review board approval, incontinent patients referred to 2 anorectal physiology departments between December 2003 and July 2006 were prospectively selected for transsphincteric silicone injection. Inclusion criteria were mild-to-moderate anal incontinence related to simple or multiple internal anal sphincter defects. Exclusion criteria were pregnancy, symptomatic hemorrhoids, inflammatory bowel disease, radiation proctitis, anorectal tumors, rectal prolapse, acquired immunodeficiency syndrome, diabetes, fecal impaction, and a history of allergies to any of the antibiotics or medications required before or after the injections. Prior to injection, severity of incontinence and quality-of-life impact were measured using the Cleveland Clinic Florida Fecal Incontinence Scoring System[3] (CCF-FI) and the Fecal Incontinence Quality of Life Scale[4] (FIQOL), respectively. Physiologic assessment was performed in all patients by anal manometry and endoanal ultrasound before and 3 months after injection. Manometry

was performed with a stationary 8-channel water perfused system (Dynapack MPX 816; Dynamed, São Paulo, Brazil) using a 4.8-mm diameter radial catheter (Arndorfer, Inc, Greenvale, WI).[5] Manometric parameters evaluated included mean resting pressures, mean and maximal squeeze pressures, and high-pressure zone (HPZ). In addition, the asymmetry index (AI) was observed in each centimeter of the anal canal during recording of the resting pressures with stationary pullthrough.[6] Endoanal ultrasound was performed using a 7.5-MHz ultrasound probe with assessment of the upper, mid, and lower anal canal.[7] Internal anal sphincter defects were considered when discontinuity or breaks of the inner hypoechoic ring were observed. Silicone injection site images were observed at the level of the mid or upper anal canal beyond the level of the puborectalis ring as a hyperechoic round image on endoanal ultrasound.

A control group of 20 continent healthy volunteers (10 females and10 males) was used primarily for AI comparison with patients prior to silicone injection; the same manometric parameters were evaluated and compared with the patient group before injection. All controls were given an informed consent prior to undergoing anal manometry. None of the participants had anorectal surgery or any symptoms related to anal incontinence.

After all patients signed an informed consent, ambulatory transsphincteric silicone (Uroplasty Inc, Geleen, the Netherlands) injections were performed with patients placed in the prone jackknife position under local anesthesia. The silicone was injected into the intersphincteric space by transdermal transsphincteric injection, guided by a digital exam. Three injections of 2.5 ml of silicone (PTQ; total of 7.5 mL) were performed at the right anterior, right posterior, and left lateral sphincter quadrants as established by initial protocols.[8] Venous broad-spectrum antibiotics were administered before the injections and continued orally for a period of 5 days postinjection.

Clinical follow-up was performed after 1 week and at 1 and 3 months postinjection. At the 3-month follow up, all patients underwent postinjection CCF-FI and FIQOL assessment as well as anal manometry and endoanal ultrasound.

Statistical Analysis

Statistical analysis was performed using Stata and Graph Pad Instat programs. Differences between patients and controls were evaluated using Student's *t* test and χ^2 test. Comparison of degree of fecal incontinence was performed using the χ^2 McNemar test. Comparisons of manometric pressures and AI between patients and controls were performed using the Student *t* test and analysis of variance test. A 2-sided *P* value of <.05 was considered statistically significant.

Table 1. Etiology of anal Incontinence

Etiology	n	Percentage
Surgical trauma	19	54.3
Hemorroidectomy	10	28.9
Fistulotomy	4	11.4
Sphincterotomy	2	5.7
Anal dilatation	2	5.7
Imperforate anus	1	2.9
Obstetric trauma	10	28.6
Episiotomy	10	28.6
Idiopathic	6	17.1

Table 2. Anal Ultrasound Findings

	n	Percentage
Single internal sphincter muscle defect	17	48.5
Multiple internal sphincter muscle defect	3	8.5
Internal sphincter defect and isolated external sphincter defect	15	43

Results

A total of 35 incontinent patients (28 females and 7 males) with a mean age of 60.3 years (range 19-80 years) underwent transsphincteric silicone injection under local anesthesia. Anal incontinence was related to sphincter trauma (obstetric and postsurgical) in 29 patients (82.8%; Table 1). In 6 patients, no specific traumatic cause was observed although all patients had an internal sphincter defect as evaluated by endoanal ultrasound (Table 2). The 20 patients in the control group had a mean age of 52 years (range 25-75 years).

