



Patients' satisfaction and safety of bulk injection therapy Urolastic for treatment of stress urinary incontinence: A cross-sectional study

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Abstract

Aims: Primary outcome was to evaluate patients' satisfaction after being treated with bulk injection therapy polydimethylsiloxane Urolastic (PDMS-U) for stress urinary incontinence (SUI). Secondary outcomes were: subjective cure, objective cure, severity of SUI symptoms, complications, reintervention rate, and disease-specific quality of life. Furthermore, to determine if outcomes worsened during time-after-treatment (time-frames: 0-12, 13-24, and ≥ 25 months).

Methods: In a cross-sectional design, patients treated with PDMS-U were recruited for hospital revisit. The primary outcome, patients' satisfaction, was assessed by the surgical satisfaction questionnaire. Subjective cure, objective cure, and severity of symptoms were assessed by the patients global impression of improvement, standardized cough stress test, and Sandvik severity scale, respectively. Medical charts and face-to-face interviews were used to determine complications and reinterventions.

Results: About 110 patients participated, 87 revisited the hospital. Median follow-up was 25 months (interquartile range: 14;35 months). Patients' satisfaction rate was 51%. Subjective and objective cure were respectively 46% and 47%. Most prevalent complications were: urinary retention (22%), pain (15%), and dyspareunia (15%). Exposure and erosion occurred in 7% and 5%, respectively. Reintervention rate of reinjection and excision of bulk material was 6% and 18.0%, respectively. Objective cure significantly worsened during time-after-treatment ($P < .05$).

Conclusions: About half of the patients being treated with PDMS-U were satisfied and subjectively cured 2 years after treatment, although the majority still experienced symptoms of SUI. Most complications were mild and transient, however, in 18% excision of bulk material was indicated for severe or persistent complications such as pain, exposure, or erosion.

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1 | INTRODUCTION

Symptoms of urinary incontinence (UI) are highly prevalent and can affect a patient's quality of life (QoL) severely.^{1,2} When involuntary urine leakage occurs during increased abdominal pressure such as coughing, sneezing, or physical exertion, it is defined as stress UI (SUI) which comprises about half of UI cases.³ Behavioral and pharmacological therapies, pelvic floor muscle exercises, vaginal devices (eg, pessary), and surgical options such as synthetic slings, colposuspension, autologous sling surgery, and bulking agents cover the treatment options for female SUI. Consensus statement of the European Urology Association and the European Urogynaecological Association conclude that synthetic slings have a good efficacy and acceptable morbidity, but alternative options must be considered.⁴

Urethral bulk injection therapy is an alternative noninvasive, ambulatory treatment that involves injecting a bulk material transurethral or periurethral, with or without urethroscopic view, in the mucosa of the urethra between the mid-urethra and bladder neck. The injected material gives resistance to the urine flow and thereby aims to prevent leakage of urine, although it is hypothesized that mid-urethral support is needed for the closure mechanism of the urethra as well.⁵ To date, randomized controlled trials comparing bulk injection therapy with other surgical options show significant lower objective cure rates regarding urethral bulk injection therapy.^{6,7} Periurethral injection therapy polydimethylsiloxane Urolastic (PDMS-U) (Urogyn BV Nijmegen, The Netherlands) is one of the latest developed bulking agents and consists of a smooth, non-degradable biocompatible polymer texture. This unique character implies that the bulk material is not absorbed by the body and will stay positioned over time. Using a disposable injecting device, four depots of 0.8 to 1.0 cc are injected periurethral at 2, 5, 7, and 10 O'clock at the mid-urethral level, without cystoscopic control.

From 2011, multiple hospitals have included PDMS-U a standard treatment option for patients with SUI or mixed urinary incontinence (MUI). Objective and subjective success rates at 6 to 12 months follow-up varied from 59% to 89% and 35% to 90%, respectively.⁸⁻¹⁰ At 2 years follow-up, objective cure rates of 33% to 66% were reported.^{11,12} Although the variety of used study outcomes, patient selection and the learning curve of the physician may have contributed to the wide range, the reported objective cure rate seemed to worsen with longer follow-up. Efficacy rates are in line with bulking agents "Macroplastique" and "Bulkamid" showing subjective success rates of 66% to 90% at 12 months follow-up and objective success rates of 25% to 73%.¹³ Safety studies

show that patients treated with PDMS-U, compared with other bulking agents, were more likely to be indicated for excision of the bulk material due to complications like exposure or pain.¹⁴

As there are no studies that investigated the patients' satisfaction or safety after 2 years follow-up, we have set up this cross-sectional study in a population of patients that have been treated with PDMS-U from 2014 up to 2018 through standard care. In this retrospective case series our primary aim was to determine patients' satisfaction. Other outcomes were: subjective cure, objective cure, severity of SUI symptoms, complications and reinterventions, and disease-specific QoL. Second, we aimed to determine if outcomes would worsen during time-after-treatment, following the time frames: 0 to 12 months, 13 to 24 months, and more than 25 months after treatment.

