The Light-weight Mid-urethral Sling Implant for Female Stress Urinary Incontinence Treatment: A One-Year Postoperative Follow-up Study

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ABSTRACT **Background:** Serasis® (Serag-Wiessner KG, Naila, Germany) is a light-weight mid-urethral sling for treating stress urinary incontinence (SUI). Its insertion is considered less traumatic than other mid-urethral slings.

Objectives: To define postoperative outcomes following Serasis implantation. To compare the efficacy and complication rates of the implant to those of other common techniques.

Methods: Our retrospective study evaluated patients who underwent Serasis mid-urethral sling surgery for SUI. Data were collected from medical records prior to and at the time of surgery and by telephonic interview for postoperative pain and complications. Follow-up of patients was performed for up to one year postoperatively. Patients rated pain or discomfort according to the Visual Analogue Scale (VAS). The primary outcome was the development of early postoperative pain during the first month after surgery. Secondary outcomes were relief of SUI symptoms, groin pain or discomfort, and other postoperative complications up to 12 months after surgery.

Results: The study cohort included 50 consecutive patients aged 31 to 68 years. All patients underwent Serasis implantation procedures by a single surgeon and completed interviews. In total, 35 patients underwent concomitant anterior colporrhaphy. In the immediate postoperative period and at one month after the procedure, complaints were mild. No complaints were recorded during the 12-month follow-up period. Overall, 90% and 92% of the patients were free of SUI symptoms at one month and 12 months after surgery, respectively.

Conclusions: Serasis mid-urethral sling is safe, effective, and associated with mild postoperative pain and a low incidence of complications.

IMAJ 2023; 25: 52–58

KEY WORDS: light weight mid-urethral tape (Serasis®), postoperative pain, quality of life, stress urinary incontinence (SUI)

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Stress urinary incontinence (SUI) is the most common type of incontinence disorder in women. It can affect 25–45% of all women, especially patients aged 45–65 years [1,2]. Caucasian women had a higher prevalence than Afro-American or Asian women [3]. The complaint of involuntary loss of urine on effort or physical exertion (e.g., sporting activities, sneezing, or coughing) was attributed to pubourethral ligament dysfunction, which is more prevalent in multipara patients [4]. Risk factors of SUI may included a history of vaginal delivery, weight gain (30–50% increase in risk) [5,6], estrogen hormonal therapy (double the risk) [5-10], consumption of carbonated drinks [11], polymorphisms of the collagen type I gene (*COL1A1*), and family history [12].

Currently, there are an array of surgical procedures available for the treatment of SUI. The current standard is the mid-urethral sling [13], which was evaluated by Spinosa and Dubuis [14]. These procedures are considered minimally invasive in comparison to colposuspension operations that require laparotomy or laparoscopy [4]. Mid-urethral slings may be successfully implanted under regional/local anesthesia. Implantation techniques for mid-urethral slings have evolved from the retropubic approach to transobturator techniques. Transobturator techniques are reported to have had objective (cough stress test and 24-hour pad weighing test) and subjective (questionnaires) effectiveness ratings of approximately 90% for over a 10-year period [15]. These techniques are also associated with fewer urinary bladder injuries and less retropubic bleeding into the Retzius space due to blind blunt passage of the trocar through the retropubic space [16]. Alternatively, the tension-free vaginal tape obturator approach (TOT) is sometimes associated with postoperative groin/thigh pain that persists after one year in up to 3% of cases [17-21]. This technique is also associated with voiding difficulties, urgency, and urge incontinence, which manifests in up to 7% of patients [22-24].

The Serasis® (Serag-Wiessner KG, Naila, Germany) used for TOT, which uses a softer fabric, potentially causes less

trauma and damage to the tissue, thus diminishing postoperative pain and the extent of tissue scarring. There are currently no long-term follow-up studies regarding the effectiveness and postoperative adverse events of Serasis sling implantation. We hypothesized that the use of Serasis would result in lower occurrence and severity of postoperative pain compared to other TOT procedures reported in the literature.

The purposes of this study were to evaluate postoperative outcomes following Serasis implantation and to compare the efficacy and complication rates of the Serasis implant to those of other commonly used techniques reported in the literature.