At 1 week after injection, 1 (2.8%) patient presented with an anal abscess on the left quadrant site of injection, 2 patients (5.7%) complained of anal discomfort requiring oral analgesics, and 2 patients (5.7%) presented with a perianal hematoma (5.7%)

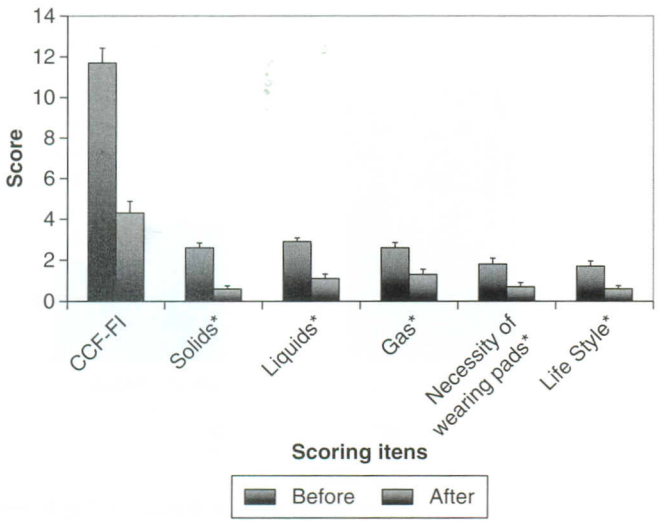

Figure 1. Cleveland Clinic Florida Fecal Incontinence Scoring System before and after silicone injection (*$P < .001$, mean ± standard error of mean).

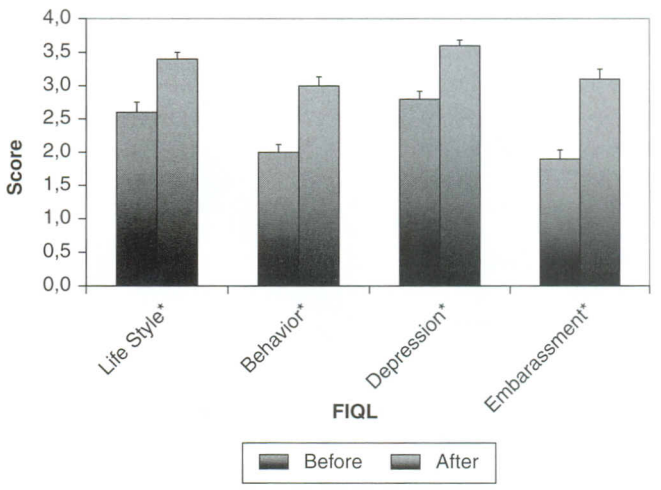

Figure 2. Fecal Incontinence Quality of Life Scale before and after silicone injection (*$P < .05$, mean ± standard error of mean).

with spontaneous resolution. The abscess was managed with local drainage and oral antibiotics, and the patient improved within 2 weeks. At 1-month follow-up, the patient presented with complete resolution of the inflammatory process and, despite having lost part of the injected silicone, achieved continence to solid and gas. None of the patients presented with severe pain, fecal impaction, or allergic reaction to the silicone.

After 1 month, 32 of the 35 (91.4%) patients reported an overall improvement in fecal incontinence. In addition, the mean CCF-FI scores improved from 11.3 to 4.3 ($P < .001$; Figure 1), and there was a significant improvement in all 4 domains of the FIQOL at 3 months (Figure 2). At 1-year follow-up, clinical improvement was maintained as observed by a significant change in the CCF-FI scores (Figure 3). Patients who did not experience clinical improvement after 1 month of injections (n = 3) had a history of constipation, fistulectomy, or obstetrical trauma.

