

Single incision slings: Are they ready for real life?

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Abstract

AIM: To review of the efficacy and safety outcomes of different single incision slings (SIS) systems, also in comparison with traditional slings.

METHODS: A literature search was conducted in PubMed/MEDLINE database. The research was restricted to randomized and/or prospective trials and retrospective studies, published after 2006, with at least 20 patients with non-neurogenic stress urinary incontinence (SUI). The studies had to assess efficacy and/or safety of the SIS with a minimum follow-up of 12 mo. All the paper assessing the performance of tension free vaginal tape secur were excluded from this review. The final selection included 19 papers fulfilling the aforementioned criteria. Two authors independently reviewed the selected papers.

RESULTS: Four different SIS systems were analysed: Ajust[®], Ophira[®], Altis[®] and MiniArc[®]. The average objective cure rate was 88%. Overall no statistically significant differences were found between SIS and traditional mid-urethral slings (MUS) in terms of objective cure (all $P > 0.005$). Only one paper showed a statistically lower success rate in MiniArc[®] vs Advantage[®] slings (40% vs 90%) and higher rates of failure in the SIS group. Since there was a great variability in terms of tests performed, it was not possible to compare subjective cure between studies. The vast part of the studies showed no major complications after SIS surgery. We also observed very low reported pain rates in SIS patients. The RCTs on Ajust[®] and MiniArc[®], showed better outcomes in terms of post-operative pain compared to MUS. None of the patients reported long-term pain complains.

CONCLUSION: SIS showed similar efficacy to that of traditional slings but lower short-term pain, complication and failure rates.

Key words: Female urological diseases; Urinary stress

incontinence; Pelvic floor disorders; Minimally invasive surgery; Mid-urethral slings

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Core tip: This review shows an average objective cure rate of 88% in minisling patients and underlines their comparable efficacy with traditional slings. Short term pain, complication and failure rates are lower in the minisling group.

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INTRODUCTION

Stress urinary incontinence (SUI) is the involuntary leakage of urine associated with effort on exertion, sneezing or coughing. The estimated prevalence is roughly 30% in women aged > 40 years. The annual incidence increases with age (aged > 65 years, annual incidence rates approximately 9%)^[1-3]. Several treatment options for SUI exist, including physical therapy, urethral bulking injections, and surgery.

Surgery traditionally consisted of Burch urethropexy or pubovaginal slings^[3]. These procedures were found to give adequate results but were also associated with long recovery time and complications such as frequent post-operative voiding dysfunction^[4].

Mid urethral slings (MUS) were developed as a less invasive approach to the treatment of SUI. Since the introduction in 1996 of retropubic tension free vaginal tape (TVT), the use of synthetic MUS has grown to become the most common surgery performed for SUI in women.

These procedures have evolved and multiple types of MUS have been launched on the market, enabling treating physicians to offer different therapeutic options to patients with SUI. The single-incision slings (SIS) are one of the latest innovations for female SUI. They were introduced with the concept of using a shorter tape through a single vaginal incision providing a similar "suburethral hammock" to classical MUS^[5].

Their anchoring mechanism (to the obturator membrane or muscle) avoids the passage of trocars through the obturator foramen^[6]. SIS represent a minimal invasive innovation for the surgical treatment of SUI. Some studies have already proven their efficacy on the short, medium and long term^[5,7-9].

The purpose of this study is to review the evidence for different SIS systems, to compare this relatively new system with traditional MUS and to give the reader

an overview on the principal SIS currently available, defining their efficacy and safety. Moreover we aim at giving the physician a tool to simplify the clinical decision-making on the base of the existing literature.

MATERIALS AND METHODS

Evidence acquisition

The literature search was conducted on PubMed in June 2015. The search strategy included the following terms: "SUI" AND "mid urethral slings", AND "SISs" AND "female".

Our research was restricted to randomized and/or prospective trials and retrospective studies with at least 20 patients with non-neurogenic SUI, published after 2006 in English. To be included in the review the studies had to assess efficacy and/or safety of the SIS and have a minimum follow-up of 12 mo. It is important to underline that all the paper assessing the performance of TVT secur were excluded from this review. The reason is the worldwide withdrawal of this sling from practice in March 2013.

Two independent researchers evaluated the articles with one researcher making the final decision.

Evidence synthesis

Using the aforementioned research strategy, 102 studies were identified. After applying the eligibility criteria a total of 19 papers were included in the review. Of these, 8 reported efficacy and/or safety outcome on Ajust® (C.R. Bard, Inc., Murray Hill, NJ, United States), 2 on Ophira® (Promedon, Cordoba, Argentina), 2 on Altis® (Coloplast), and 7 on MiniArc® (American Medical System, Inc., Minnesota, United States) (Figure 1). The statistical review of the study was performed by a biomedical statistician.

RESULTS

Ajust® (Figure 2)

Method of action/working mechanism: The Ajust® sling provides a strong insertion into the obturator muscle/membrane and allows immediate post insertion adjustment of the tape. A 1 cm incision is made and a bilateral tunnel is created as far as the posterior margin of the inferior pubic ramus. The trocar with the fixed anchor is then introduced and pivoted slowly in the obturator internus and membrane. The adjustable anchor is subsequently placed at the contralateral side and the tape tension is adjusted. A flexible "sylet" is used to lock the adjustable anchor^[10].

