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A Prospective Evaluation of the AJUST® Single-Incision Sling in the Surgical Treatment of Stress Urinary Incontinence: Two Years of Follow-Up

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ABSTRACT

Introduction: The mid-urethral sling has become the mainstay in the surgical management of stress urinary incontinence. Early meta-analyses suggested that the obturator approach (TOT) may be preferable in women with a high body mass index (BMI), concomitant voiding difficulties (VD), mixed urinary incontinence (MUI), or previous retropubic surgery. However, this approach is associated with increased and prolonged de novo groin pain. The AJUST® single-incision sling (SIS) was developed as an alternative to the retropubic and obturator slings and has been shown to be an effective treatment for urodynamic stress incontinence (USI) in the short term. We aim to assess if the AJUST® SIS would be an effective alternative to the TOT in a cohort of patients who have urodynamic stress incontinence (USI) with concomitant detrusor overactivity (DO), VD, high BMI, or those with previous retropubic surgery.

Methods: Women with USI and either concomitant DO, VD, previous failed retropubic surgery, or a BMI > 35 underwent treatment with the AJUST® SIS. Women were asked to complete the International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF) and an Urgency Perception Scale (UPS) preoperatively and then at 6 weeks, 6 months, 12 months, and 24 months postoperatively along with the PGI-I form. The numerical rating scale (NRS) was used to score pain 3 hours postoperatively and prior to discharge. Changes in ICIQ-UI-SF and UPS scores were measured.

Results: Twenty-five women were recruited. The mean age was 58 years. Of these, 28% had USI and 72% had mixed incontinence. There were no major perioperative complications. Mean postoperative pain scores were low with no de novo groin pain. All women had satisfactory postoperative voiding and a negative cough stress test at 6 weeks of follow-up. At the 2-year follow-up, 89% had still improved.

Conclusion: The AJUST® SIS appears to have promising medium-term efficacy in this challenging cohort of women. The long-term results are awaited.

INTRODUCTION

Stress urinary incontinence (SUI) is a prevalent condition affecting 50% of incontinent women [1]. Pelvic floor muscle training (PFMT) improves symptoms in up to 60% of women [2]. However, since the introduction of mid-urethral slings, with high efficacy and low morbidity, surgical intervention has become the mainstay of treatment [3]. Furthermore, Hilton [4] showed that in England between 1997 to 1998 and 2006 to 2007, due to the rapid dissemination of suburethral slings, there was a 28% increase in the annual number of continence operations; a 90% reduction in the number of colposuspensions; and a 50% reduction in bladder neck buttress, sling, and urethral bulking procedures.

In an attempt to reduce the risk of visceral and vascular injury

KEYWORDS: Stress urinary incontinence, retropubic sling, transobturator sling, AJUST® sling

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associated with retropubic slings [5], a transobturator approach was introduced in the year 2000 [6]. This was shown in the short and medium term to have similar efficacy to the retropubic approach in treating urodynamic stress incontinence (USI) [7]. As the obturator approach avoids the retropubic space and is less likely to cause outflow obstruction, some meta-analyses suggest it may be preferable to a retropubic sling in women with a high body mass index (BMI), concomitant voiding difficulties (VD), concomitant detrusor overactivity (DO), or previous retropubic surgery [8,9]. However, compared with the retropubic sling, the obturator approach has been shown to have a higher incidence of de novo persistent pain (32% vs 10%) and dyspareunia (18% vs 3%) [10,11]. It is thought that this is caused by injury to the neuromuscular structures that are traversed by the sling distal to the obturator externus muscle between the obturator foramen and the skin of the groin [12]. In light of this data, the protocol in our unit was to offer a retropubic sling as a first surgical treatment in women with USI (and a normal BMI). Women with USI and concomitant high BMI, voiding difficulties, detrusor overactivity, or retropubic surgery were offered an obturator sling but counseled about the risk of de novo pain or dyspareunia.