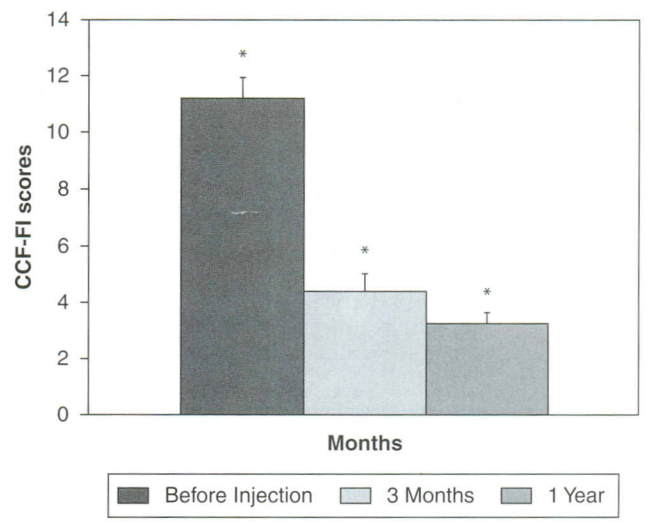

Figure 3. Cleveland Clinic Florida Fecal Incontinence Scoring System before and after silicone injection at 3 months and 1 year (*$P < .001$, mean ± standard error of mean).

Manometric Results

Manometry pressures were generally low in patients when compared with the controls (Table 3). Comparison of the HPZ between patients and controls showed a significant difference in the length of the functional anal canal, with male patients presenting a longer anal canal in both groups (Figure 4). Comparison of the asymmetry index between patients and controls demonstrated that patients had a more asymmetrical anal canal (Table 4).

Comparison of the patients' manometry pressures before and after injection did not show any statistically significant differences (Table 5). However, comparison of the HPZ before and after injection demonstrated a significant change. Specifically, the HPZ increased from 1 to 1.7 cm after injection in all patients (Figure 5).

Table 3. Results of Anal Pressures Between Patients and Controls

	Controls (n = 20)	Patients (n = 35)	P^a
Mean resting pressure (mm Hg)			<.001*
Mean	61.2	29.4	
Median	61.9	27.0	
Standard deviation	21.2	16.0	
Range	31.0-106.0	10.0-86.0	
Mean squeeze pressure (mm Hg)			<.001*
Mean	121.0	68.6	
Median	122.5	60.0	
Standard deviation	46.2	39.2	
Range	41.5-210.0	15.0-186.0	
Maximal squeeze pressure (mm Hg)			.02*
Mean	150.2	112.2	
Median	146.5	110.0	
Standard deviation	48.5	59.3	
Range	69.0-231.0	22.0-290.0	

[a] Student's *t* test.
NOTE: *P < .05 = mean ± standard error of mean

Table 4. Asymmetry Index of Controls and Patients

	Controls (n = 20)	Patients (n = 20)	P^a
Asymmetry at 4 cm			<.001*
Mean	26.4	50.9	
Median	22.2	49.5	
Standard deviation	15.9	21.1	
Range	9.7-62.4	22.1-96.2	
Asymmetry at 3 cm			<.001*
Mean	19.5	44.1	
Median	15.1	38.7	
Standard deviation	12.8	18.2	
Range	5.4-43.5	12.2-87.1	
Asymmetry at 2 cm			<.001*
Mean	20.2	43.4	
Median	17.5	39.2	
Standard deviation	7.4	17.7	
Range	13.0-40.7	13.9-91.2	
Asymmetry at 1 cm			<.001*
Mean	25.5	42.8	
Median	21.9	39.4	
Standard deviation	13.6	16.6	
Range	5.6-52.1	22.9-79.0	

[a] Student's *t* test.
NOTE: *P < .05 = mean ± standard error of mean

Asymmetry index evaluations in 20 patients showed significant differences before and after silicone injection, and its correlation with clinical