Population: A total of 8 studies assessing efficacy and/or safety of Ajust® slings have been included in the review^[11-18]. All patients included presented with SUI or MUI with predominant stress symptoms. In all the studies, patients with concomitant organ prolapse, predominant overactive bladder symptoms or patients

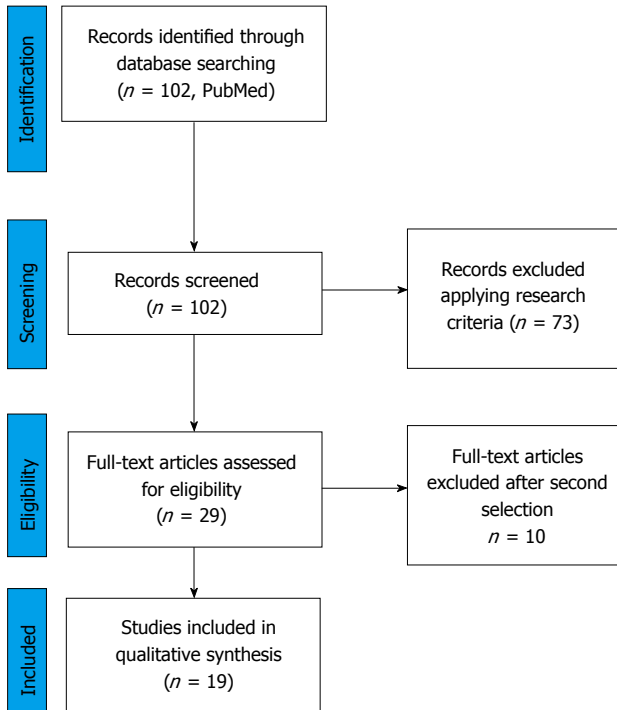


Figure 1 Prisma flow chart.

with a history of previous incontinence and/or anterior vaginal wall surgery were excluded. The majority of the studies included do not differentiate the severity of the incontinence. Overall severity information were available for a total of 374 patients who showed moderate to severe SUI^[11,15,16].

Evidence efficacy (Table 1): Ajust® sling efficacy was investigated in a total of 3 randomized controlled trials (RCT)^[9,11,12].

Two of them compared the efficacy of the adjustable sling system with the classic MUS TOT in a total of 293 patients. At 1-year follow-up, both studies demonstrated no difference between groups in terms of objective cure (assessed with cough stress test - CTS): 90.8% vs 88.6%^[11] and 81.2% vs 82.3%^[9] in Ajust® and TOT respectively, all $P > 0.05$. Subjective cure was also assessed. In the paper by Schweitzer *et al.*^[11], subjective cure was defined as a negative answer to the UDI-6 question: "do you still experience any leakage related to physical activities?". In the paper by Mostafa *et al.*^[9], it was assessed using the patient global impression of improvement (PGI-I) questionnaire. Using the aforementioned criteria, neither RCT showed any difference in subjective cure rate between the two groups. Failure was defined as any surgical retreatment for urinary incontinence. Schweitzer *et al.*^[11] showed a failure rate of 2.2% and 2% in Ajust® and TOT slings at 1-year. Mostafa *et al.*^[13] showed a 7.2% and 4.4% failure rate in Ajust® and TOT respectively. These differences between groups were not statistically significant in both papers^[9,11].

The third RCT is a comparison between three



Figure 2 Ajust sling.

SISs, namely TVT Secur®, MiniArc® and Ajust®^[12]. As mentioned before, we did not include the results concerning TVT Secur. The other two arms (namely MiniArc® and Ajust®) did not show any difference in terms of subjective and objective cure rates at 6, 12, 18 and 24 mo follow-up. It is important to underline that both objective and subjective cure rates decreased significantly in each arm between 6 and 24 mo. At 24 mo, no difference was found between groups in total failure rates: 60% in the Ajust® group and 55% in MiniArc® group.

In the matched paired study performed by Grigoriadis *et al.*^[14] on 171 patients diagnosed with urodynamic SUI, we observed similar results in terms of objective and subjective cure rates at 22 mo follow-up for both the Ajust® and TOT group. Failure rate varied between 8.1% and 10.6%^[14].

We also collected data of 4 prospective studies assessing the efficacy of Ajust® slings up to 1-year follow-up. The results were comparable with those of the RCTs: Objective cure varied from 82.4% to 83.7%. Patient reported cure varied from 80% to 83%^[15-18]. However, it has to be underlined that each study used different objective and subjective parameters to assess continence after surgery. Failure of the procedure defined as persisting SUI or need of other types of incontinence surgery vary widely from 0.0% to 14%.

Evidence safety (complications and pain) (Table 2): No major complications were observed in all the studies analysed. In a cohort study, Cornu *et al.*^[17] described a post-operative vaginal bleeding managed surgically 8 h after the initial surgery. Also a total of 2 mesh erosions (on 95 patients) requiring surgery were observed after a mean follow-up of 21 mo^[17].

In the RCT comparing Ajust® and MiniArc® the number of patients using analgesic tablets during the first 30 d from surgery ($P = 0.349$) and the number of analgesic tablets used ($P = 0.124$) were similar among both groups.

Complications occurred in 7 (17.5%) and 2 (5.0%), cases from the Ajust® and MiniArc® groups respectively. All post-operative complications were Dindo grade 1,