PATIENTS AND METHODS

ETHICS STATEMENT

The study was approved by the local IRB (Helsinki committee), authorization number 0024-17-NHR, on 17 March 2017, with exemption from obtaining written informed consent in this retrospective chart review study.

STUDY DESIGN AND POPULATION

This retrospective cohort study included 50 women diagnosed with primary stress urinary incontinence who were candidates for operative treatment using the Serasis implant. The procedures were performed by a single surgeon (MN). Inclusion criteria were women previously diagnosed with SUI who were chosen to be treated using a primary trans-obturator surgical procedure with the Serasis implant. These patients were contacted within a period of no less than 1 year from the operation. Exclusion criteria consisted of patients with a postoperative time shorter than one year, any prior surgical procedure for the treatment of SUI, co-existing significant overactive bladder symptoms, incomplete medical records, or the inability to obtain a proper interview at the study's conclusion.

DATA COLLECTION

Data was collected from a preoperative interview and a physical examination of the patient by the surgeon. Demographic data including age, parity, body mass index (BMI), prior surgeries, background illnesses, family history of urinary incontinence, dyspareunia, age at onset, duration of symptoms, diagnosis prior to the procedure, preoperative and postoperative evaluation, and postoperative complications were recorded from medical records. Incontinence was graded according to the patients' subjective perception of impairment to quality of life.

OUTCOME MEASURES

The primary outcome measures were early (one month) and late (one year) postoperative pain occurrence measured by VAS pain scores and intraoperative and postoperative complications. Secondary outcomes were subjective success rates estimated by patient responses to a questionnaire.

The operative outcomes were stratified into two grades:

- Improvement where the leakage had resolved or was significantly reduced compared to pre-operative symptoms
- Failure where there was inadequate improvement or worsening of the patient's symptoms

EVALUATIONS OF PATIENT SATISFACTION AND PAIN

Patients were asked to complete questionnaires before surgery and at the first, third, and twelfth postoperative months regarding SUI symptoms, pelvic pain, and degree of satisfaction from the surgical procedure. The last postoperative interview was performed via telephone to evaluate patient satisfaction with the procedure performed and with the overall process. The interview consisted of several questions, which were answered subjectively by the patients.

Patient postoperative pain was evaluated by the Visual Analogue Scale (VAS) [25], with numeric descriptions ranging from 0 (absence of pain) to 10 (maximum pain possible). All study participants evaluated their postoperative pain. All the patients who described postoperative pain localized it to the groin area. Severe pain was arbitrarily defined as a VAS score ≥ 5 to facilitate a comparison with prior studies in the literature [25].

OPERATIVE PROCEDURE

The surgery was performed in a standard manner with the patients under general anesthesia. With the patient in the lithotomy position, bilateral tunneling was performed under the urethra and under the anterior vaginal wall, using a 1-cm incision under the mid-urethra, through which arcuate tape drivers were introduced to the obturator foramen as close as possible to the inferior pubic ramus and then to the groin skin at the lateral aspect of the labia majora. The tape was then positioned without tension underneath the mid-urethra and the incision was closed. No cystoscopy or cough tests were performed.

STATISTICAL ANALYSIS

Quantitative data are presented as means and standard deviations or medians and ranges. Qualitative data are described using frequencies and percentages. A comparison of ordinal data between time points was obtained by using the Wilcoxon signed-rank test.

To compare quantitative data between the groups and compare our data with findings from studies in the literature, the independent *t*-test was used. Ordinal data were compared using the Wilcoxon rank-sum test. Comparisons of qualitative data were achieved using the binomial test, chi-square test, or Fisher exact test. The choice between these tests was based on the data reported in the literature and according to preliminary assumptions that had been required. *P* values $< 5\%$ were considered significant.

RESULTS

PATIENT DEMOGRAPHICS

A cohort of 50 patients who underwent TOT for SUI using the Serasis implant was enrolled. The same surgeon (MN) performed all operations. No patient withdrew from the study or follow-up process.