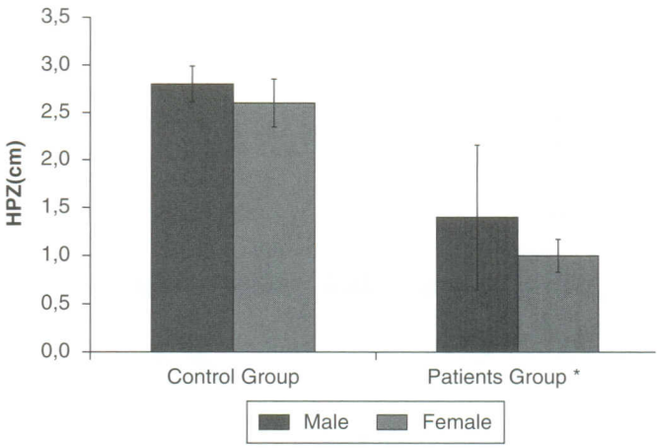

Figure 4. High-pressure zone between controls and patients (*P < .001, mean ± standard error of mean).

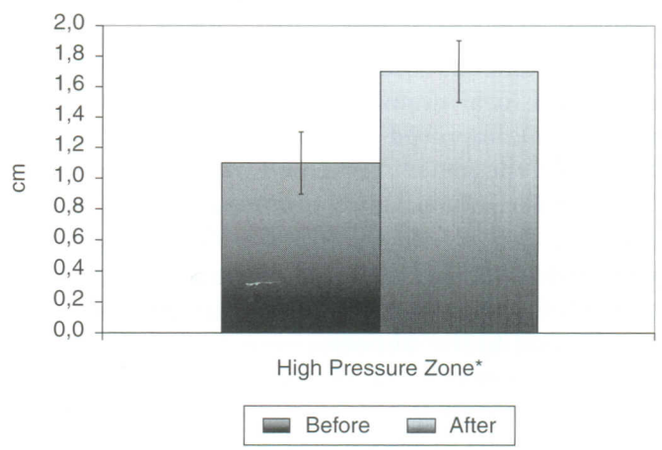

Figure 5. High pressure zone of patients before and after injection (*P < .002, mean ± standard error of mean).

improvement was the only functional parameter that could be related to correction of anal incontinence. Asymmetry index comparison before and after silicone injection, because of technical reasons, was available for analysis only in 20 cases. For the 20 evaluated patients, improvement in sphincter asymmetry was observed at 2 cm from the anal verge, at the level of the HPZ (Table 6). Within the group of patients with poor outcome (n = 3), AI was not performed before injection in 1 patient and comparison of results was not possible. However, all 3 patients presented with a very asymmetrical sphincter at 1 and 3 months after injection. Configuration of vector volume reconstruction of the anal sphincter before (Figure 6) and after

Table 5. Manometric Pressures of Patients Before and After Silicone Injection

	Before (n = 35)	After (n = 35)	P^a
Mean resting pressures (mm Hg)			.07
Mean	29.4	34.1	
Median	27.0	28.0	
Standard deviation	16.0	21.0	
Range	10.0-86.0	8.0-101.0	
Mean squeeze pressures (mm Hg)			.20
Mean	68.6	75.9	
Median	60.0	62.0	
Standard deviation	39.2	42.6	
Range	15.0-186.0	10.0-186.0	
Maximal squeeze pressure (mm Hg)			.11
Mean	112.2	127.0	
Median	110.0	109.0	
Standard deviation	59.3	68.6	
Range	22.00-290.0	36.0-290.0	

[a] Paired Student's *t* test.

Table 6. Asymmetry Index Before and After Silicone Injection

	Before (n = 20)	After (n = 20)	P^a
Asymmetry at 4 cm			.03*
Mean	50.9	37.0	
Median	49.5	40.4	
Standard deviation	21.1	17.1	
Range	22.1-96.2	10.6-67.5	
Asymmetry at 3 cm			.05*
Mean	44.1	32.0	
Median	38.7	28.7	
Standard deviation	18.2	13.6	
Range	12.2-87.1	9.9-64.5	
Asymmetry at 2 cm			<.001*
Mean	43.4	26.1	
Median	39.2	25.6	
Standard deviation	17.7	10.6	
Range	13.9-91.2	4.0-47.5	
Asymmetry at 1 cm			.02*
Mean	42.8	30.2	
Median	39.4	27.5	
Standard deviation	16.6	12.1	
Range	22.9-79.0	12.6-53.4	

