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A retrospective, single-center safety audit of the altis® single incision sling in the surgical treatment for female stress urinary incontinence

A RETROSPECTIVE, SINGLE-CENTER SAFETY AUDIT OF THE ALTIS® SINGLE INCISION SLING IN THE SURGICAL TREATMENT FOR FEMALE STRESS URINARY INCONTINENCE

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BACKGROUND

(Adjustable) single incision slings (SIS) are the latest generation of midurethral slings (MUS), used for the surgical treatment of female stress urinary incontinence, that seek to minimize the morbidity and complications associated to the conventional retropubic and transobturator midurethral slings. Its use has recently come under scrutiny following concerns about long-term complications.

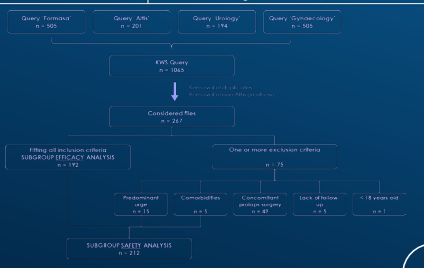
AIMS

We conducted an internal audit of the short-to-medium term safety and absence of (reported) complications of the Altis® SIS in our medical center (University Hospital of Leuven, Belgium). Secondary outcome was treatment efficacy, defined as no self-reported SUI symptoms.

METHODS

File review of all patients implanted with an Altis® sling, since its introduction at our institution in 2014 until May 2021 was performed.

INCLUSION CRITERIA	EXCLUSION CRITERIA
Altis® Sling as used prosthese	< 18 years old (n=1)
Implantation between 2014 and May 2021	Lack of follow-up (n=5)
Adult age (≥ 18 years old)	Concomitant pelvic organ prolapse surgery
≥ 1 follow-up consultation	Predominant Urge (incontinence) (ONLY EXCLUDED FROM EFFICACY ANALYSIS)
	Co-morbidities affecting bladder function (ONLY EXCLUDED FROM EFFICACY ANALYSIS)



STUDY POPULATION

212 women were included in our safety analysis, 192 women in the efficacy analysis.

RESULTS Highlights

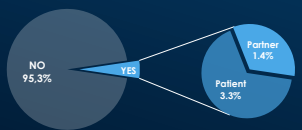
MESH EXPOSURE

	NO	YES	
Separation of Vaginal Mucosa *	195	16	
Exposure of Vaginal Mesh **	195	16	< 1 CM: 12; > 1 CM: 4
Perforation/ Erosion into Urethra	212	0	

* Separation defined as a physical disconnection of, in this case, the vaginal
** Exposure defined as displaying and revealing the Altis® sling through separated vaginal epithelium

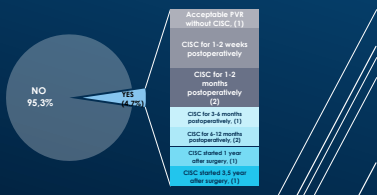
Mesh exposure occurred in **16 women** (7.5%) after a mean period of **15 months postoperative**. 11 women (5.2%) underwent excision of the exposed mesh.

DYSPAREUNIA



Dyspareunia for the **patient (3.3%)** or her **partner (1.4%)** was encountered in nine cases. Four cases were linked to mesh exposure of which three underwent partial sling excision.

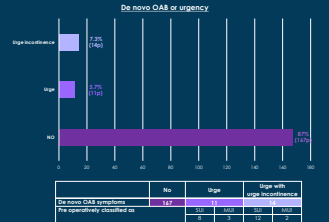
POST-VOIDING RESIDU



Ten women (4.7%) who did suffer from postoperative retention or elevated residue, needing CISC **in seven (3.3%) cases**, for varying period of time.

MORE RESULTS

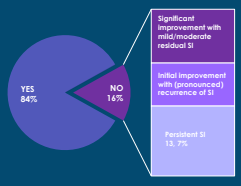
URGENCY



	No	Urge	Urge with urge incontinence
De novo OAB symptoms	182	11	
Pre operatively classified as		SUI: 8	MUI: 3 / SUI: 12 / MUI: 2

De novo urgency (5.7%) and **urge incontinence (7.3%)** were reported in 25 women (13%) and was managed with anticholinergic drugs.

2nd OUTCOME: SUBJECTIVE SUCCESS RATE



83.8% reported no residual urine loss at the first post-operative consultation. Thirteen women (6.7%) had persistent SUI. Eight women (4.2%) underwent reintervention receiving a second sling.

REINTERVENTION

In total, 10.4% underwent a reintervention:

- In eleven women (5.6%) the Altis® sling was excised. All of them, except for one, due to mesh exposure. Afterwards, three women got a new sling implantation (TOA® or Altis® sling).
- Eight women (3.8%) received a second sling, due to persistent (5 cases) or recurrent (3 cases) SUI.