Symptom Improvement After Prolapse and Incontinence Graft Removal in a Case Series of 306 Patients

Lisa Rogo-Gupta, MD, Tamara Grisales, MD,† Linda Huynh, MD,‡ Larissa V. Rodríguez, MD,§ and Shlomo Raz, MD||*

Objectives: We report our experience with removal of synthetic and biologic implants used in pelvic reconstruction in a tertiary referral center from 2005 to 2012.

Methods: We performed a retrospective cohort study of all consecutive patients who underwent surgical implant removal for treatment of implant-related complications. Symptoms were determined by patient self-assessment including validated questionnaires. One hundred seventy-nine patients completed follow-up.

Results: Three hundred six patients underwent removal for exposure or erosion (57%), pain (46%), and urinary symptoms or incontinence (54%). Ninety patients (29%) had previous revision. Eleven percent had pelvic organ prolapse (POP) implants, 48% had sling implants, and 41% had both implants. Mean time from removal to follow-up was 2 years (median, 2 years; range, <1–7).

The majority of patients experienced symptom improvement after implant removal. Seventy-eight percent of those with pain reported pain improvement, 9% reported no change, and 14% experienced worsening. Symptom improvement was reported by 79% of those who underwent removal of a POP implant alone, 79% of those who underwent removal of POP and sling implants, and 83% of those who underwent removal of a sling alone. Quality of life was significantly improved after implant removal overall ($P < 0.05$) for those who underwent removal of POP and slings, and slings alone, but not for those with POP removal only.

Conclusions: Pain is among the most common symptoms reported in women referred to our institution for implant-related complications. In a series of 306 complex patients with a range of implants and symptoms, removal improved implant-related pain in the majority of patients.

Key Words: mesh removal, pelvic organ prolapse, sling, surgical outcome, urinary incontinence

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Pelvic floor disorders including pelvic organ prolapse (POP) and urinary incontinence (UI) are among the most common chronic illnesses affecting women. The increasing number of women at risk for pelvic floor disorders, many of whom require 1 or more surgeries, adds additional pressure on pelvic surgeons to critically evaluate currently available surgical techniques. Augmentation of traditional vaginal prolapse techniques using nonabsorbable prosthetic implants and grafts demonstrated low morbidity and high anatomic success when initially described.[1,2] This seemingly reassuring data resulted in the rapid and widespread adoption of such techniques by pelvic surgeons worldwide, and many products are available for this purpose.[3] Currently, polypropylene is the most commonly used synthetic material and was widely adopted after demonstration of significantly lower complication rates compared to its synthetic predecessors.[4–6]

Prosthetic implants may be partially or entirely surgically removed to treat related complications. Partial excision is often performed to relieve organ obstruction or exposure, whereas entire implant removal is often for those suffering from infection or pain. Published series note up to an 88% improvement after implant removal in patients presenting with severe pain, however technical difficulty of removal limits the performance of these procedures.[7,8] For example, surgical removal may create large urethral or vaginal wall defects and hemorrhage among other surgical challenges.[7,8]

The primary objective of this paper is to report our experience with surgical removal of implants used in pelvic reconstruction (PRS) in a tertiary referral center from 2005–2012. The secondary objective is to report surgical outcomes as reported by subjective improvement after removal in patients presenting with pain symptoms as measured by patient questionnaires. We previously published long-term outcomes after mesh removal among the subset of our cohort with at least 2 years follow-up (n = 79).[9] The current case series is among the largest described from a single referral center that includes multiple implant types.

MATERIALS AND METHODS

We performed a retrospective study of all consecutive patients between January 1, 2005, and July 31, 2012, at a single institution who underwent removal of a prosthetic implant placed for POP or UI. Patients were identified by the presence of one or more Current Procedural Technology (CPT) codes for removal of implants and charts were reviewed by physicians, who were not the treating physicians, for clinical information. Preoperative evaluation included history, physical examination, cystoscopy when appropriate, and symptom questionnaires.

Subjective outcome was determined by patient self-assessment using questionnaires which are routinely collected at our institution to monitor postoperative improvement. Condition-specific questionnaires are widely used in the literature to evaluate the efficacy of POP and UI repairs.[10,11] The questionnaires include validated standardized condition-specific symptom questionnaires that assess the presence or absence of bother due to symptoms. The validated short form of the Urogenital Distress Inventory (UDI-6) has been validated in women with symptomatic UI conditions.[12] The 6 questions included evaluation of urinary frequency, urge UI, stress UI, small leakage of urine, difficulty with bladder emptying, and lower abdominal or genital pain. Patients completed the questions answered on a scale ranging from 0—no bother, to 3—most frequent bother, and scoring was performed as initially described.