The mean patient age was 45.76 ± 8.9 years, ranging from 31 to 68 years, and the mean BMI was 24.22 3.3 ± kg/m^2. Mean parity was 3.2 (range 1–11).

Six patients (12%) had received various previous pelvic operations, none of which was for treatment of SUI [supplemental Tables 1 and 2]. Nineteen patients (38%) had a family history of urinary incontinence. Eight patients (16%) had different systemic co-morbidities (e.g., diabetes, hypertension) as shown in supplemental Table 3.

Fifteen patients (30%) were diagnosed solely with SUI with no concomitant pelvic organ prolapse (e.g., cystocele, cysto-rectocele). The other 35 patients underwent a simultaneous colporrhaphy or another a surgical repair of defects in the vaginal wall to support the vaginal walls [supplemental Table 1]. Twenty-nine patients (58%) had presented with SUI for up to 3 years, while the remaining 21 patients had been experiencing symptoms for over 3 years.

Significant intra-operative or early postoperative complications were not reported, and all patients were discharged on either the day of surgery or the day after according to their hospitalization records.

POSTOPERATIVE PAIN

In the immediate postoperative period, pain was recorded in five patients (10%), of whom one woman complained of severe pain, as shown in supplemental Table 4. Pain within the first postoperative month was also recorded in 10% of patients. However, there was no complaint of severe pain during this period. At 3 months, the prevalence of pain was 6%. Last, when asked to report the level of pain experienced at 12 months, only two patients (4%) reported feeling persistent mild groin pain [Figure 1, supplemental Table 5].

Table 1. SUI cure rate

		Admission, n=50	1 month, n=50	3 months, n=50	12 months, n=50	*P value, admission vs. 1 month	*P* value, admission vs. 12 months	*P value, 1 month vs. 12 months
Degree of SUI (0–2)	0	0 0%	28 56%	35 70%	35 70%	< 0.001 (2-sided & 1-sided)	< 0.001 (2-sided & 1-sided)	0.056 (2-sided) 0.028 (1-sided)
	1	0 0%	17 34%	12 24%	11 22%			
	2	50 100%	5 10%	3 6%	4 8%			