Table 1 Efficacy

Ref.	Design	Participants	Intervention (n)	Comparison	Follow-up	Cure assessment	Cure rate	Assessment of improvement or success	Improv. rate	Success rate	P
Schweitzer <i>et al</i> ^[11]	RCT	156	Ajust: 100 TOT: 56	TOT	12 mo	OC: CST SC: UDI-6	OC: 90.8% <i>vs</i> 88.6% SC: 77.2% <i>vs</i> 72.9%		-	-	OC: 0.76 SC: 0.57
Palomba <i>et al</i> ^[12]	RCT (Multi)	80	Ajust: 40 MiniArc: 40	MiniArc	24 mo	OC: CST SC: % dry? Or improved?	OC: 47% <i>vs</i> 55% SC: 52.5% <i>vs</i> 65%		-	-	<i>P</i> > 0.05 <i>P</i> > 0.05
Mostafa <i>et al</i> ^[13]	RCT (Multi)	137	Ajust: 69 TVT-O: 68	TOT	12 mo	OC: CST SC: PGI-I	OC: 81.2% <i>vs</i> 82.3% SC: 85.5% <i>vs</i> 84%				<i>P</i> = 1 <i>P</i> = 1
Grigoriadis <i>et al</i> ^[14]	Prosp matched controlled	171	Ajust: 85 TOT: 86	TOT	22.3 mo (mean)	OC: CTS SC: Patient impression	OC: 84% <i>vs</i> 86% SC: 81.2% <i>vs</i> 82.6%	-			
Natale <i>et al</i> ^[15]	Prosp. (Multi)	92	Ajust: 92	-	24 mo	OC: CST SC: PGI-I	OC: 83.7% SC: 81.5%		-	-	-
Naumann <i>et al</i> ^[16]	Prosp. (Multi)	51	Ajust	-	25.2 ± 2.24 mo (mean)	OC: CTS	82.4%	Ingelmann-Sundberg scale	3.9%	86.3%	-
Cornu <i>et al</i> ^[17]	Prosp.	95	Ajust		21 ± 6 mo (mean)	OC: Pad usage SC: Subjective reports of leakage	OC: 80% SC: 83%	-	-	80%	-
Abdel-fattah <i>et al</i> ^[18]	Prosp. (Multi)	90	Ajust	-	12 mo	-	-	PGI-I	86%	80%	-
Palma <i>et al</i> ^[19]	Prosp. (Multi)	124	Ophira		12 mo	OC: 1 h-PWT	OC: 85.3%	Leakage < 50%	6.30%		
Djehdian <i>et al</i> ^[20]	RCT	120	Ophira: 64 TOT: 56	TOT	12 mo	OC: CST/ 20 min pad test SC: Patient satisfaction	OC: 68.1% <i>vs</i> 81.9% (ITT) and 73% <i>vs</i> 89% (PP) SC: 81.1% <i>vs</i> 88.5% (ITT) and 87.5% <i>vs</i> 96.4% (PP)	-	-	-	<i>P</i> = 0.43 and 0.54 <i>P</i> = 0.11 and 0.10
Dias <i>et al</i> ^[21]	Prosp.	50	Altis	-	12 mo	CST ICIQ-SF = 0	OC: 90.2% SC: 84%	ICIQ-SF lower than pre-op or > 0	8%		
Kocjancic <i>et al</i> ^[22]	Prosp. (Multi)	101	Altis	-	12 mo	OC: PWT (< 50% pad weight compared to baseline) and CST SC: PGI-I	OC: 90% SC: 90.1% SC: 89.3%	-	-	-	-
Lee <i>et al</i> ^[25]	RCT	206	MiniArc: 103 Monarc: 103	Monarc	12 mo	CST (negative) SC: Negative reply to ICIQ 3 and 5 and UI-SF	OC: 94% <i>vs</i> 97% SC: 92% <i>vs</i> 94%	-	-	-	OC: 0.78 SC: 0.50
Schellart <i>et al</i> ^[26]	RCT	173	MiniArc: 86 Monarc: 87	Monarc	12 mo	OC: CST SC: PGI-I	OC: 89% <i>vs</i> 91% SC: 83% <i>vs</i> 86%				<i>P</i> = 0.65 <i>P</i> = 0.46
Basu <i>et al</i> ^[27]	RCT	71	MiniArc: 38 Advantage: 33	Advantage	36 mo			KHQ	48% <i>vs</i> 90%		All <i>P</i> < 0.05

Oliveira <i>et al</i> ^[23,30]	Prosp.	71	MiniArc	-	12 mo	SC: No leakage and no protection	77%	Use of protection decreased > 50% and affirmative reply to the question: are you satisfied with the results?	11%	88%
Deole <i>et al</i> ^[29]	Prosp.	59	MiniArc		12 mo	OC: CST SC: ICIQ-SF	OC: 66% SC: median score 6	-	-	-
Presthus <i>et al</i> ^[24]	Prosp.	31	MiniArc		24 mo	PGL-I OC: CST and PWT	64% 93.5%			
Kennelly <i>et al</i> ^[31]	Prosp. (Multi)	142	MiniArc		24 mo	OC: CST and PWT SC: UDI-6	90.3% 84.5% 80.1% 92.9%	-	-	-

RCT: Randomized controlled trial; TOT: Trans obturator tape; OC: Objective cure; SC: Subjective cure; PGL-I: Patient global impression of improvement; CST: Cough stress test; PWT: Pad weight test; ITT: Intention to treat; PP: Per protocol; ICIQ-SF: International Consultation on Incontinence Questionnaire - Short Form; UI-SF: Urinary incontinence-Short form; UDI-6: Urogenital Distress Inventory; Prosp.: Prospective; Multi: Multicentric.

and they were not significantly different among the groups ($P = 0.897$).

Schweitzer *et al*^[11] showed a significantly lower pain score in the Ajust® group vs the TOT group during the first week. However no differences were found after day 6 between both groups ($P = 0.75$).

OAB symptoms: In the RCT by Schweitzer only women with moderate to severe SUI were included. Seven out of 100 women in the Ajust® group and four out of 56 in the TOT group reported new onset of OAB. Both the RCT by Mostafa *et al*^[13] and Palomba *et al*^[12] included also patients with mixed urinary incontinence. In the first paper the authors showed a trend toward higher rates of *de novo* urgency and/or worsening of the pre existing urgency in the Ajust® group during the first 4 mo (although it was found not to be statistically significant) but this finding was not retained at 1-year. Moreover there was no significant difference between the two groups (6.5% vs 8.7% in TOT vs Ajust®, $P = 0.74$)^[12].