From the *Division of Urogynecology and Pelvic Reconstructive Surgery, Department of Obstetrics and Gynecology, Stanford University Medical Center, Stanford; †Division of Pelvic Medicine and Reconstructive Surgery, Department of Obstetrics and Gynecology, University of California Los Angeles; ‡David Geffen School of Medicine, University of California Los Angeles; §Division of Pelvic Medicine and Reconstructive Surgery, Institute of Urology, University of Southern California; and ||Division of Pelvic Medicine and Reconstructive Surgery, Department of Urology, University California Los Angeles, Los Angeles, CA.

Correspondence: Lisa Rogo-Gupta, MD, Urogynecology and Pelvic Reconstructive Surgery Obstetrics and Gynecology, Stanford University, 300 Pasteur Drive, HG332, Stanford, CA 94305-5317. E-mail: lrgupta@stanford.edu.

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Questions related to quality of life due to symptoms, overall improvement of condition and improvement rating score were also included. A global question assessing overall quality of life due to symptoms was modified from the International Prostate Symptom Score, previously validated in women with lower urinary tract symptoms,[13] which asks, "If you were to spend the rest of your life with your mesh pain condition just the way it is now, how would you feel about that?" The question is answered on a scale of 0—delighted, 1—pleased, 2—mostly satisfied, 3—mixed, 4—mostly dissatisfied, 5—unhappy, 6—terrible. Patients were asked to report whether or not they underwent additional treatments for pain. The Patient Global Impression of Improvement has been validated for use in women with UI.[14,15] This scale uses 1 question to assess postintervention condition compared to preintervention condition answered on a scale of 1—very much better, 2—much better, 3—a little better, 4—no change, 5—a little worse, 6—much worse, 7—very much worse. A follow-up question asked patients to rate their improvement on a scale from 0% to 100%.

Statistical analysis was performed using paired samples t-tests to compare preoperative and postoperative questionnaire response using Microsoft Excel 2007 (Microsoft Corporation; Redmond, Washington). This analysis was approved by the University of California Los Angeles Institutional Review Board.

RESULTS

Baseline Characteristics

Three hundred six patients underwent an excision procedure during the study period (Table 1). Preoperative cystoscopy was performed in 282 patients and identified genitourinary tract exposure or erosion in 26 patients (9%). Operative reports from the initial surgery were reviewed for implant details. Report review revealed 93% of POP implants were synthetic mesh, whereas 7% were biologic, compared to 91% of synthetic mesh UI implants and 9% biologic UI implants. Reports were unavailable or did not include implant name in 88 patients. One hundred eighty-two (59%) had POP implants, and 271 (88%) had sling implants (Table 2). The POP implants were located in multiple compartments (anterior, apical, or posterior) in 93 patients.

TABLE 1. Demographics

Characteristics	Patients
Age: mean (standard deviation), y	59 (12)
Parity: mean (standard deviation)	3 (1)
Body mass index: mean (standard deviation)	27 (6)
Time since insertion: mean (standard deviation), y	3 (3)
Postmenopausal	200 (65)
Tobacco use, current	53 (17)
Hysterectomy	229 (75)
Hysterectomy with implant placement	100 (33)
Previous implant revision	90 (29)
One	47
Two	21
Three	8
Four	3
Nine	1
Not recorded	10

Data are patients, n (%) unless otherwise specified.

TABLE 2. Implant Characteristics and Presenting Symptoms Stratified by Implant Type

	Implant Type		
Characteristics	POP	UI	POP and UI
Implant composition			
Biologic	1 (3)	10 (8)	10 (7)
Synthetic	25 (71)	94 (76)	101 (69)
Biologic and synthetic	0 (0)	4 (3)	2 (1)
Not recorded	9 (26)	16 (13)	34 (23)
Implant compartments			
Single	14 (40)	n/a	63 (43)
Multiple	19 (54)	n/a	74 (50)
Not recorded	2 (6)	n/a	10 (7)
Presenting symptoms (not mutually exclusive)			
Erosion or exposure	24 (69)	59 (48)	91 (62)
Urgency, frequency, urinary incontinence	9 (26)	78 (63)	77 (52)
Pain or dyspareunia	22 (63)	49 (39)	69 (47)
Infections	10 (29)	27 (22)	31 (21)
Multiple, including pain or dyspareunia	25 (71)	68 (55)	87 (59)
Total	35	124	147

Data are patients, n (%).