2 | MATERIALS AND METHODS

A multicenter, cross-sectional study was performed in four experienced centers. Site specific information is shown in Appendix 1. To evaluate the influence of a learning curve, only centers that had performed more than 20 PDMS-U procedures were considered to be eligible. The study was reviewed and approved by the ethical committee of all participating centers.

The study population consisted of patients who had been treated with PDMS-U as part of standard care. Women more than or equal to 18 years who received PDMS-U as primary treatment for SUI, secondary for recurrent SUI, or MUI were found eligible. Patients were excluded if they had received PDMS-U for neurogenic bladder, participated in clinical studies or were incapable of giving informed consent.

2.1 | Enrollment

Patients were informed about the study by a patient information leaflet. Patients who were willing to participate were asked to revisit the hospital. Written informed consent was obtained for subjects on the day of the revisit. Patients who declined participation could give consent to share information from their medical chart by means of an additional informed consent form.

2.2 | Study procedure

All patients were asked to revisit the hospital where they had been treated. A paper questionnaire was used to

obtain patients characteristics and determine the severity and impact of UI symptoms, complications, and re-interventions. In case patients were unable to revisit the hospital, a paper questionnaire was sent to their homes. Patient characteristics, complications, and reinterventions were retracted from the medical charts. Patients who revisited the hospital underwent a face-to-face interview with an independent investigator at the hospital to obtain more information on complications. Physical examination was performed to detect possible exposure of the bulk material and assess the objective cure by means of a standardized cough stress test (CST). Physical examination was performed by the treating doctor, but in presence of an independent investigator, to limit bias.

2.3 | Outcomes

The primary outcome was patients' satisfaction which was determined by three questions from the validated surgical satisfaction questionnaire (SSQ-8)¹⁵: "How satisfied are you with the results for your surgery?," "Looking back, if you had to do it all over again, would you have the surgery again?," and "Would you recommend this surgery to someone else?." Answers of the SSQ questions consisted of a 5-point Likert scale ranging from "very satisfied" to "very unsatisfied" or from "yes" to "never." Patients' satisfaction was defined if answers corresponded with "very satisfied" and "satisfied" or "yes" and "maybe."

Secondary outcomes were: subjective cure, objective cure, severity of SUI symptoms, complications and re-interventions, and disease-specific QoL. Subjective cure was assessed by the patients global impression of improvement (PGI-I).¹⁶ The PGI-I is a validated question to determine the patients improvement of symptoms compared with how it was before the treatment. Answers ranges from "very much better" to "very much worse." We defined patients "subjectively cured" if answers corresponded with: "very much better" or "much better." Objective cure was defined as a negative standardized CST. The CST was performed in lithotomy position with a minimum of 250 mL in the bladder. The Sandvik severity

scale (two questions that corresponds with the amount and frequency of UI) and patients global impression of severity (PGI-S) were used to assess the severity of SUI symptoms.^{6,17} Complications were determined by a face-to-face interview and from medical charts. Urinary tract infections (UTI) within 6 weeks after treatment were scored as a complication. Reintervention was defined as any surgical intervention after bulk injection therapy Urolastic to treat recurrent, persistent SUI symptoms or complications. This implied: reinjection of Urolastic, excision of bulk material, suburethral sling surgery or other (surgical) treatments for SUI. The following disease-specific QoL questionnaires were used: International Consultation on Incontinence Questionnaire (ICIQ-short form),¹⁸ Incontinence Impact Questionnaire short form (IIQ-7), and Urogenital Distress Inventory short form (UDI-6).¹⁹

Patients' satisfaction, subjective cure and objective cure were presented as the time-after-treatment, according to the following time frames: 0 to 12 months, 13 to 24 months, and ≥ 25 months posttreatment.

2.4 | Statistical analysis

Demographic and baseline characteristics were summarized using standard descriptive methods. Nominal and ordinal data were described using frequencies and percentages. Normally distributed continuous data were described using mean and standard deviation. All used questionnaires were calculated as proposed by the composers. χ^2 and Mann-Whitney U were used for categorical data and linear data, respectively. A $P < .05$ was considered statistically significant. Statistical analysis has been performed using IBM SPSS Statistics 24.