De novo or worsened urgency UI was noted in 5 patients, in the paper by Palma *et al*^[19], occurring in 3/40 (7.5%) and 2/40 (5.0%) cases in the Ajust® and MiniArc® groups, respectively^[16].

In the study by Grigoriadis *et al*^[14], there was a total of 10/85 (11.6%) vs 8/86 (9.4%) patients that complained of early post-operative symptoms of frequency and urgency in the TOT group vs Ajust® groups respectively ($P < 0.05$). No DO was demonstrated on urodynamic investigation^[14].

In the prospective study by Mostafa *et al*^[13], the authors assessed post-operative urgency in a group of pure SUI and mixed incontinence patients, using the urgency perception scale (UPS). Pre operative assessment of urgency showed 53/90 patients (59%)

to have urgency symptoms. Of them, 35/53 (66%) reported post-operative improvement of urgency (29 of them reported total cure). However, 18/53 (20%) patients reported no improvement or even worsening of the symptoms. No data on *de novo* urgency was described by the authors^[18].

Cornu *et al*^[17] also showed a decreasing trend in OAB symptoms after surgery compared to the pre-operative assessment (35% vs 25%). Of them 12/95 (12.6%) had *de novo* urgency and 12/95 (12.6%) reported persistent OAB symptoms^[17].

Natale *et al*^[15] reported a rate of post-operative urgency of 5.4% (5/92), 9.8% (9/92) of which *de novo* urgency. In the group of patient with pre-operative OAB symptoms ($n = 36$, 39.1%), 27 reported persistence of urgency and of them 18 had a good response to pharmacotherapy (30%)^[15].

Naumann *et al*^[16] reported on 6/51 patient (12%), having a preoperative patient perception of intensity of urgency scale higher than 1 (*i.e.*, at least moderate urgency). However, 3 of them (60%) reported improvement of urgency compared to their situation before surgery and 2 (40%), reported severe urgency (2/5: 4%)^[16].

Ophira® (Figure 3)

Method of action/working mechanism: Ophira®, has blue loosening sutures inserted in the base of both fixation arms, giving the ability to correct tension during the procedure. The fixation system has multiple fixation points along its self-fixating arms.

The system includes a "Retractable Insertion Guide" to improve control and ease when inserting the sling and releasing it in the correct position. The connectors located at the ends enable the Retractable Insertion Guide to be inserted easily and safely.

Table 2 Safety

Ref.	Design	Participants	Intervention	Comparison	Timing	Assessment	Pain rate/ complications	P
Schweitzer <i>et al</i> ^[11]	RCT	156	Ajust: 100 TOT: 56	TOT	Immediate post-op and up to week 6	VAS	Median score week 1: Ajust: 0.2 TOT: 1.0 Median score week 2: Ajust: 0.0 TOT: 0.5	< 6 d: 0.01 > 6 d: > 0.05
Palomba <i>et al</i> ^[12]	RCT (Multi)	80	Ajust: 40 MiniArc: 40	MiniArc	24 mo follow-up	VAS	Pain score Ajust: 5.3 ± 3.8 Pain score MiniArc: 5.0 ± 3.5 Complications: Ajust: 17.5% MiniArc: 5% 1 mesh erosion in Ajust group (no surgical revision) 3.5% vs 5.8%	All P > 0.05
Grigoriadis <i>et al</i> ^[14]	Prosp. matched controlled	171	Ajust: 85 TOT: 86	TOT	Post-op and during follow-up	Patient's impression		-
Natale <i>et al</i> ^[15]	Prosp. (Multi)	92	Ajust n = 92	-	Post-op and during follow-up	Patient's impression	1 leg pain, 3 mesh extrusion (of which 1 mesh removal)	-
Naumann <i>et al</i> ^[16]	Prosp. (Multi)	51	Ajust	-	1 d after surgery and at during follow-up	VAS	1 patient day 1	-
Cornu <i>et al</i> ^[17]	Prosp.	95	Ajust	-	1-6 and 12 mo and yearly thereafter	Use of pain medication and surgeon's and patient's reports	1 vaginal bleeding managed surgically 8 h after surgery. At last follow- up 2 patients still complained of tight and vaginal pain respectively	-
Abdel-fattah <i>et al</i> ^[18]	Prosp. (Multi)	90	Ajust	-	Intra-op., after 30 min and 3 h post- surgery or at the time of discharge	10 point Likert scale	1 case had to be converted in standard MUS (kit fault). Median pain rate at the time of the discharge was 0 and didn't change during follow-up	-
Palma <i>et al</i> ^[19]	Prosp. (Multi)	124	Ophira	TOT	1-yr and 2 yr	Patient's impression	1 patient severe intraoperative pain sedation. 2 mesh resection: 1.6% 0% vs 1.7%	P > 0.05
Djehdian <i>et al</i> ^[20]	RCT	120	TOT: 56 Ophira: 64	-	Day 1 and after 4-6 wk	VAS		P = 0.04
Dias <i>et al</i> ^[21]	Prosp.	50	Altis	-	12 mo	Patient's report	1 mesh erosion treated surgically (2%)	
Kocjancic <i>et al</i> ^[22]	Prosp. (Multi)	101	Altis	-	During 12 mo follow-up	Patient's and surgeon's reports	Non-pelvic pain: 9 (8%) 3 serious adverse events (1 bleeding, 2 mesh extrusion requiring surgery)	
Lee <i>et al</i> ^[25]	RCT	206	MiniArc: 103 Monarc: 103	Monarc	24 h after surgery and 12 mo follow- up	Patient's and surgeon's reports	Women requiring analgesia: 0.5 vs 2 tablets) and groin pain 9.7% vs 33% 1 mesh erosion in the MiniArc group at 1 yr follow-up	P = 0.02 P < 0.01
Schellart <i>et al</i> ^[26]	RCT	173	MiniArc: 86 Monarc: 87	Monarc	3 d and 4 wk	VAS Use of pain medications	2 vs 3 8% vs 3%	P = 0.90 P = 0.37