The single-incision slings (SIS) were introduced in an attempt to reduce both the risk of viscera-vascular injury caused by retropubic slings, and groin pain caused by obturator slings as they avoid both the retropubic space and neuromuscular structures distal to the obturator membrane and obturator externus muscle. However, success rates of the SIS have been poor compared with either the retropubic or obturator procedures. It is thought that this may be due to inadequate fixation and anchoring of the sling [13]. The AJUST® Adjustable Single-Incision Sling System (C.R. Bard, Inc., NJ, USA) is a single-incision sling, with a unique anchoring system that secures into the obturator internus muscle and punctures the obturator membrane. In addition, the system allows for adjustment of tension at the time of surgery [14]. There is growing data suggesting the AJUST® SIS is an effective treatment for USI in the short term [15].

The primary aim of this prospective study was to assess the efficacy and incidence of de novo groin pain after using the AJUST® SIS in a cohort of women offered surgery for USI, who also had concomitant detrusor overactivity, voiding disorder, high BMI, or previous retropubic surgery, and would otherwise have used an obturator sling.

METHODS

This was a single-center prospective study of women referred to our urogynecology unit between 2009 and 2012. All women meeting the inclusion criteria were entered into a database for service evaluation and audit purposes. The Research and Development Department was consulted and ethical approval was not required.

The inclusion criteria included women with urodynamically proven stress urinary incontinence with either concomitant detrusor overactivity, voiding difficulty (defined as a peak flow rate of less than 15 mL/minute and post-void residual urine volume of more than 100 mL for a voided volume of more than 150 mL), a BMI of more than 40, or previous retropubic surgery. Women with stage 2 or more pelvic organ prolapse (POP) on the POP quantification system (POPQ), predominant overactive bladder (OAB) symptoms, or patients requiring concomitant POP surgery were excluded. Twenty-five women met the criteria and were included.

All women were offered supervised pelvic floor muscle training (PFMT) for 3 months. Only those that were still symptomatic were offered surgery. In addition, women with concomitant detrusor overactivity or significant symptoms of overactive bladder had their symptoms appropriately controlled with antimuscarinics and bladder training prior to surgery.

Preoperative assessment included clinical history, pelvic examination, and conventional subtracted cystometry. Before surgery and at each postoperative follow-up visit, all women were asked to complete the International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF) [16], and a validated Urgency Perception Scale (UPS) [17]. This was part of the standard evaluation of patients in our unit. Women were offered to have the procedure done under general (GA) or local anesthesia (LA).

Intraoperatively, data regarding the duration of the operation, intraoperative complications, and blood loss measurement were collected. Cystoscopy was routinely performed after sub-urethral tape insertion. Prophylactic intravenous antibiotics were administered, as per our unit protocol.

Postoperatively, pain assessment was performed 3 hours following surgery and at the time of discharge, using a validated 10-point Numerical Rating Scale (NRS). Patients were then reviewed 6 to 8 weeks following surgery. Evaluation included pelvic examination to exclude tape exposure and a cough stress test. In addition to the ICIQ-UI-SF, patients were asked to complete a UPS and Patient Global Impression of Improvement (PGI-I) [18]. These were repeated at 6, 12, and 24 months. Changes in the ICIQ-UI-SF and UPS were analyzed using a paired t test. GraphPad Prism 2012 software was used for statistical analysis.

The primary outcome was that the patient reported a successful operation, defined as "improved, much improved, or very much improved" on PGI-I at 24 months. Other outcomes were to measure the changes in postoperative ICIQ-UI-SF, UPS, and postoperative pain scores.

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Table 1. Patient demographics.

		% (N)
age	30-39	8 (2)
	40-49	44 (11)
	50-19	32 (8)
	60-69	16 (4)
	mean	50.28
	range	38-65
previous surgery	TAH[1]	8 (3)
	AR[2] and /or PR[3]	12 (2)
	none	80 (20)
smoker		20 (5)
HRT[4]		4 (1)
PFMT[5]		88 (22)
antimuscarinic therapy		68 (17)
UDS[6]	USI	32 (8)
	mixed	68 (17)

1: Total abdominal hysterectomy; 2: Anterior repair; 3: Posterior repair; 4: Hormone replacement therapy; 5: Pelvic-floor muscle training; 6: Urodynamic diagnoses

RESULTS

Demographics

Twenty-five women were included in this study. Of those, 18 women (72%) completed the 2-year follow-up. The mean age was 58 years (range: 38 to 65 years). Urodynamic diagnoses were USI (with either concomitant voiding difficulties, a BMI > 35, or previous retropubic surgery) in 28% and urodynamic mixed urinary incontinence in 72%. Due to the small sample size, it was not feasible to categorize women into subgroups of women with USI, MUI, VD, or a high BMI, and therefore data was analyzed as a single heterogeneous cohort. Patient demographics are outlined in Table 1.