3 | RESULTS

Eligible patients treated between May 2014 and July 2018 were invited to participate. Figure 1 presents the flowchart of the enrollment. Table 1 shows the patient's and

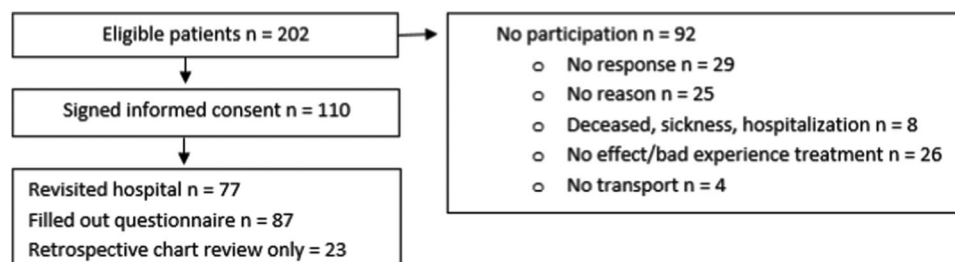


FIGURE 1 Flowchart patient recruitment

TABLE 1 Patient and procedural characteristics

	Total 110	
	N	%
Age mean (SD)	64 (13)	
BMI mean (SD)	27 (5)	
Parity median (IQR)	2 (2-3)	
Smoker at time of procedure	12	11
Postmenopausal status	90	82
Type of urinary incontinence		
Stress urinary incontinence	51	46
Mixed urinary incontinence	59	59
Recurrent urinary tract infections		
Yes	24	22
No	58	53
Unknown	26	24
Preoperative pad use per day mean (SD)	3 (2)	
Sexually active	59	54
Previous treatment for SUI ^a		
No treatment	23	21
Pelvic floor muscle therapy	45	41
Suburethral sling surgery (≥ 1)	29	26
Injection therapy bulking agent	5	5
Burch colposuspension	3	3
Other ^b	10	9
Unknown	2	2
Indication for Urolastic treatment		
Preference patient/physician	67	61
After failed surgery	42	38
Contra-indication anesthesia	1	1
Amount (cc) of injected bulk material per location in median (range)		
2 O'clock	1 (0.4-1.2)	
5 O'clock	1 (0.0-1.2)	
7 O'clock	1 (0.0-1.2)	
10 O'clock	0.8 (0.0-1.2)	
	N = 87	
Time-after-treatment median (IQR)	25 (14;35)	
0-12 mo	18	21
13-24 mo	25	29
>24 mo	44	51
Frequency of urinary incontinence before Urolastic treatment		
Less than one time a month	2	2
Once or a few times a week	16	18
Every day/night	68	78

TABLE 1 (Continued)

	N = 87	
Amount of urinary incontinence before Urolastic treatment		
Droplets	10	11
More than droplets	76	87

Abbreviations: BMI, body mass index; IQR, interquartile range; SD, standard deviation; SUI, stress urinary incontinence.

^aTotal number is n = 119, due to the fact that some patients have had multiple therapies.

^bOther: Anterior colporrhaphy (n = 4), laser (n = 2), myoblasts injection (n = 2), pessary (n = 1), and estrogen (n = 1).

procedural characteristics of the 110 patients and symptom scores based on completed questionnaires (n = 87). The mean age was 64 years. The median time-after-treatment for hospital revisit was 25 months (interquartile range: 14;35 months, range, 1-58 months). Appendix 1 shows overall outcomes and outcomes per study site.

3.1 | Patients' satisfaction and subjective cure

Patients' satisfaction was 51%. Sixty-two percent of the patients would have PDMS-U again and 69% would have recommended PDMS-U to someone else. The subjective cure was 46%. Subjective outcomes following time-after-treatment time frames did not significantly differ (Figure 2).

3.2 | Objective cure

The CST was examined in 74 patients and overall 47% (n = 35) were objectively cured. The objective cure decreased significantly following the time-frames 0 to 12, 13 to 24, and more than or equal to 25 months: 77%, 56%, and 35% ($P = .02$).

3.3 | Severity of SUI symptoms

Overall 85% (n = 74) still experienced symptoms of SUI after PDMS-U treatment; 53% experienced SUI symptoms every day/night and 49% experienced urine leakage "more than droplets." Incontinence material for SUI symptoms after PDMS-U was used in 47%.

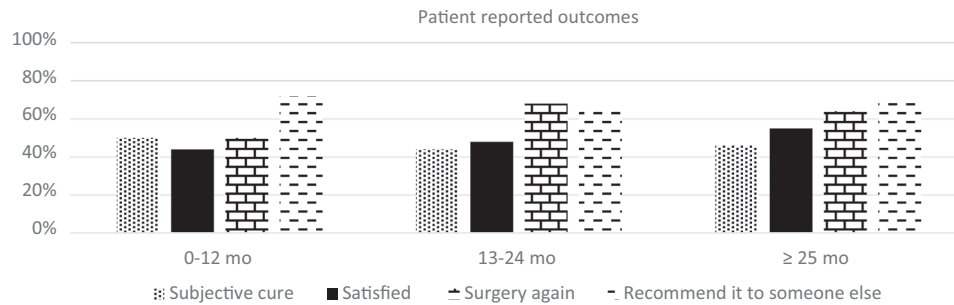


FIGURE 2 Patients' satisfaction and subjective cure following time-after-treatment. Subjective cure is defined as: answers corresponding to “very much better” or “much better” on the Patient Global Impression of Improvement. Satisfied is defined as: answers corresponding to “very satisfied” or “satisfied” on the surgical satisfaction questionnaire (SSQ-8). Surgery again is defined as: answers corresponding to “yes” and “maybe (probably yes)” on the SSQ-8. Recommend it to someone else is defined as: answers corresponding to “yes” and “maybe (probably yes)” on the SSQ-8

Forty-six percent ($n = 40$) found the remaining form of UI acceptable, while 17% ($n = 15$) scored their symptoms of SUI “severe” on the PGI-S.