Basu <i>et al</i> ^[27]	RCT	71	MiniArc: 38 Advantage: 33	Advantage	During follow-up	Patient's response on late adverse events	No late adverse events	-
Oliveira <i>et al</i> ^[23,30]	Prosp.	71	MiniArc	-	First 24 h	VAS	1.0 ± 1.4 (one patient had pain for 6 mo)	-
Deole <i>et al</i> ^[29]	Prosp.	59	MiniArc	-	Intra and post-op	Surgeon's and patient's reports and Wong-Baker score	No major intraoperative complications Wong-Baker score: 2 ± 1.5	-
Presthus <i>et al</i> ^[24]	Prosp.	31	MiniArc	-	Intra and post-op	Surgeon's and patient reports and Wong Baker faces	No major intraoperative complications Pain rate 9.6%	-
Kennelly <i>et al</i> ^[31]	Prosp. (Multi)	142	MiniArc	-	At discharge and at 7 d post-op	Surgeon's and patient's reports and Wong-Baker score	No major complications Median pain score 0	-

RCT: Randomized controlled trial; TOT: Trans obturator tape; Prosp.: Prospective; Multi: Multicentric.

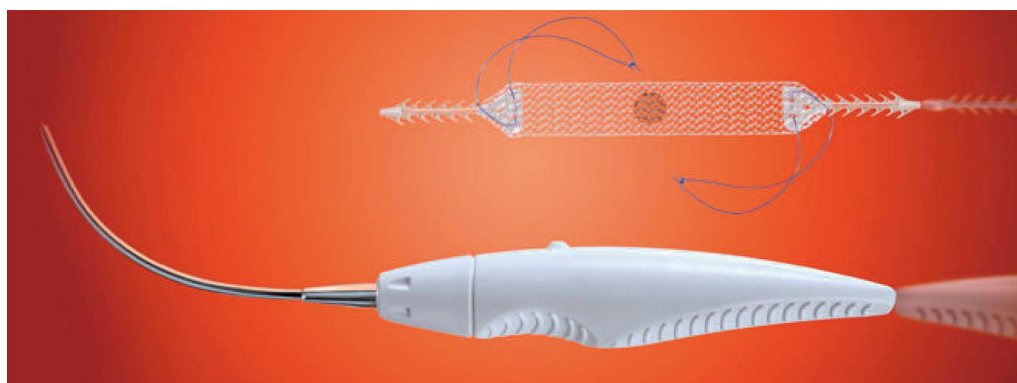


Figure 3 Ophira sling.

The delivery trocar is inserted in the small vaginal incision and guided by the surgeon toward the obturator internus. When half of the mesh is within the incision, the deployment button on the needle is pressed and the sling is kept in place by the self-anchoring fishbone columns.

Population: A total of two studies on Ophira® slings have been included in the review. One study is a prospective cohort study ($n = 124$) that includes women older than 18 years with a urodynamically confirmed diagnosis of SUI in absence of neurological disease^[19]. The second one is a RCT including also women ($n = 120$) older than 18 years but with positive CST, urine leakage greater than 2 g (measured by a standardized pad test with 250 mL bladder volume) and urodynamic stress incontinence^[20].

Evidence efficacy (Table 1): In the prospective cohort study by Palma *et al*^[19] 124 women were included in the study to assess efficacy, safety and predictors of failure of Ophira® slings. The authors compared also the results

at 1 and 2 years after surgery. Objective cure at 24 mo was 85.3% and improvement 6.3%. Overall 8.4% patient had failure and the only predictor of failure was previous incontinence surgery ($P = 0.04$)^[19].

In the randomized prospective trial by Djehdian *et al*^[20] comparing Ophira® and TOT, the efficacy at 12 mo was analysed using a non-inferiority test. They demonstrated no differences in terms of objective and subjective cure rates between the two slings in both intention to treat and per protocol analyses (all $P > 0.5$).

Overall failure rate was 19%. In the Ophira® group 5/64 patients (7.8%) did not achieve an objective and subjective cure, and were submitted to a second surgery. In TOT group, 1/56 (1.8%) of patients were submitted to a second surgery for failure. However no statistically significant differences have been found between groups^[20].

Evidence safety (complications and pain) (Table 2): No major complications were reported in both studies. In the prospective randomized paper there was no difference in terms of complications between the two



Figure 4 Altis sling.

groups. However the number of patients complaining of tight pain resulted to be significantly higher in the TOT group compared to the Ophira® group (7.1% vs 0% respectively; $P = 0.04$). Two patients in the Ophira® group had the tape cut for voiding obstruction^[20].

OAB symptoms: In the prospective cohort study, *de novo* urgency was reported in 9/124 patients (7.3%)^[19]. In the prospective randomized study comparing Ophira® slings with TOT, symptoms of urgency were determined by patient's self reported response to urogenital distress inventory short form 1 and 2. The authors reported a significant reduction of in urge symptoms in both surgeries; Ophira®: 35.9% vs 3.1% and TOT 15.7% vs 3.5% (all $P < 0.01$) but no statistically significant difference was found between groups^[20].

Altis® (Figure 4)

Method of action/working mechanism: The Altis® SIS is a low elasticity sling. The dynamic adjustability of the sling allows for accurate tensioning and placement of the sling in relation to the urethra. Its low elasticity and adjustability allows tensioning, placement and positioning of the sling under the urethra without compression.

The introducers are curved in shape and come as a set for the inside-out approach. They are designed for holding the anchor on the tip until insertion into the obturator membrane complex.