Presenting symptoms are reported (Table 2). The most common were exposure or erosion (n = 174, 57%), pain or dyspareunia (n = 140, 46%), and de novo urgency, frequency, or incontinence (n = 164, 54%). One hundred eighty (59%) presented with multiple symptoms, including pain and a combination of exposure, infection, voiding dysfunction, and POP. One hundred sixty-six patients (54%) reported having no pain.

Implant Removal Procedures

Procedures were performed at a single academic institution by surgeons trained in PRS. The decision for removal was at the discretion of the surgeon and patient. Removal is defined as the partial or complete surgical excision of implant material. In 51% of procedures, a UI implant alone was removed, in 28%, a POP implant alone was removed, and both implant types were removed in 21%. Of those who had both implant types, 60 (41%) underwent removal of both implants, 56 (38%) underwent removal of the POP implant alone, and 31 (21%) underwent removal of the UI implant alone. One hundred twenty (39%) underwent concurrent procedure at the time of removal (Table 3). The POP repair was performed using standard plication of the perivesical fascia in cases of anterior compartment POP, and plication of the perirectal fascia in cases of posterior compartment prolapse. Enterocele repair was performed by McCall culdoplasty, and posthysterectomy prolapse repair using bilateral sacrospinous ligament fixation. Hysterectomy was performed in 3 patients, and trachelectomy in 1 patient. Of those who did not undergo a concurrent procedure at the time of implant removal, 10 (3%) underwent an additional or staged procedure during the study period.

Implant removal technique was determined by implant location and previous revisions. In general, patients who underwent partial removal often presented with exposure or pelvic organ dysfunction without pain or infection. The surgical technique of POP and UI implant removal has been previously described with some variation between institutions based on experience. For POP removal at our institution, typically, a vertical or inverted U incision

TABLE 3. Procedures Performed at Implant Removal

Procedure	Patients
Concurrent procedure	120 (39)
POP repair	58
UI repair	37
POP and UI repair	9
Urethral reconstruction	6
Removal of scar or inclusion cyst	5
Urethrolysis	3
Laparotomy	2
None	186 (61)

Data are patients, n (%).

is made in the covering vaginal epithelium. Dissection is then carried out laterally to isolate the implant arms or fixation devices in appropriate cases. Once the implant is exposed, it can be transected vertically in the midline with care not to injure the underlying organ. Using Allis clamps, one half of the implant can be placed on gentle traction and gently separated from the underlying organ. The implant is followed laterally and then released from the surrounding tissues and excised. This is repeated on the contralateral side. Infiltrated or eroded vaginal wall is excised, and the remaining tissue closed using absorbable sutures.

In complete excision of retropubic midurethral slings at our institution, once the sling is identified, an incision is made horizontally across the sling, with care not to incise it. The central incision is then extended laterally, and bilateral vertical incisions are made in the vaginal epithelium at the level of the sulci to facilitate entry into the retropubic space. The sling is then isolated from the vaginal wall and transected in the midline with the lateral portions held for countertraction during dissection. Infiltrated or eroded vaginal wall is excised. Starting with the central free portion, the sling arms are dissected laterally until the retropubic spaced is reached. Using a curved scissor, the retropubic endopelvic fascia is sharply entered at the location of the sling arm. At this juncture, the medial portion is dissected from the perivesical tissue and the anterior portion from the posterior pubic symphysis. Once the mesh arm is released from the bone and perivesical tissues, gentle traction reveals the location of attachment to the anterior abdominal wall. An incision through the skin and subcutaneous reveals the sling, which is then grasped with a clamp for retraction. The fascia as perforated sharply at the location of penetration, resulting in entirely free sling arms which are then removed. The procedure is repeated on the contralateral side.

Excision of complete transobturator slings begins similarly.[16] Once the midportion of the sling is released to the lateral incisions, the obturator fascia and obturator internus are perforated and the mesh freed from its attachments circumferentially. The implant is then carefully dissected off the pubic bone, obturator membrane and obturator externus, and gentle traction reveals the location as it traverses the adductor fossa toward the lateral labial or medial thigh exit site. The skin is incised to reveal the adductor fascia, gracillis, and adductor longus muscles beneath. The implant is separated from these structures and transferred through the adductor fossa for removal. This process is then repeated on the contralateral side.