3.4 | Complications and reinterventions

Perprocedural complications did not occur. Table 2 represents the postprocedural complications and reinterventions. Overall, 60% ($n = 66$) encountered postoperative complications. Most prevalent complications were: urinary retention (22%), pain (15%), dyspareunia (15%), and experience of an uncomfortable hard feeling in the vagina (15%). Urinary retention was treated with a catheter-a-demeure or clean intermittent catheterization for a median duration of 4 days. One patient needed excision of the bulk material, 7 days after the procedure to resolve the retention. Eight patients had exposure of bulk material through the vaginal wall. Seven patients were treated with excision of bulk material, in one patient the treatment of the exposure was unknown. None of the patients with exposure showed signs of infection. Hair-like strands of bulk material coming out of the injection site was observed in 13 patients (noticed mostly during the revisit), however, this adverse event was not counted as a complication, as this was a common part of the procedure and did not need any further treatment or were easily removed by tweezers. Erosion of the bulk material to the urethra ($n = 2$), to the bladder ($n = 2$), or elsewhere under vaginal wall ($n = 2$) occurred in six patients. Urethral erosion caused local pain, but could easily be removed by urethroscope. Patients with bladder erosion complained of pain, recurrent UTI's or hematuria. Both patients were free of complaints after removal of the bulk material by cystoscopic approach. Patients with erosion under the vaginal wall showed a thin

epithelial layer and were treated with local estrogen, later excision of the bulk material was still indicated. One patient had a small vaginal abscess 4 days after Urolastic treatment which was treated with antibiotics, followed by excision 2 months later. Other complications were: UTI ($n = 8$), urgency de novo ($n = 7$), spontaneous loss of bulk material ($n = 3$), hematoma ($n = 1$), and hematuria ($n = 1$).

Prevalence of reintervention including reinjection, excision, or other reinterventions was 33% ($n = 36$). Reinjection of PDMS-U was done in seven patients (6%). Median time-after-treatment of reinjection was 4 months (range: 0 days to 18 months). In three patients the reinjection was performed directly after the initial procedure. Five of the seven patients that had undergone reinjection revisited the hospital. At the study visit, four out of five were not subjective and objectively cured and all five patients were unsatisfied with the results. Excision of bulk material was indicated in 18% ($n = 20$). Median time-after-treatment to excision was 10 months (range: 7 days to 26 months). Reasons for excision were: pain other than dyspareunia ($n = 9$), exposure ($n = 7$), erosion ($n = 6$), persistent SUI ($n = 3$), dyspareunia ($n = 2$), recurrent UTI ($n = 1$), and urinary retention ($n = 1$). Forty-five percent ($n = 9$) of the excisions were done under local analgesia and 55% ($n = 11$) were done under general or spinal anesthesia.

3.5 | Quality of life

Table 3 shows the scores of disease-specific QoL questionnaires related to the PGI-I. A significant better QoL of UDI-6, IIQ-7, and ICIQ-SF was found in patients with improved symptoms ($P < .01$).

TABLE 2 Complications and reinterventions

Adverse events	Total 110	
	N	%
Urinary retention	24	21.8
CAD for <48 h	7	29.2
CAD for ≥48 h	13	54.2
Unknown	3	12.5
Pain ^a	16	14.5
Dyspareunia	16	14.5
Uncomfortable hard feeling vagina ^b	16	14.5
Urinary tract infection	10	9.1
Exposure (through vaginal wall)	8	7.3
Urgency incontinence de novo	7	6.4
Erosion (through urethra or bladder)	6	5.4
Spontaneous loss bulk material	3	2.7
Infection at injection site	1	0.9
Hematuria	1	0.9
Hematoma at injection site	1	0.9
Reinterventions		
Excision of Urolastic	20	18.1
2 O'clock location	4	20
5 O'clock location	8	40
7 O'clock location	11	55
10 O'clock location	5	25
Unknown location	1	0.5
Other location ^c	5	25
Reinjection	7	6.3
MUS-operation after Urolastic treatment	6	5.5
Other reintervention ^d	3	2.7

Note: Overview of complications and reinterventions.

^aPain urogenital area >2 wk after treatment, other than dyspareunia.

^bAn uncomfortable feeling of the presence of bulk material during daily activities without pain.