All women were offered supervised PFMT for 3 months. While 88% of the women had PFMT, 12% declined. Of the procedures performed, 92% were under GA and 8% under LA.

Perioperative Details

The mean operation time was 18 minutes (range: 13 to 30 minutes), and mean intraoperative blood loss was 28 mL (range: 10 to 50 mL). No patients had major blood loss (defined as > 500 mL), and no one needed a blood transfusion. No bladder or urethral injuries were recorded. Two women had "buttonholing" to the vaginal sulcus, which were repaired intraoperatively. One woman (4%) had tape exposure diagnosed at 6 weeks of follow-up. This was treated as a day case following a trial of topical estrogens. None of the patients in this study underwent concomitant hysterectomy or POP surgery at the time of the AJUST® sling procedure. It is our unit's practice to perform incontinence procedures at an interval following prolapse surgery.

Voiding Difficulties

All patients in our study performed a voiding trial with postmicturition bladder scans following 3 voids prior to discharge. None complained of newly developed poor voiding or incomplete emptying, except 1 patient who, in addition to stress urinary incontinence, was having voiding difficulty preoperatively and was using clean intermittent self-catheterization (CISC). She continued to perform CISC postoperatively.

Pain

The mean pain scores (95% CI) 3 hours postoperatively and at discharge were 2.5 (1.3 to 3.7) and 1.8 (0.7 to 2.9), respectively. No patients reported prolonged leg/thigh pain at the 6- to 8-week follow-up visit or at the 6-, 12-, and 24-month follow-up. Furthermore, there were no cases of de novo dyspareunia at postoperative follow-up. The only patient who developed mesh exposure was not sexually active.

Efficacy

All patients were "cured" at their 6-week follow-ups according to PGI-I. The cough stress test was also negative for all women at the 6-week follow-up. At the 2-year follow-up, 61% of patients reported their symptoms as "very much improved" or "much improved" on PGI-I. A further 28% reported symptoms were "improved." One woman (5%) stated her urinary symptoms were the same as before surgery, and another woman (5%) stated her SUI had become worse. Both reported the new symptoms had started around 18 months, postoperatively. Both had subsequent urodynamic studies that confirmed USI, and both underwent a retropubic sling and improved (Table 2).

Analysis showed a statistically significant difference in the ICIQ-UI-SF between preoperative and postoperative data, with a clear trend toward improvement, which was maintained all through the 2-year follow-up period (Table 3). A similar trend was also noted in the UPS (Table 4).

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Table 2. Patient Global Impression of Improvement (PGI-I).

		6-week follow-up	6-month follow-up	12-month follow-up	24-month follow-up
	N (%)	25 (100%)	20 (80%)	12 (48%)	18 (72%)
PGI-I N (%)	worse	0 (0%)	0 (0%)	0 (0%)	1 (5%)
	same	0 (0%)	0 (0%)	1 (8%)	1 (6%)
	improved	3 (13%)	2 (10%)	3 (25%)	5 (28%)
	much improved	6 (22%)	4 (20%)	2 (17%)	3 (17%)
	very much improved	16 (65%)	14 (70%)	6 (50%)	8 (44%)

Table 3. Changes in the ICIQ-UI-SF.

		Preoperative	6-week follow-up	6-month follow-up	12-month follow-up	24-month follow-up
% women at FU (N)			100 (25)	80 (20)	48 (12)	72 (18)
ICIQ-UI-SF	Mean (95% CI)	15.8 (14.2-17.4)	1.8 (0.5-3.0)	0.8 (0.0-1.8)	2.3 (0.0-4.6)	3.4 (2.1-5.8)
	P value*		< 0.0001	< 0.0001	< 0.0001	< 0.0001

*Compared to preoperative values

Table 4. Changes in the Urgency Perception Scale (UPS).