[a] Student's *t* test.
NOTE: *P < .05 = mean ± standard error of mean

(Figure 7) silicone injection in 1 patient with a successful outcome demonstrated correction of asymmetry from 68% to 19%. Endoanal ultrasound was performed at 3 months postinjection in all patients,

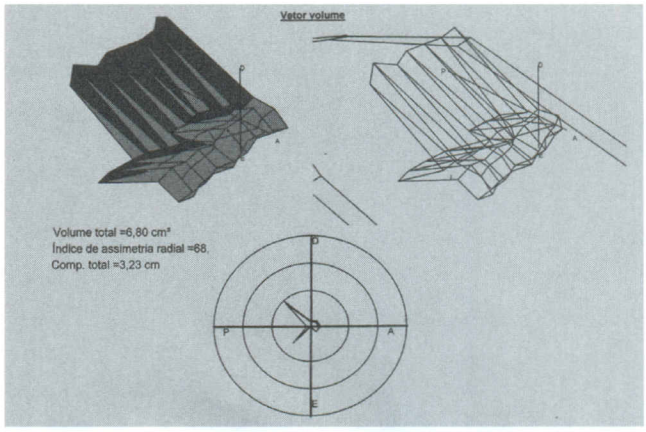

Figure 6. Asymmetry index before silicone injection in a patient.

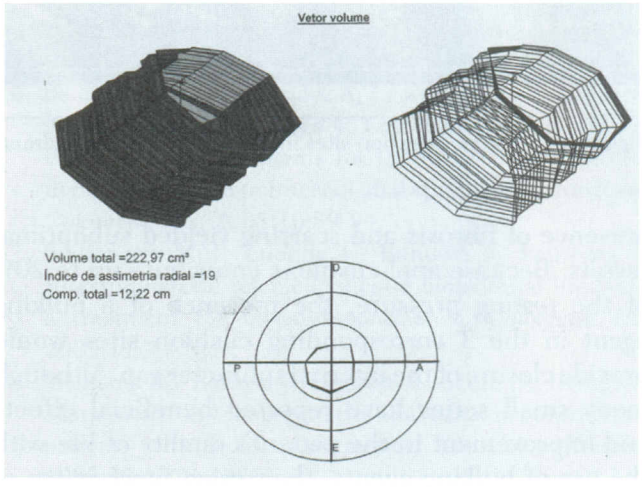

Figure 7. Asymmetry index after silicone injection in the same patient.

and silicone injection sites were demonstrated as a hyperechoic image at the mid anal canal (Figure 8).

Discussion

In recent years, treatment of anal incontinence has been evolving toward nonsurgical methods, mainly because of the suboptimal long-term surgical results.[9,10] One of these less invasive options is the injection of bulking agents.[11-15]

The ideal method of injection around the anal canal has not been established yet. Injection of the silicone into the internal sphincter defect was performed in the beginning of our experience, but the