^cOther location of excision: bladder (n = 2), para-urethral left (n = 2), para-urethral left, and right (n = 1).

^dRectus fascia sling (n = 1), PFMT (n = 1), and excision hematoma (n = 1). Abbreviations: CAD, catheter a demeure; MUS, mid-urethral sling; PFMT, pelvic floor muscle training

3.6 | Subgroup analysis

Appendix 2, an overview of subgroup analysis on patient characteristics, showed that clinical success and satisfaction was not influenced by patient's age or body mass index. Patients who have had previous surgery before PDMS-U were more likely to be objectively cured compared with patients with no prior or only conservative

treatment (61% vs 37%; $P = .04$). Patients undergoing PDMS-U as secondary intervention did not encounter more complications (61% vs 58%; $P = .686$). Regarding the physicians learning curve, patients of the first 20 procedures were more likely to be satisfied compared with the patients more than 20 procedures (75% vs 41%; $P = < .01$). No statistically significant differences were found regarding the procedure number and complication rate (66% vs 57% $P = .403$), nor for subjective cure or objective cure. Analysis on site dependent outcomes showed that only site 2 had higher objective cure rates compared with site 3 (odds ratio, 8.69; $P < .01$).

4 | DISCUSSION

In this study, we primarily evaluated the patients' satisfaction being treated with PDMS-U for SUI. Second, we assessed the subjective cure, objective cure, severity of symptoms, complications, and reintervention rate and disease-specific QoL. Although 85% of the patients still experienced symptoms of SUI after a median period of 25 months, 51% were satisfied with the results and 69% would recommend the treatment to someone else. The patients' satisfaction and subjective cure remained stable during time-after-treatment up to more than or equal to 25 months, whereas objective cure significantly worsened over time. Although reinjection of PDMS-U is a common option to improve outcomes, this was only done in 6% and the outcomes did not improve. Urinary retention, pain, and dyspareunia were the most prevalent complications. Excision of bulk material to treat severe or persistent complications such as pain, exposure or erosion was indicated in 18%.

Our study shows that almost half of the patients were satisfied after PDMS-U, 34% were not. The high number of SUI symptoms after treatment (85%), relative high chance to encounter complications (60%), and undergo a reintervention (33%) can contribute to dissatisfaction. The results on subjective and objective cure are comparable with other studies regarding PDMS-U. Kowalik et al⁸ included patients with complicated SUI with a poor expected outcome and reported an equal subjective cure rate of 50% at 6 months follow-up. Another study performed a telephonic survey among patients treated with Urolastic for regular care in a general hospital and tertiary referral hospital. The subjective cure of the general hospital with a median follow-up time of 12 months was higher (61% vs 50%), but the subjective cure of the tertiary referral hospital after a median follow-up of 25 months was similar (43% vs 46%).²⁰ The objective cure, also assessed by the CST, showed a similar decreasing trend corresponding with time-after-treatment of 6 months, 12 months, and 24 months follow-up (65%, 59%, and 33%).^{8,9,12} In conclusion,

TABLE 3 Disease-specific quality of life

	Improved	Similar	Worsened	P-value
UDI-6 total <i>mean</i> (SD)	29.2 ± 18.7	44.1 ± 17.7	52.3 ± 25.1	<.01
Irritative subscale	31.1 ± 28.5	46.0 ± 26.8	60.3 ± 30.1	<.01
Stress subscale	38.8 ± 26.6	54.9 ± 27.5	65.3 ± 29.7	<.01
Obstructive subscale	18.3 ± 19.1	31.4 ± 35.3	37.2 ± 28.8	.17
IIQ-7 total <i>mean</i> (SD)	22.6 ± 22.1	40.1 ± 29.0	47.9 ± 29.9	<.01
Physical activity	23.9 ± 22.8	35.4 ± 34.9	50.0 ± 31.8	.03
Mobility	22.1 ± 26.1	39.6 ± 35.9	46.2 ± 36.1	.03
Social function	25.2 ± 31.9	41.2 ± 38.2	53.8 ± 34.8	.02
Emotional health	18.6 ± 23.5	39.2 ± 38.6	53.8 ± 32.7	<.01
ICIQ-SF total <i>mean</i> (SD)	9.2 ± 4.5	15.4 ± 4.2	15.9 ± 4.9	<.01

Disease-specific quality of life related to improved, similar or worsened outcome on the Patient Global Impression of Improvement (PGI-I) scale.

Abbreviations: ICIQ-SF, International Consultation on Incontinence Questionnaire Short Form; IIQ-7, Incontinence Impact Questionnaire; SD, standard deviation; UDI-6, Urogenital Distress Inventory.

patients can be satisfied while having persistent symptoms of SUI.