		Preoperative	6-week follow-up	6-month follow-up	12-month follow-up	24-month follow-up
UPS	Mean (95% CI)	6.0 (4.5-7.5)	2.2 (0.8-3.5)	1.3 (0.0-2.6)	2.1 (0.1-4.1)	2.8 (1.3-4.3)
	P value*		<0.001	<0.001	0.0004	0.0003

* Compared to preoperative values

DISCUSSION

There is limited medium to long-term data on the efficacy of the AJUST® SIS. The majority of data published only extends up to 12 months following surgery. Our 2-year follow-up study adds to the evidence on the efficacy of the AJUST® SIS.

Naumann et al. [19] showed, after 29 months following surgery, that the AJUST® SIS was effective in restoring or improving continence in 86.3% of women treated for pure USI. Another prospective report with a mean follow-up of 21 months showed a success rate of 80% and concluded that the AJUST® sling was both safe and effective in treating women with pure USI [20]. Short-term reports on the efficacy and safety of the AJUST® SIS suggest similar results. Abdel-Fattah et al. [15] reported a

1-year success rate of 80%.

All these studies assessed the efficacy of the procedure in women with pure USI. In our unit, women with pure USI are offered a retropubic sling under local anesthesia and sedation. We offered the AJUST® SIS only to women shown to have USI but with concomitant conditions that can adversely affect the outcome of the retropubic approach: DO, VD, raised BMI, or previous retropubic surgery. Within this challenging group of patients we found the medium term (2-year) success rate for the AJUST® SIS was still 89%: 61% reported they were either "much improved" or "very much improved," and a further 28% reported they were "improved." Only 11% reported their procedure as failure. This is similar to other reports for a similar follow-up period [21].

The National Institute for Health and Clinical Excellence (NICE) [19] recommends that SIS should only be used in a research setting or under evaluation with auditing of results. Of the women in this study, 72% completed the 2-year follow-up period. This is low compared with other long-term reports [18]. There were various potential reasons; patients may move to other regions. None declined follow-up but some were not contactable despite numerous attempts.

We performed 92% of the AJUST® SIS procedures under GA, and 8% (2 women) under LA. In our unit, it is our current practice to perform almost all TVTs under LA and sedation, and the TOT under GA. Having explained that the AJUST® SIS was under evaluation, and its similarities to the TOT, the majority of women chose GA rather than LA. Due to the small sample size, it was not possible to compare the GA and LA groups. We acknowledge, however, that the AJUST® sling has been performed under LA with a similar success rate to GA [13].

We report no major intraoperative or postoperative complications such as visceral injury or major blood loss, which is similar to other reports. One patient (4%) developed tape exposure, which was diagnosed at a 6-week follow-up visit, and was treated successfully by excision of the exposed mesh and re-suturing of the vaginal skin; we did not have to remove the tape. The apparently high tape exposure rate as compared to other reports (2%) [20,21] may be due to the relatively small sample size.

In light of our results we may conclude that the medium-term results are promising in this heterogeneous cohort of patients. However, long-term results are still needed and are unlikely to be published in the near future. The majority of women within this cohort had MUI. These women either demonstrated DO on urodynamic studies or had significant symptoms of urgency. Although the women were treated with antimuscarinics before surgery, we found that urgency (measured on the urgency perception scale) significantly improved after the AJUST® SIS. Although initial studies suggested the obturator approach may be less likely to cause de novo DO (and hence our rationale for using AJUST® for treating MUI), subsequent data has demonstrated equal efficacy between the retropubic and transobturator approach in treating MUI [13].

In light of this data and the current paucity of long-term (5-year or greater) data on the AJUST® SIS, we would now only offer the AJUST® in women with preexisting poor voiding symptoms, previous retropubic surgery, or with a high BMI.

We acknowledge the limitations of our study. The sample size was small and the group heterogeneous. Furthermore, the main objective assessment of a cure was a PGI-I score and ICIQ-UI-SF score. In addition, patients from our learning curve were also included within the cohort.

CONCLUSION

The AJUST® single-incision adjustable mini-sling appears to have promising medium-term efficacy with no major intraoperative or postoperative complications. The reported thigh/leg pain associated with the TOT seems to be much less with the AJUST® sling. The AJUST® sling may be considered an alternative to the TOT. Retropubic slings remain the treatment of choice for pure USI and MUI in our unit, as the follow-up data is much longer. We therefore need longer follow-up studies before changing over to an SIS.

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