Removal of isolated arms in patients with previous revisions is significantly more challenging. A vaginal incision is performed over the cut arm identified during examination under anesthesia and the dissection carried out as above.

Erosion into the genitourinary tract identified during cystoscopy was addressed at the time of implant removal. After removal of an implant with erosion into the bladder, the bladder was closed in 2 layers of absorbable sutures. Interposing perivesical fat was used as an additional layer, followed by closure of the vaginal wall. Defects in the urethra were closed in a horizontal fashion so as not to narrow the urethra lumen. After a single-layer closure using interrupted sutures, the periurethral fascia was repaired, and interposing tissue flaps was used at the discretion of the surgeon. The vaginal wall was closed using interrupted absorbable suture.

Outcomes

One hundred seventy-nine patients completed follow-up evaluation. Mean time from removal to follow-up was 2 years. The number of removal procedures performed at our institution increased over time and peaked in 2011. In 2005, a total of 9 removal procedures were performed, increasing to 68 procedures in 2011 and 49 procedures in 2012. At the time of postoperative assessment, 89 (50%) were 0 to 2 years after implant removal, 30 (17%) were 2 to 3 years, 26 (15%) were 3 to 4 years, 12 (7%) were 4 to 5 years, and 22 (12%) were 5 to 7 years after implant removal.

Patient UDI self-assessment questionnaires are reported as mean score (Fig. 1). Across all patients, there was a significant

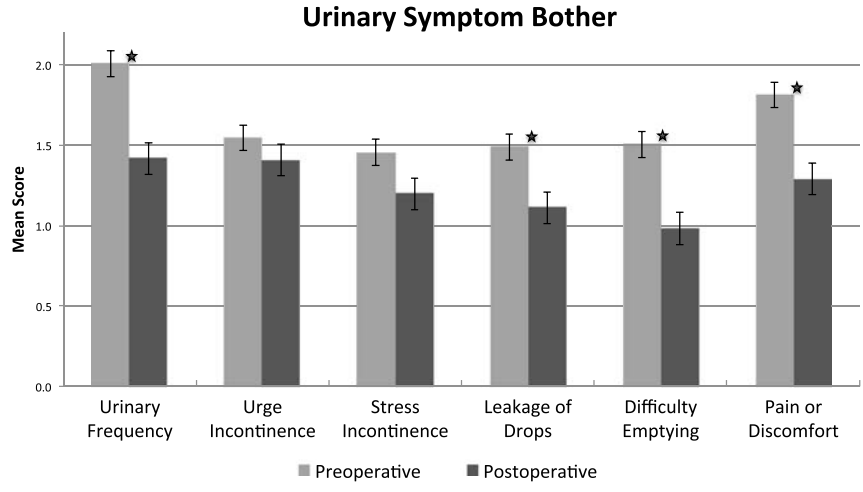

FIGURE 1. Urinary symptom improvement after implant removal, measured by the Urogenital Distress Inventory bother score (*$P < .05$).

TABLE 4. Quality of Life in Patients Presenting With Implant Complications and After Implant Removal

	Presenting Symptom			Implant Type		
Quality of Life	**All Patients**	**Pain**	**Multiple**	**POP**	**UI**	**POP and UI**
At presentation						
Delighted	4 (2)	3 (3)	2 (2)	0 (0)	1 (1)	3 (3)
Pleased	4 (2)	3 (3)	2 (2)	0 (0)	3 (4)	1 (1)
Mostly satisfied	12 (6)	7 (7)	6 (5)	4 (18)	3 (4)	5 (6)
Mixed	24 (12)	14 (14)	13 (11)	4 (18)	11 (13)	9 (10)
Mostly dissatisfied	20 (10)	10 (10)	14 (12)	1 (5)	10 (12)	9 (10)
Unhappy	36 (19)	19 (19)	22 (19)	2 (9)	11 (13)	23 (26)
Terrible	94 (48)	45 (45)	59 (50)	11 (50)	44 (53)	39 (44)
After removal						
Delighted	25 (15)	12 (15)	17 (18)	2 (11)	7 (10)	16 (19)
Pleased	26 (15)	8 (10)	17 (18)	1 (6)	9 (13)	16 (19)
Mostly satisfied	27 (16)	12 (15)	9 (9)	3 (17)	9 (13)	15 (18)
Mixed	23 (13)	11 (14)	12 (13)	4 (22)	13 (19)	6 (7)
Mostly dissatisfied	15 (9)	6 (8)	6 (6)	0 (0)	9 (13)	6 (7)
Unhappy	21 (12)	11 (14)	11 (12)	6 (33)	7 (10)	8 (10)
Terrible	34 (20)	20 (25)	23 (24)	2 (11)	15 (22)	17 (20)