Bulk injection therapy is known for the attractive safety profile, with having less complications as compared with open surgery.^{6,7} Complications occur in one out of three patients and are mostly transient without requiring surgical treatment.²¹ Our study shows a higher risk of complications (60% vs 24%) and higher number of reinterventions (18% vs 11%) compared with PDMS-U outcomes reported in a systematic review.¹⁴ This could be due to the fact that the follow-up in our study was longer so the chance on a complication was higher. To improve the acceptance of PDMS-U for patients, future studies can look into options to lower the number of operative reinterventions, for example, inject a lower amount bulk material, determine the ideal position of the bulk material, and if necessary adapt the injection device to achieve this. For example, although we reported patients with “erosion,” it is not certain whether migration of the bulk material resulted in erosion or that the bulk material was initially injected too superficial under the epithelial layer or in the urethra or bladder.

In this study, we have evaluated the learning curve of the physician. Subgroup analysis remarkably showed that patients of procedure number 0 to 20 were more satisfied with results than patients of procedure number more than 20, while objective cure or complication rate did not differ. Because in general physicians learn a procedure, beginning with the most complicated patients that already have undergone multiple treatments, it could be that these patients were more easily satisfied.

This study has several limitations. First, inherent to the nature of a cross-sectional design, some patients were not willing to participate or did not respond. Hence, it is uncertain whether our findings are representative for the whole population of women indicated for a bulking agent. Second,

lack of preoperative data is a major limitation that could have affected the interpretation of outcomes. Missing information on micturition status or inaccurate recall by the patient made it uncertain to what extent symptoms have improved. Third, the retrospective data collection from medical charts could be insufficient, especially complications may have been underreported. Fourth, one should be careful to interpret the outcomes of the objective cure, because the baseline measurements were not available. Finally, one could argue that validated questionnaires such as the ICIQ-SF have no additional value when assessed only after surgery. However, a strong correlation between PGI-I and ICIQ-SF as well as validation of a cutoff score of the ICIQ-SF postoperatively have been reported.²²

The European Union medical device regulation has set several goals regarding legislation, among other to strengthening postmarketing surveillance and risk evaluation.²³ PDMS-U has been in the market for several years and although cohort studies have been performed, no study has evaluated this product for over 2 years follow-up, like we did. This is the first study that also evaluated patients' satisfaction and long-term safety assessment of PDMS-U. As we obtained data from standard care, the results are generalizable and useful to counsel patients about satisfaction and safety of SUI treatment with PDMS-U.

5 | CONCLUSIONS

About half of the patients being treated with PDMS-U were satisfied and subjectively cured 2 years after treatment, although the majority still experienced symptoms of SUI. Most complications were mild and transient, however, in 18% excision bulk material was indicated for severe or persistent complications such as pain, exposure, or erosion.

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APPENDIX 1

TABLE A1 Overview outcomes per site

	Overall	Site 1	Site 2	Site 3	Site 4
Patient characteristics					
Eligible patients	202	65	64	57	16
Included patients	110	25	36	40	9
Filled out questionnaire	87	25	36	24	2
Age mean (SD)	64 ± 13	61 ± 10.6	64 ± 12	63 ± 14.4	77.4 ± 6.3
No surgery before PDMS-U n (%)	70 (64)	11 (44)	10 (27.8)	37 (92.5)	9 (100)
With surgery before PDMS-U n (%)	40 (36)	14 (56)	26 (69.4)	3 (7.5)	0 (0)
Mixed urinary incontinence n (%)	59 (54)	10 (0.4)	22 (61.1)	19 (47.5)	8 (88.9)
Procedural characteristics					
Amount (cc) of injected bulk material per location in median (range)					
2 O'clock	1.0 (0.4-1.2)	0.8 (0.6-0.8)	1.0 (0.8-1.2)	1.0 (0.4-1.0)	1.0 (0.8-1.0)
5 O'clock	1.0 (0.0-1.2)	1.0 (0.8-1.2)	1.0 (0.0-1.2)	0.8 (0.4-1.0)	1.0 (0.8-1.0)
7 O'clock	1.0 (0.0-1.2)	1.0 (0.8-1.2)	1.0 (0.0-1.2)	0.8 (0.4-1.0)	1.0 (0.0-1.0)
10 O'clock	0.8 (0.0-1.2)	0.8 (0.6-0.8)	1.0 (0.8-1.2)	1.0 (0.4-1.0)	0.8 (0.0-1.0)
Time-after-treatment median (IQR)	25 (14;35)	34 (25;38)	13 (7;18)	33 (28;40)	31 (34;-)
0-12 mo n (%)	21 (18)	0 (0)	17 (47)	1 (4.2)	0 (0)
13-24 mo n (%)	29 (25)	4 (16)	19 (53)	2 (8.3)	0 (0)
>24 mo n (%)	51 (44)	21 (84)	0 (0)	21 (87.5)	2 (100)
Site and physician characteristics					
Type of hospital		Academic hospital	General hospital	General hospital	Teaching hospital
Profession physician		Gynecologist	Urologist	Urologist	Urologist
Total performed Urolastic procedures		67	67	57	23
Outcomes					
SSQ-8: "How satisfied are you with the results for your surgery?" n (%)					
Very satisfied	22 (25.3)	6 (24)	10 (27.7)	5 (20.8)	1 (50)
Satisfied	22 (25.3)	4 (16)	10 (27.7)	8 (33.3)	0 (0)
Neutral	13 (14.9)	3 (12)	7 (19.4)	3 (12.5)	0 (0)
Unsatisfied	24 (27.6)	9 (36)	8 (22.2)	6 (25)	1 (50)
Very unsatisfied	6 (6.9)	3 (12)	1 (2.7)	2 (8.3)	0 (0)
Satisfaction rate n (%)	44 (51)	10 (40)	20 (55.6)	13 (54.2)	1 (50)
SSQ-8: "Looking back, if you had to do it all over again, would you have the surgery again?" n (%)					
Yes	46 (52.9)	12 (48)	22 (61.1)	11 (45.8)	1 (50)
Maybe	8 (9.2)	1 (4)	2 (5.5)	5 (20.8)	0 (0)
Unsure	8 (9.2)	1 (4)	5 (13.8)	2 (8.3)	0 (0)
I don't think so	15 (17.2)	5 (20)	6 (16.6)	3 (12.5)	1 (50)
Never	10 (11.5)	6 (24)	1 (2.7)	3 (12.5)	0 (0)
SSQ-8: "Would you recommend this surgery to someone else?" n (%)					
Yes	51 (58.6)	11 (44)	23 (63.8)	16 (66.7)	1 (50)
Maybe	9 (10.3)	2 (8)	4 (11.1)	3 (12.5)	0 (0)
Unsure	13 (14.9)	6 (24)	6 (16.6)	1 (4.1)	0 (0)
I don't think so	8 (9.2)	3 (12)	2 (5.5)	2 (8.3)	1 (50)
Never	6 (6.9)	3 (12)	1 (2.7)	2 (8.3)	0 (0)