SUI = stress urinary incontinence

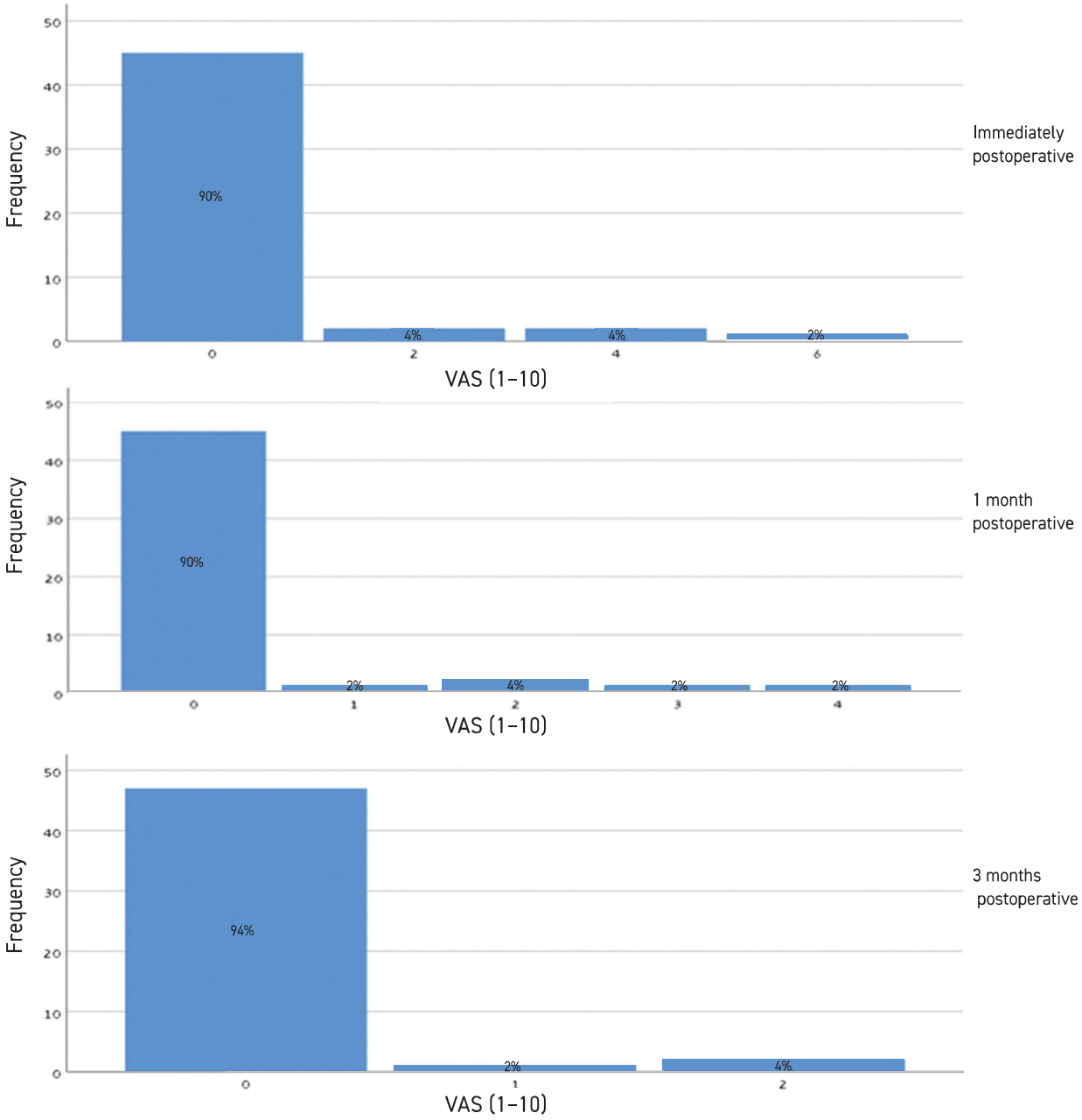
Table 2. Pain data comparison

			Discharge	1 month	12 months
1	Current study	Our data	10%	10%	4%
2	de Leval et al. [19]	Data	59.1%	13.6%	3.4%
		P	< 0.01*	**0.28***	0.511*
3	Neuman et al. [29]	Data	14.3%	0%	0%
		P	0.582*	**0.011*****	**0.172***
4	Riinne et al. [21]	Data	0.8%	0.8%	0%
		P	**0.007*****	**0.007*****	**0.075***
5	Lim et al. [22]	Data	–	–	3.7%
		P			≈ 1
6	Descazeaud et al. [30]	Data	–	–	6.4%
		P			0.704***
7	Laurikainen et al. [23]	Data	16%	2.3%	0%
		P	0.349**	**0.041****	**0.078********
8	Tommaselli et al. [24]	Data	4.5 ± 2.3	1.5 ± 0.5	–
		P	< 0.05********	< 0.05********	
9	Tommaselli et al. [25]	Data	–	0.5 ± 0.2	–
		P		< 0.05********	
10	Canel et al. [26]	Data	–	–	8%
		P			0.678**

*Binomial test, **2-sided chi-square test, ***Fisher Exact Test, ****2-sided *t*-test

Bold signifies statistically weakened

Figure 1. Occurrence of postoperative pain



VAS = Visual Analogue Scale

As shown in supplemental Table 2, 70% of the study population had coexisting conditions aside from SUI, which required additional colporrhaphy. Further investigation was executed in these patients to show the effect of an extended procedure on study outcomes.

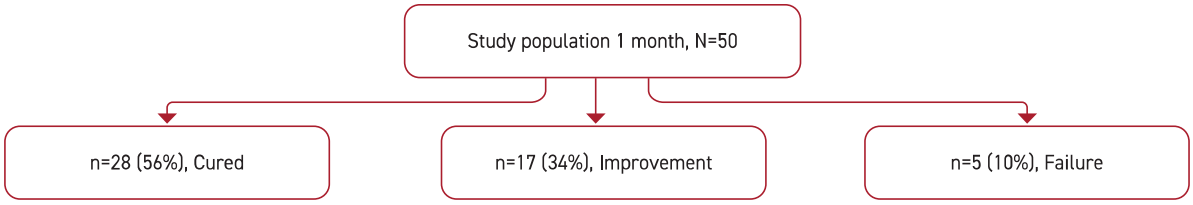
As displayed in supplemental Table 6, there was a significantly higher occurrence of persistent SUI at one and 3 months after an extended procedure than after only a standard procedure, according to the Wilcoxon rank-sum test (1 month-extended vs. standard $P = 0.042$, 3 month-extended vs. standard $P = 0.039$, and 12 month-extended vs. standard $P = 0.15$).