A monofilament suture is attached to the sling body and extends over the sides of the sling. The suture is connected to a dynamic anchor, which allows tensioning of the sling after placement. Positioning of the sling should be without tension to the urethra as the Altis® sling has a low 7.5% elasticity.

The surgical procedure is similar to the others single incision approaches. Using the introducer, the static anchor is placed through the obturator membrane. The dynamic anchor is then placed on the other side to be sure not to have tension. The suture extending from the sling and through the dynamic anchor is designed for two-way adjustability (metti Erwin). In all the studies included, a CST was performed to adequately tension

the sling. The dynamic anchors holding force and suture design prevents sling movement during the tissue in-growth period. This also eliminates the need for a locking mechanism. Following the procedure, the excess suture is cut and discarded.

Population: In the prospective observational study by Dias *et al*^[21], a total of 50 women completed the 1-year follow-up and were included in the analysis. All women had SUI or MUI (mixed urinary incontinence) with predominant stress component, a positive cough test and a previous failure of conservative treatments^[21]. The same inclusion criteria were used in the prospective multicentre study of Kocjancic *et al*^[22] ($n = 101$) where they demonstrated pre-operative incontinence also with urodynamic exam.

Evidence efficacy (Table 1): In the small observational prospective study by Dias *et al*^[21] the patient's reported subjective cure is 84% at 12 mo with an additional 8% of reported improvement. The objective cure, assessed with a standard CST is 92%. Failure was defined as the indication for mesh removal or absence of cure or improvement. Overall failure rate was 8%^[21].

In the prospective study of Kocjancic *et al*^[22] the overall objective cure tested with 24 PWT was 90% and CST was negative in 90.1% of patients. PGI-I was 89.3%. At 12 mo, 1 patient reported no changes compared to baseline and 2 patients reported the situation to be a little bit worse. Overall 2.9% of patients were not satisfied with the results^[22].

Evidence safety (complications and pain) (Table 2):

Dias *et al*^[21] demonstrated no major complications in their observational study. The authors report none of the patients to require significant analgesics (only oral ibuprofen and/or acetaminophen in the first few days were used), however we have no clear data on pain because of the lack of validated scale in this study^[21].

Kocjancic *et al*^[22] registered three serious adverse events: One included a pelvic hematoma after revision surgery for urinary obstruction, the second one was a mesh extrusion categorized as a serious adverse event because the patient withdrew the study before revision surgery. The third event was a mesh extrusion for which the sling was trimmed on two separate surgeries. No cases of persistent pelvic pain were reported^[22].

OAB symptoms: Just one of the included studies on Altis® sling analysed also the new onset of OAB symptoms. Dias *et al*^[21] reported *de novo* urge incontinence rate to be 5.9% (3/50 patients).

MiniArc® (Figure 5)

Method of action/working mechanism: One of the most widely used and studied SIS is the MiniArc®. It has been used to treat female SUI since 2007, when the original MiniArc® Single-Incision Sling System was



Figure 5 Miniarc sling.

introduced.

As the others, this is a minimally invasive procedure using a small (1.5 cm) vaginal incision and a sharp dissection to the inferior pubic ramus in order to create the trajectory for the needle. The tip of the needle is keyed to the sling extremity so that the mesh lay on the convexity of the needle. The sling is advanced through the trajectories created with the scissors bilaterally and its self anchoring tip pushed along the posterior surface of the of the ischio-pubic ramus, taking care not to perforate the obturator membrane^[23].

Population: A total of 7 studies analysing efficacy and/or safety of MiniArc[®] slings were included in the review^[23-29]. A total of 753 patients had a follow-up \geq 12 mo. All studies included women with SUI or mixed incontinence with predominant complains of stress. Only in one study women with mixed incontinence were excluded and only women with documented pure SUI were included^[23]. Women with a story of previous incontinence surgery, previous sling operation, concomitant pelvic prolapse \geq 2, neurogenic bladder, or predominant urodynamic detrusor overactivity, were excluded from the analysis in the majority of the studies.

Evidence efficacy (Table 1): Our selection of papers on MiniArc[®]^[25-27] slings includes two randomized clinical trials comparing MiniArc[®] and Monarc slings and one comparing MiniArc[®] and Advantage sling. In the RCT by Lee *et al*^[25] 103 patients in each group reached 1-year follow-up. There was no statistically significant difference in terms of subjective and objective cure rates between groups. Failure rate was 2.7% vs 1.8% in the MiniArc[®] group and in the Monarc group respectively; $P = 0.68$ ^[25].

In the RCT by Schellart *et al*^[26], comparing MiniArc[®] and Monarc women, subjective cure was similar between both groups. The objective cure rate, defined as negative CST during follow-up, was also not statistically different between groups. Overall a total of 4 failures requiring a second surgery for SUI were identified: 3 in the Monarc group and 1 in the MiniArc[®] group^[26].

Basu *et al*^[27] in 2013 published the three-years

results from their randomized trial comparing Advantage[™] slings and MiniArc[®][™]. They reported a success rate of 48% for MiniArc[®][™] with a failure rate of 52% (combining subjective failures with the need for repeat continence surgery). Moreover the MiniArc[®] were associated with a higher rate of persistent SUI (34% vs 9%)^[27].

Overall 5 prospective studies on MiniArc[®] slings were included in the review^[23,24,28,29]. Oliveira *et al*^[23,30] reported 12 mo follow-up of patients with pure SUI. The intention to treat analysis showed a subjective cure rate of 80% and an improvement of 11%. The same group updated the analysis at 45 mo and showed 70 patients of the 77 responders to maintain the initial improvement/cure rate (91%).

All the other cases were reported as failures (7% in patients with 1-year follow-up)^[23,30].