(Continues)

TABLE A1 (Continued)

	Overall	Site 1	Site 2	Site 3	Site 4
Patient global impression of improvement (PGI-I) n (%)					
Very much better	22 (25.3)	4 (16)	12 (33.3)	6 (25)	0 (0)
Much better	18 (20.7)	3 (12)	8 (22.2)	6 (25)	1 (50)
A little better	17 (19.5)	5 (20)	6 (16.6)	6 (25)	0 (0)
No change	17 (19.5)	7 (28)	7 (19.4)	3 (12.5)	0 (0)
A little worse	3 (3.4)	1 (4)	1 (2.8)	0 (0)	1 (50)
Much worse	6 (6.9)	3 (12)	2 (5.5)	1 (4.2)	0 (0)
Very much worse	4 (4.6)	2 (8)	0 (0)	2 (8.3)	0 (0)
Subjective cure n (%)	40 (46)	7 (28)	20 (55.6)	12 (50)	1 (50)
Still have symptoms of stress urinary incontinence (%)	74 (85)	24 (96)	30 (83)	18 (74)	2 (100)
Sandvik severity scale: frequency of urinary incontinence n (%)					
Less than one time a month	4 (4.6)	1 (4)	3 (8.3)	0 (0)	0 (0)
Once or a few times a month	11 (12.6)	5 (20)	4 (11.1)	2 (8.3)	0 (0)
Once or a few times a week	15 (17.2)	6 (24)	5 (13.8)	4 (16.7)	0 (0)
Every day/night	46 (52.9)	13 (52)	20 (55.5)	11 (45.8)	2
Amount of urinary incontinence n (%)					
Droplets	32 (36.8)	13 (52)	13 (36.1)	6 (25)	0 (0)
More than droplets	43 (49.4)	12 (48)	17 (47.2)	12 (50)	2 (100)
Patient global impression of severity (PGI-S) n (%)					
Not applicable, I don't have voiding problems		0 (0)	13 (36.1)	1 (4.2)	0 (0)
Normal	5 (5.7)	9 (36)	3 (8.3)	11 (45.8)	1 (50)
Mild	24 (27.6)	11 (44)	12 (33.3)	5 (20.8)	1 (50)
Moderate	29 (33.3)	4 (16)	7 (19.4)	4 (16.7)	0 (0)
Severe	15 (17.2)	1 (4)	1 (2.7)	3 (12.5)	0 (0)
Objective cure n (%)	35/74 (47.3)	8/25 (32)	19/24 (79.2)	7/23 (30.4)	1/2 (50)
Complications and reinterventions n (%)					
Urinary retention	24 (21.8)	1 (4)	10 (27.7)	8 (20)	5 (56)
Pain	16 (14.5)	5 (20)	3 (8.3)	4 (10)	4 (44)
Dyspareunia	16 (14.5)	7 (28)	4 (11.1)	5 (12.5)	0 (0)
Uncomfortable hard feeling	16 (14.5)	5 (20)	5 (13.8)	4 (10)	2 (22)
Urinary tract infection	10 (9.1)	0 (0)	6 (16.6)	2 (5)	2 (22)
Urgency de novo	7 (6.4)	3 (12)	0 (0)	4 (10)	0 (0)
Exposure	8 (7.3)	2 (8)	3 (8.3)	1 (2.5)	2 (22)
Erosion	6 (5.4)	2 (8)	0 (0)	2 (5)	2 (22)
Reinjection	7 (6.3)	1 (4)	0 (0)	3 (7.5)	3 (33)
Excision	20 (18.1)	6 (24)	4 (11.1)	6 (15)	4 (44)
ICIQ-SF-score mean (SD)	11.5 ± 5.4	12.9 ± 5.2	10.6 ± 5.6	11.1 ± 5.6	13 ± 2.8
IIQ-SF-score mean (SD)	30.0 ± 26.6	39.0 ± 29.7	25.0 ± 23.5	25.9 ± 26.5	37.5 ± 11.8
UDI-SF-score mean (SD)	35.7 ± 21.4	43.3 ± 22.8	31.3 ± 18.9	32.4 ± 21.1	47.2 ± 27.5