Data are patients, n (%)

improvement in urinary frequency, leakage of small drops of urine, difficulty emptying, and pain or discomfort in the lower abdominal or genital area ($P < 0.05$). In patients who underwent removal of prolapse implants alone, there was no significant difference in preoperative and postoperative symptoms as measured by the UDI ($P > 0.05$). In patients who underwent removal of prolapse and sling implants, there was a significant improvement in urinary frequency, leakage of small drops, and difficulty in emptying ($P < 0.05$). Improvement was also seen in those who underwent removal of slings alone in urinary frequency, difficulty emptying, and pain or discomfort in the lower abdominal or genital area ($P < 0.05$).

Implant removal improved quality of life on self-assessment questionnaires (Table 4). When patients were asked to report on their overall quality of life due to implant-related pain symptoms before implant removal, 48% of the cohort described themselves as "terrible," which improved to 20% postoperatively, and this difference was statistically significant ($P < 0.05$). Similar trends were noted across subgroups and remained statistically significant for those who underwent removal of POP and UI implants, UI implants alone, and those who presented with pain as one of multiple symptoms ($P < 0.05$). Before implant removal, 10% responded positively regarding overall quality of life, 12% mixed, and 77% negatively which improved to 46%, 13%, and 44%, respectively, and similar trends were noted across all subgroups.

Overall, 80% of patients reported symptom improvement and 41% reported their improvement was greater than 90% as determined by patient questionnaires (Table 5). Similar trends were seen when patients were stratified by implant type. Nine percent reported no change in symptoms and 11% reported worsening symptoms, and these trends were similar across all subgroups.

Fifty-one patients (28% of respondents, 17% of cohort) underwent 1 or more additional treatments for pain symptoms after mesh removal. Twenty-one percent of respondents (12% of

TABLE 5. Symptom Improvement After Implant Removal

	Presenting Symptom			Implant Type		
Improvement	**All Patients**	**Pain**	**Multiple**	**POP**	**UI**	**POP and UI**
Symptoms						
Very much better	50 (29)	22 (27)	28 (29)	2 (11)	23 (32)	25 (30)
Much better	45 (26)	20 (25)	18 (19)	5 (26)	13 (18)	27 (33)
A little better	44 (25)	21 (26)	29 (30)	8 (42)	19 (26)	17 (20)
No change	15 (9)	7 (9)	11 (11)	2 (11)	9 (13)	4 (5)
A little worse	5 (3)	4 (5)	3 (3)	1 (5)	2 (3)	2 (2)
Much worse	7 (4)	3 (4)	4 (4)	0 (0)	2 (3)	5 (6)
Very much worse	8 (4)	4 (5)	3 (3)	1 (5)	4 (6)	3 (4)
Global sense						
Overall improved	141 (80)	64 (78)	77 (77)	15 (79)	58 (82)	68 (79)
> 90% improved	70 (41)	22 (29)	34 (36)	4 (24)	29 (41)	37 (46)
> 50% improved	123 (73)	49 (64)	60 (64)	10 (59)	49 (69)	64 (79)

Data are patients, n (%).

cohort) received additional medical therapy including narcotics, hormonal therapy, or antibiotics. Twenty-two percent of the respondents (13% of cohort) underwent additional surgery at ours and other institutions, and 6% of respondents (4% of cohort) reported other treatments including biofeedback, physical therapy, and acupuncture.