Deole *et al*^[29] showed lower rates of objective and subjective cure at 1-year compared to other studies (66% and 64% respectively). They did demonstrate a statistically significant difference in post-operative subjective cure rates (defined as mean ICIQ-SF scores) compared to pre-operative scores (mean 8.6% \pm 6.6% vs 16% \pm 3.7% respectively, $P < 0.001$). Failure was reported in a total of 3/59 patients (5%) of which 1 was lost at follow-up but included in the analysis as failure. The other 2 patients reported persistent obstructive symptoms (requiring transection) and erosion of the mesh respectively^[29].

In the prospective cohort study by Presthus *et al*^[24] the objective cure ranged between 90% and 93% at 24 mo. Moreover patients reported a statistically significant improvement in UDI-6 and II Q-7 compared to baseline. The percentage of patients with improvement in UDI-6 and IIQ-7 scores was 90.3% and 100% respectively. Failure rate was 9.6% (a total of 3 patients at 24 mo)^[24].

Kennelly *et al*^[28,31] in 2012 reported objective and subjective cure to be 84.5% and 93% respectively. Moreover a significant improvement occurred in UDI-6 and II Q-7 compared to baseline. In their first paper of 2010, a total of 4 patients were reported to have surgical failures within the first year of follow-up. However no additional cases of surgical failure or adverse events have been reported from 12 to 24 mo^[28,31].

Evidence safety (complications and pain) (Table 2): No major complications were reported in all the studies assessing MiniArc[®] safety. Lee *et al*^[25] reported a statistically significant higher rate medication use and groin pain in Monarc group (all $P < 0.05$). Schellart *et al*^[26] demonstrated a statistically significant difference pain score in the first 3 d after surgery in favour of MiniArc[®] patients.

No late side effects, pain or complications were registered by Basu *et al*^[27], at 3-year follow-up^[25-27].

Overall low pain scores were registered also in the prospective studies included in this review. Only one patient reported groin pain for more than 6 mo after

MiniArc® implant. Pain rates were generally very low either using VAS or patient reported impressions during the entire follow-up^[23,24,28,29].

OAB symptoms: In the RCT by Lee *et al*^[25] there was no difference in terms of post-operative OAB symptoms between the two groups at 1-year follow-up (median ICIQ OAB scores: 3 vs 3 in MiniArc® and monarc respectively; $P = 0.48$). However a difference was registered in terms of use of anticholinergic medications (5.5% vs 15.8% in MiniArc® and Monarc respectively; $P = 0.034$)^[25]. On the other end Schellart *et al*^[26] did not show any difference in terms of UDI-6 domain score for irritative symptoms between the two groups at 1-year follow-up.

Oliveira *et al*^[30] showed a new onset of OAB symptoms in a total of 7 patients (6%). However the symptoms were classified as mild to moderate and solved spontaneously or were well controlled with anticholinergics. Deole *et al*^[29] reported a 24% of *de novo* urgency symptoms of which 9% required anticholinergics at 3 mo follow-up. *De novo* urgency incontinence rate was reported to be 10% at 24 mo by Kennelly *et al*^[31]. Presthus *et al*^[24] reported only one patient to have *de novo* urge incontinence after surgery (3.2%) and of 10 patients witheline OAB symptoms, 90% reported no more symptoms at 24 mo.

DISCUSSION

The European Association of Urology Guidelines, concerning the treatment of female SUI, report that MUS, inserted by either the transobturator or retropubic route, give equivalent patient-reported outcome at 12 mo^[7].

SIS represent the last modification to the MUS for SUI. They require very limited dissection and might further increase safety of sub-urethral slings. Many options have been proposed on the market but despite the increasing interest in SIS and their widespread use, there are still conflicting results on their effectiveness and safety.

Many recent reviews and meta-analysis on effectiveness and complications of SIS vs standard MUS have shown better outcomes for SIS in terms of operating time, better recovery and less intraoperative bleeding^[5,13,32]. However there is still a lack of standardized characteristics for the ideal candidate for minislign surgery. There exist several different types of SIS systems with different characteristics that show different outcomes. The results of a particular SIS system cannot be transposed to another. In this review we report efficacy and safety of SIS and their effect on OAB symptoms, in patient with more than one year follow-up. We didn't focus our research on the advantages of SIS in terms of operating time or intraoperative bleeding already extensively assessed in previous reviews.

In our review we analysed different SIS systems,

namely: Ajust®, Ophira®, Altis® and MiniArc®. Given that 63% of the studies included in the review are prospective or retrospective studies (level of evidence 3) we have to conclude that the evidence for SIS remains quite weak^[7].

Nevertheless 2 randomized studies including 293 patients and comparing Ajust® sling with traditional TOT sling demonstrated high objective and subjective cure rates (ranging between 81% and 91% for objective cure and between 77% and 85% for subjective cure) and no difference between groups. Failure rate ranged between 2.2% and 7.2% but no difference was found between groups^[9,11].

A third randomized study including Ajust® and MiniArc® slings showed no differences between the two slings in objective and subjective cure on the short term (OC: 80% vs 82.5% and SC: 90% vs 92.5%). However, a statistically significant difference was found when comparing the results at 6 mo with the results at 24 mo (OC: 47% vs 55% and SC: 52.5% vs 65%) in Ajust® and MiniArc® respectively, with lower rates of objective and subjective cure compared to the short term follow-up and other studies^[12]. This decline, in OC and SC rates, has not been demonstrated in other studies by several other groups. The reason for this inferior resulted in this particular study is not clear.

Data from prospective studies analysing the efficacy of Ajust® sling on a total of 328 patients showed an objective cure rate between 80% and 84% and a subjective cure between 81% and 83%. However there was a variability between studies in terms of failure rates (range 0.02% and 14%).