Note: Total overview of outcomes per study site: patients' satisfaction, PGI-I, Sandvik severity scale, PGI-S, objective cure, complications, reinterventions, and quality of life.

Abbreviations: ICIQ, International Consultation on Incontinence Questionnaire Short Form; IIQ, Incontinence Impact Questionnaire Short Form; IQR, interquartile range; PDMS-U, polydimethylsiloxane-Urolastic; PGI-I, patients global impression of improvement; PGI-S, patients global impression of severity; SD, standard deviation; SSQ-8, Surgical Satisfaction Questionnaire; UDI, Urogenital Distress Inventory Short Form.

APPENDIX 2

TABLE A2 Subgroup analysis

	Objective cure		Subjective cure	Satisfied
Subanalysis for patient characteristics				
Age, continuous ^a		0.34		0.11
Age (median, IQR)	66.0 (60.0-74.0)		64.0 (56.8-70.8)	66.5 (59.5-72.0)
Age, categorical (p) ^b		0.12		0.29
Lowest-50 (n,%) ^c	3 (33.3)		5 (38.5)	4 (38.8)
50-75 (n,%) ^c	25 (44.6)		31 (38.4)	34 (39.1)
>75-highest (n,%) ^c	7 (77.8)		4 (40.0)	6 (60.0)
BMI, continuous ^a		0.51		0.71
BMI (median, IQR)	26.9 (24.2-29.4)		26.5 (24.4-30.1)	27.2 (24.4-30.1)
BMI, categorical (p) ^b		0.53		0.59
0-25 (n,%) ^c	11 (52.4)		27 (45.8)	12 (46.2)
>25 (n,%) ^c	23 (44.2)			31 (52.5)
MUI vs SUI (p) ^b		0.80		0.59
MUI (n,%) ^c	19 (48.7)		20 (48.8)	22 (47.8)
SUI (n,%) ^c	16 (45.7)			22 (53.7)
No surgery before PDMS-U vs with surgery before PDMS-U (p) ^b		0.04		0.27
No surgery before PDMS-U (n,%) ^c	16(37.2)		20 (40.8)	23 (46.9)
With surgery before PDMS-U (n,%) ^c	19 (61.3)		20 (52.6)	21 (55.3)
Subanalyses for procedural characteristics				
Procedure 1-20 vs >20 (p) ^b		0.42		0.06
1-20 (n,%) ^c	12 (54.5)		15 (62.5)	18 (75)
>20 (n,%) ^c	23 (44.2)		25 (39.7)	26 (41.3)
Subanalyses per center				
Center (p) ^b		<0.01		0.19
1 ^d (n,%) ^c	8 (32)		7 (28)	10 (40)
2 ^e (n,%) ^c	19 (79.2)		20 (55.6)	20 (55.6)
3 ^f (n,%) ^c	7 (30.4)		12 (50)	13 (54.2)
4 ^g (n,%) ^c	1 (50)		1 (50)	1 (50)

Note: Total overview of outcomes per study site: objective cure, subjective cure, and satisfaction.

Abbreviations: BMI, body mass index; IQR, interquartile range; MUI, mixed urinary incontinence; PDMS-U, polydimethylsiloxane-Urolastic; SUI; stress urinary incontinence.

^aMann-Whitney U.

^b χ^2 .

^cPercentages presented as within categorical group.

^dSite 1: Academic hospital.

^eSite 2: General hospital.

^fSite 3: General hospital.

^gSite 4: Teaching hospital.