DISCUSSION

PRS is overall considered minimally invasive with a low complication rate. Complications are estimated to occur in 1% to 15% of augmented vaginal repairs,[17,18] and risk factors include smoking, lack of estrogen, use of prostheses for multiple compartments, and concomitant hysterectomy.[19] Preoperative pain and dyspareunia, urinary frequency and urgency are risk factors for postoperative experience of these symptoms[20,21] and synthetic implants alone have not been consistently shown to adversely affect sexual function.[22,23]

Pain is one of the more challenging surgical complications though the presentation and clinical implications vary greatly. Most patients do not suffer from pain but some do experience refractory pain, the etiology of which is unknown. Some suggest contributing factors, such as the active processes of tissue incorporation and implant shrinkage.[24,25] This is supported by our evidence that implant removal alone does not completely resolve pain symptoms and further surgery carries the risk of worsening pain. In contrast, treatment of other complications, such as implant exposure or urinary retention, can be more straightforward.[26]

Our findings demonstrate removal of prosthetic implants used in PRS improves related pain symptoms and can be compared to similar reports in the literature.[27] Tijdink and colleagues[8] reported over 90% symptom improvement in a series of 73 diverse patients who underwent surgical removal of a variety of different prostheses. Although these findings are relatively reassuring for physicians performing implant removal, other reports are less so. In a series of 54 patients who underwent POP implant removal over a 4-year period, Skala and colleagues[28] reported only 25% of patients were improved by implant removal alone. Many patients pursue nonsurgical treatments before discussing removal. Investigators at the Cleveland Clinic removed POP implants in 19 patients over a 2-year period and found 84% had been treated with medication and 16% with surgery before referral to their institution.[29] Similarly, surgical removal is not always the final treatment as reflected by our cohort. These findings highlight the unfortunate truth that complex complications sometimes require multiple treatments.

The decision to proceed with partial or complete excision is a difficult one, especially in patients whose POP and UI have been relieved. For this reason, we encourage careful patient selection, thorough counseling, and expectation management. Complete resolution of complication-related symptoms is rare and typically reported in cases where removal occurs early in the postoperative period.[30]

Many factors contribute to overall patient satisfaction after surgery. Symptomatic improvement after POP repair has been demonstrated despite high rates of complications in the same cohort,[31] and multiple trials have demonstrated subjective success is similar for augmented and nonaugmented repairs.[32] Quality of life is improved by the majority of women after any UI treatment.[33–35]

Strengths of this case series include those associated with academic referral centers including overall cohort size and patient diversity. Our findings may be generalized to other similar centers in the US performing prosthetic implant removal procedures. Utilization of validated questionnaires and quality of life measures also strengthen this study and may be incorporated into patient counseling. These data may be used to design future prospective studies on the impact of implant removal on symptoms and quality of life. However, there are also several limitations to this study. First, as this is a case series, patients who did not complete preoperative questionnaires did not have this data available for analysis. The study was not designed nor has sufficient power to evaluate the impact of prosthetic implant removal on pain compared to other medical interventions. Second, our center has seen an increase in referrals for complications requiring removal; however, we do not report on cases from other centers or done throughout the nation. Thus, we cannot form conclusions regarding the overall incidence of removal procedures. Third, clinical examination was documented without the use of a standard classification system. Although some have found standard systems useful in clinical practice, others have found it cumbersome and with poor interexaminer reliability.[36–38] We recognize that with the recent change in our practice to include an increasing number of patients with prosthetic implant-related complications, we ought to consider incorporating standard terminology into our clinical practice for future treatment and research. Lastly, we discovered that the standard questionnaires used on our urology-based practice may not be ideal for this patient population. The less than 1 point improvement seen in the UDI questionnaire scores postoperatively does not adequately reflect, in our opinion, the clinical improvement experienced by 80% of patients. However, this may reflect the fact that urinary symptoms are not the most bothersome of symptoms experienced by patients with implant-related complications. In our future practice, we ought to consider standardized questionnaires specifically focused on implant-related pain or overall health-related quality of life. Additionally, the questionnaire regarding overall symptom improvement addresses the same question as the Patient Global Impression of Improvement and results were similar, suggesting use of only one is necessary.

In conclusion, exposure and pain are among the most common symptoms reported in women referred to our institution for implant-related complications. In our cohort, the majority of women experienced improvement in related pain symptoms after implant removal. We demonstrated that in a series of 306 complex patients with a range of prostheses, symptoms, and time since insertion, removal improved symptoms in 80%, with 41% reporting over 90% improvement. However, although we were able to help nearly half of our cohort achieve satisfactory quality of life, some complications may not be surgically reversed. We suggest a multidisciplinary approach to patients with persistent symptoms that negatively impact their overall quality of life.

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