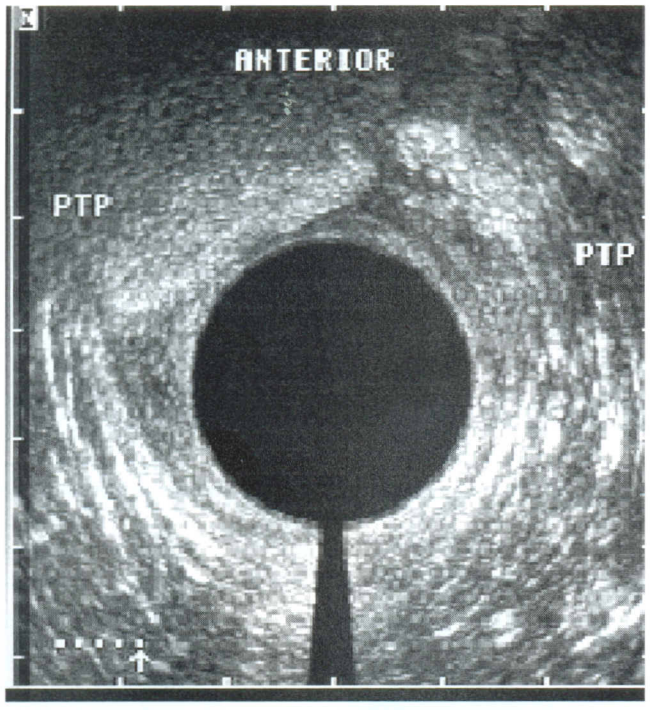

Figure 8. Silicone injection sites in the right anterior quadrant.

presence of fibrosis and scarring yielded suboptimal results. Because anal cushions contribute up to 20% of the resting pressure, the presence of a bulking agent in the 3 corresponding cushion sites would provide closure of the internal sphincter gap. Although many small series have reported beneficial effects and improvement in the patient's quality of life with the use of bulking agents, their exact mechanism of action is unclear and has not been adequately explained in any previously published series.

The hypothesis that injection of a bulking agent could increase anal pressures has been debatable because not all series in the literature could demonstrate this specific correlation. The first report to attribute improvement of anal pressures by way of explanation to improvement of symptoms after silicone injection was from Malouf et al[8] in a series of 6 incontinent patients. However, subsequent series did not demonstrate the same results, including the present one.[13,16,17] In our series of 35 patients, manometric evaluation performed before and after injection revealed no significant changes in mean values of anal pressures; however, significant differences were noted in the length of the HPZ and in the sphincter AI. We therefore used the sphincter AI as a functional parameter and observed an interesting correlation: patients who presented with a clinical improvement also demonstrated an improvement in their AI; furthermore, in patients with a poor outcome sphincter asymmetry remained high. Restoration of asymmetry was observed in the distal anal canal and was more significant within the HPZ. This manometric parameter requires an 8-channel manometry system and can be used to evaluate sphincter integrity.

Values of AI up to 20% are expected, because of the intrinsic anatomic asymmetry. However, in patients with a history of sphincter trauma, external and internal anal sphincter defects can significantly increase the sphincter AI.[18] All patients in this series had internal anal sphincter defects confirmed by endoanal ultrasound. Although injection of a bulking agent for an isolated internal anal sphincter defect was the proposed indication for this treatment modality, 10 patients in our series also presented with a small (less than 45°) external anal sphincter defect related to an obstetrical history. Twenty-nine patients with a previous traumatic history to the anal sphincters, including the 10 women with an obstetrical history, were successfully managed by the use of this minimally invasive treatment. Therefore, it was clearly demonstrated that the presence of small external anal sphincter defects should not contraindicate this treatment modality. Considering the complexity of anal incontinence and the need to provide adequate care for these patients, injection of a bulking agent is an attractive minimally invasive option. This treatment modality should be considered for patients with mild-to-moderate incontinence, even in the presence of small external anal sphincter defects.

In the 6 patients classified with idiopathic incontinence, internal anal sphincter defects were detected during endoanal ultrasound, stressing the importance of ultrasonographic evaluation in all incontinent patients despite a negative history for sphincter trauma. Furthermore, endoanal ultrasound is a simple and useful method for the follow-up of incontinent patients treated by silicone injections. Specifically, the sites of silicone injection appear as hyperechoic images, facilitating recognition of the substance for the investigator, as well as its correlation with sphincter muscles. Improvement of new ultrasound systems, specifically the 3-dimensional probes, may facilitate the identification of injection sites in the anal canal.

Because of the complexity of anal incontinence etiology, we believe that treatment options should include a variety of modalities, starting with minimally invasive options. The treatment algorithm for

anal incontinence has been modified, and certainly, future controlled randomized trials will demonstrate which methods will be the most beneficial to incontinent patients. The patients' improvement seen in our series has encouraged the indication of silicone in selected incontinent patients. Although the change in HPZ and sphincter AI may explain its mechanism, future larger prospective randomized series are necessary to improve our understanding and endorse the use of bulking agents for anal incontinence.

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