SURGICAL OUTCOME

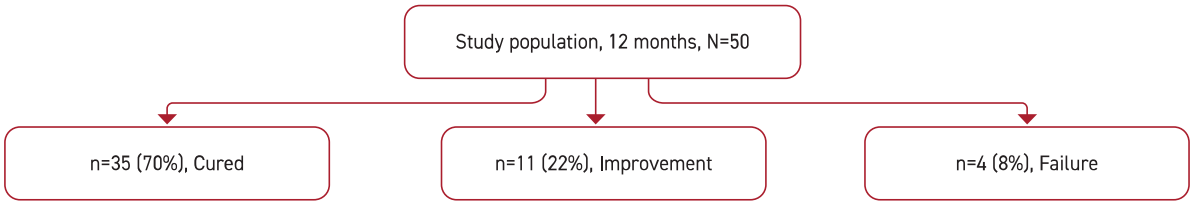
One month after surgery, 28 patients (56%) described complete

Figure 2. Surgical outcomes

[A] One-month subjective success rates



[B] 12-month subjective success rates



resolution of the symptoms, while 17 patients (34%) expressed a significant decrease in urinary incontinence. Five participants did not sense any improvement of symptoms [Figure 2A].

Of the 50 patients, 35 (70%) experienced complete resolution of SUI symptoms by 12 months after surgery, whereas 11 patients (22%) reported significant improvement with SUI. Three patients experienced treatment failure. One patient reported some decrease in incontinence at one month postoperatively, with recurrence of symptoms at the 12-month endpoint [Figure 2B]. The overall subjective cure and improvement rate of the operation was 92%. Two patients whose treatment failed (4%) underwent a second-line anti-incontinence procedure (retropubic TVT exact), one of which was successful. The other two failed patients did not opt for a second procedure.

A single patient (2%) presented with urinary retention after the operation, requiring use of an indwelling Foley catheter for one week. At the end of the 12-month period, only one patient (2%) had complaints of dyspareunia as compared to four (8%) prior to the operation. Significant differences in these symptoms at follow-up time points compared with those at admission, as determined by the Wilcoxon signed-rank test, are summarized in Table 1.

DISCUSSION

According to questionnaires answered by the patients, 90% reported complete resolution of pain within the first postoperative month, which increased to 96% after one year.

We compared relevant studies in the literature to evaluate the effectiveness of the surgery to this trial. We found that pain associated with this procedure was mostly transient and generally subsided during the first month and one year after surgery. The majority of patients were pain free. Furthermore, a small percentage of patients had complaints of pain at one year postoperatively. With this novel implant, we observed favorable outcomes regarding immediate postoperative pain compared to a number of studies, such as by de Leval et al. [19] [Table 2].

The operative success in this study was defined as patient subjective perception of cure or improvement of incontinence symptoms. This outcome was demonstrated in 90% of patients at one month after the operation and in 92% after 12 months. These scores concur with data from the literature [15].

LIMITATIONS

Our study has several limitations, mostly because of the retrospective and descriptive nature. In this descriptive trial, no control group was used as a comparison for our operative procedure. We did not find any significant differences in long-term effects on pain since this symptom is rare at 12 months post-procedure. It is possible that the study population was too small to evaluate this low prevalence finding, although it is not uncommon to carry out trials on relatively small groups. Analysis of the collected data may be subject to recall or reporting bias. The questionnaire that was intended to assess pain detected by the patients up to 12 months after the surgery was answered approximately at 2 years following surgery, weakening the accuracy of the results. Conducting the follow-up interview at shorter intervals and at the designed time interval following surgery (1, 3, and 12 months) may reduce recall bias and strengthen the accuracy of these findings.