In the RCT study comparing Ophira® slings and TOT, no difference was found in objective and subjective cure either in intention to treat analysis and per protocol analysis^[20]. Palma *et al*^[19] in their prospective study on Ophira®, showed higher rates of objective cure with a 6.3% improvement at 2 years but also higher rates of failure compared to the RCT (8.4% vs 7.8% respectively).

We found no RCT assessing the efficacy of the Altis® sling. Two prospective cohort studies on 151 patients with 12-mo follow-up did show similar results in terms of objective cure compared to the other RCTs (90.2% and 90%)^[15,21,22].

One of the most widely used SIS is the MiniArc® sling. Our review includes a total of 3 RCT comparing MiniArc® to traditional MUS (namely Monarc and Advantage) including data on 450 women. The objective cure assessed with standard CST in the studies by Lee and Schellart was respectively 94% and 92% in MiniArc® slings and no difference was found between groups in both alayses. In this case, the MiniArc® sling was not inferior to monarc with respect to both objective and subjective cure. Failure was 1.8% and 0.5 % in Lee and Schellart paper respectively.

Basu *et al*^[27] recently published the three years results of their RCT comparing MiniArc® to advantage sling. They reported a success rate of 48% in MiniArc®

slings and a failure rate of 52% (combining subjective failures with the need of repeat continence surgery). Moreover the MiniArc® slings were associated with a higher rate of persistent SUI.

Oliveira *et al.*^[30] described a success rate for MiniArc® slings of 88%, analysing only patients completing the 1 year follow-up visits. Failure rate however was higher compared to the two RCT (7%). The other prospective studies included in the paper showed results in line with the aforementioned RCT: The objective cure varied between 77% and 93%. Failures rates ranged between 3% and 7%. It is to underline that Deole *et al.*^[29] showed lower rates of cure compared to the other authors but a statistically significant difference compared to baseline.

We would like to underline that objective cure rates have been assessed using the standard cough stress test with 200 mL in the bladder in the majority of the studies, so it was possible to compare the different studies in terms of objective cure with an average objective cure rate of 88%.

It was not possible to compare subjective cure between studies since there was a great variability in terms of test performed (the majority of them were patient reported improvement or impression).

The vast part of the included studies did not show any major complication for minisliling surgery. However Cornu *et al.*^[17] reported 1 post-operative vaginal bleeding requiring surgery and Kocjancic a serious pelvic hematoma and a mesh extrusion causing the abandoning of the study before second surgery and Dias showed 1 mesh erosion requiring surgery in the Altis® group. Two mesh erosions requiring surgery were registered also in the Ajust® group. In the Ophira® group two patients had the mesh cut for post-operative voiding obstruction.

Pain rate is another parameter difficult to compare because of the lack of standardized questionnaires or examinations. The majority of data obtained on pain were assessed by patient reports or VAS scale (also a subjective scale). However we can observe very low reported pain rates.

None of the patients reported persistent pelvic pain at long term follow-up. Both RCTs on Ajust® and MiniArc®, showed better outcomes in terms of immediate post-operative pain compared to traditional slings^[25,26].

Again due to variability in the used parameters, it was not possible to systematically assess the new onset of OAB or worsening of the pre-existing OAB symptoms in all patients. It is of notice that all studies except 1 included also women with pre-existing mixed symptoms.

Some studies showed a trend toward higher rates of *de novo* urgency or worsening of pre-existing symptoms in the first months after surgery. We can assess that an average rate of 10% of *de novo* OAB symptoms or worsening of the pre-existing incontinence were reported in the minisliling studies. On the other hand, Mostafa, Cornu and Djehdian showed a decrease in post-operative urgency in patients with baseline OAB

symptoms. Moreover Presthus *et al.*^[24] demonstrated a 90% improvement in OAB symptoms after MiniArc® slings in patients with pre-operative urgency.

This review shows an average objective cure rate of 88% in minisliling patients and underlines their comparable efficacy with traditional slings. Short-term pain, complication and failure rates are lower in the minisliling group. In general we showed good results of minislings on the short and medium follow-up compared to traditional MUS. However this result supports the need of long-term follow-up, prospective, randomized trials, with adequate numbers and validated questionnaires to identify the best candidate for this type of procedure.

COMMENTS

Background

Single incision slings (SIS) represent a minimal invasive treatment for stress urinary incontinence (SUI). Some SIS have proven their efficacy on the short, medium and long-term follow in comparative studies with traditional mid urethral slings (MUS). The final purpose of this study is to guide the physician into the correct management of incontinent patient in order to give them a correct counselling in terms of surgical treatment of SUI.

Research frontiers

MUS were developed as a less invasive approach to the treatment of SUI. Nowadays the use of synthetic MUS is the most common surgery performed for SUI in women. The SIS are one of the latest innovations for female SUI. Their anchoring mechanism avoids the passage of trocars through the obturator foramen. Some studies have already proven their efficacy on the short, medium and long term.

Innovations and breakthroughs

The purpose of this study is to review the evidence for different SIS systems and to compare them with traditional MUS. The authors give an overview on the principal SIS currently available, defining their efficacy and safety.

Applications

This review can give the physician a tool to simplify the clinical decision-making on the base of the existing literature.

Terminology

SUI: Stress urinary incontinence; MUS: Midurethral slings; SIS: Single incision slings; TOT: Trans obturator tape; TVT: Tension free vaginal tape; RCT: Randomized controlled trial; OC: Objective cure; SC: Subjective cure; OAB: Overactive bladder; UPS: Urgency perception scale; PGI-I: Patient Global Impression of Improvement; CST: Cough stress test; PWT: Pad weight test; ITT: Intention to treat; PP: Per protocol; ICIQ-SF: International Consultation on Incontinence Questionnaire - Short Form; UI-SF: Urinary incontinence-Short form; UDI-6: Urogenital Distress Inventory.

Peer-review

This is a nice review.

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