In addition, at the time we conducted the study there are no validated questionnaires in Hebrew concerning the satisfaction

of an operative outcome or pain perceived by a patient. Therefore, we used a translated questionnaire previously used by another SUI study, which could be a disadvantage.

STRENGTHS

The strengths of the study derive from its originality as it is the first report on the Serasis sling method. Moreover, as the same surgeon conducted all procedures, it would be safe to assume that all patients underwent the procedure with little or no variation in the surgical approach, while the bi-center approach contributes to the generalizability of our findings.

CONCLUSIONS

Modification to the traditional mid-urethral sling technique that implements the novel Serasis implant does not seem to reduce the efficacy of the procedure. We also demonstrated that this implant is safe when a concomitant colporrhaphy procedure is added. Furthermore, we showed lower immediate postoperative pain and somewhat favorable results at one month after surgery in TOT procedures using the Serasis implant. It would be advisable to conduct more trials with a larger number of patients to achieve a more powerful conclusion regarding the long-term effects on pain and the efficacy and safety of this device.

ACKNOWLEDGMENTS

Prof Menahem Neuman is a consultant at Serag-Wiessner KG, Naila, Germany, the producers of the Serasis® sling. He is affiliated with FEMSelect, Memic, and OORO

The authors thank Mrs. Orly Yakir MA, for her assistance in the statistical analysis.

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Supplemental Table 1. History of previous pelvic surgical procedures

Previous procedures	N	Percent
No previous pelvic surgical procedures	44	88.0
Bi-lateral hip replacement	1	2.0
Hysterectomy	2	4.0
Pelvic organ prolapse	1	2.0
Urinary reflux repair	1	2.0
Posterior colporrhaphy	1	2.0
Total	50	100.0

Supplemental Table 2. Pre-operative diagnosis

Diagnosis	Frequency	Percent
SUI	15	30.0
SUI and cystorectocele	23	46.0
SUI and cystorectocele and cervical ypertrophy/elongation	1	2.0
SUI and cystorectocele and dyspareunia	1	2.0
SUI and cystocele	3	6.0
SUI and cystorectocele and uterine prolapse	5	10.0
SUI and cystorectocele and uterovaginal prolapse and cervical elongation	1	2.0
SUI and vaginal vault prolapse and cystorectocele	1	2.0
Total	50	100.0

Supplemental Table 3. Systemic co-morbidities

Co-morbidity	Frequency	Percent
No co-morbidities	42	84.0
Diabetes mellitus	1	2.0
hypertension	4	8.0
Irritable bowel disease	1	2.0
Osteoporosis, hepatitis B	1	2.0
Renal disease	1	2.0
Total	50	100.0

Supplemental Table 4. Immediate postoperative pain response

VAS score	Frequency	Percent
		90.0
0–1	45	4.0
4–5	2	4.0
6	1	2.0
7–10	0	0.0
Total	50	100.0

VAS = Visual Analogue Scale

Supplemental Table 5. Postoperative pain in simple vs. extended procedures

	Immediate postoperative pain	Pain at 1 month	Pain at 3 months	Pain at 12 months
P value (2-sided) **	0.241	0.241	0.545	0.571
P value (1-sided) **	0.153	0.153	0.334	0.486

**Wilcoxon rank-sum test

Supplemental Table 6. Operative outcome by simple and extended SUI procedures

		Simple SUI procedure			Extended SUI procedure		
		1 month n=15	3 months n=15	12 months n=15	1 month n=35	3 months n=35	12 months n=35
Degree of SUI (2–0)	0	12 80%	14 93.3%	13 86.7%	16 45.7%	21 60%	22 62.9%
	1	2 13.3%	0	1 6.7%	15 42.9%	12 34.3%	10 28.6%
	2	1 6.7%	1 6.7%	1 6.7%	4 11.4%	2 5.7%	3 8.6%

SUI = stress urinary incontinence

The question is whether or not you choose to disturb the world around you, if you choose to let it go on as if you had never arrived.

Ann Patchett (born 1963), American writer