

ABSTRACT

Background: Urinary incontinence (UI) has been described as any complaint of involuntary leakage of urine. Stress urinary incontinence (SUI) is estimated to affect 13-46% of women. The aim of this study is to report our results on the efficacy and safety of a novel adjustable single-incision sling (Altis® Coloplast, France) for the treatment of female SUI based on more than five years of follow-up.

Methods: Retrospective review of 197 patients treated with Altis® for SUI between February 2012 and March 2018. Preoperative demographic data, comorbidities, and pressure-flow studies were also recorded. Continence status and satisfaction rates were assessed using the International Consultation on Incontinence Questionnaire-short form (ICIQ-SF) and Patient Global Impression of Improvement (PGI-I) respectively.

Results: Mean follow-up time after surgery 85,3 months (82,5 – 88,1). In 2022-2023, complete continence was present in 75,4% of the patients. The presence of urinary urgency conditioned the ICIQ-SF score (10,9 vs 1,7 points, $p < 0,01$), with ICIQ-SF=0 in 84,5% of the patients with no associated urgency. Satisfaction assessed by PGI-I was high, with 84,6% of the patients showing improvement. De novo urgency was present in 37,9% of the patients by 2022. Urinary tract infections were the most frequent complication (9,7%), with only 5 documented cases of mesh erosion.

Conclusions: Altis® SIS is a safe and effective device for SUI treatment, with satisfaction rates comparable to those of the conventional slings. Persistence or development of urinary urgency influences the results.

METHODS

Retrospective, non-randomised, multicentre study.

Two-hundred twenty-three women (223) underwent sling placement in two tertiary hospitals in Spain from February 2012 to March 2018. Of these, we analyzed 197 having a minimum follow-up of 5 years. Data collected: clinical interview, physical examination of the patients with cough stress test, urinalyses, and urodynamics (flowmetry or complete study).

Outcomes: cough stress test, administration of the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) and recording of complications following IUGA recommendations. Follow-up was performed at 1, 6, 12, 24, and 60 months postoperatively. After 2 years without complications and with adequate evolution, the patients were discharged from the Functional Urology Department.

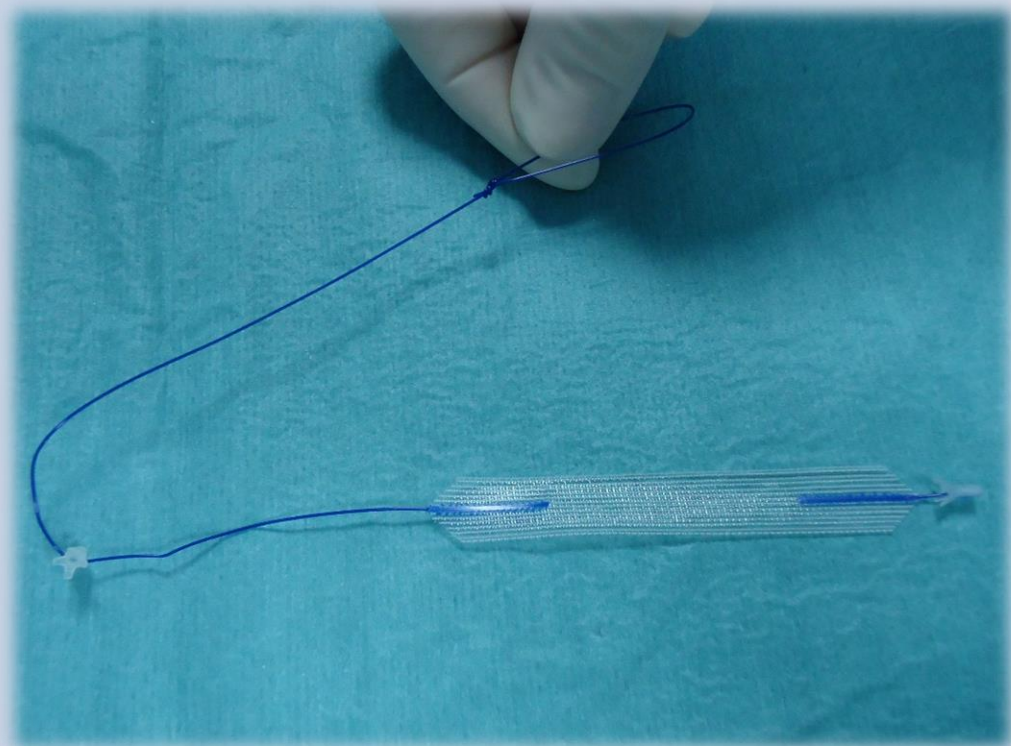
Success criteria were as follows:

- Success: negative cough stress test.
- Improvement: positive cough stress test with a lower ICIQ-SF index.
- Failure: positive cough stress test with the same or worse ICIQ-SF index.

Between 2022 and 2023, a structured telephone survey was conducted with all patients who underwent surgery during the study period, analyzing the presence of incontinence and urgency, the occurrence of complications and overall satisfaction with the procedure

Continence status was established using the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) and a subjective stress incontinence test. Satisfaction was assessed using the Personal Global Impression of Improvement scale (PGI-I).

Statistical analysis was performed using Stata 2.0.

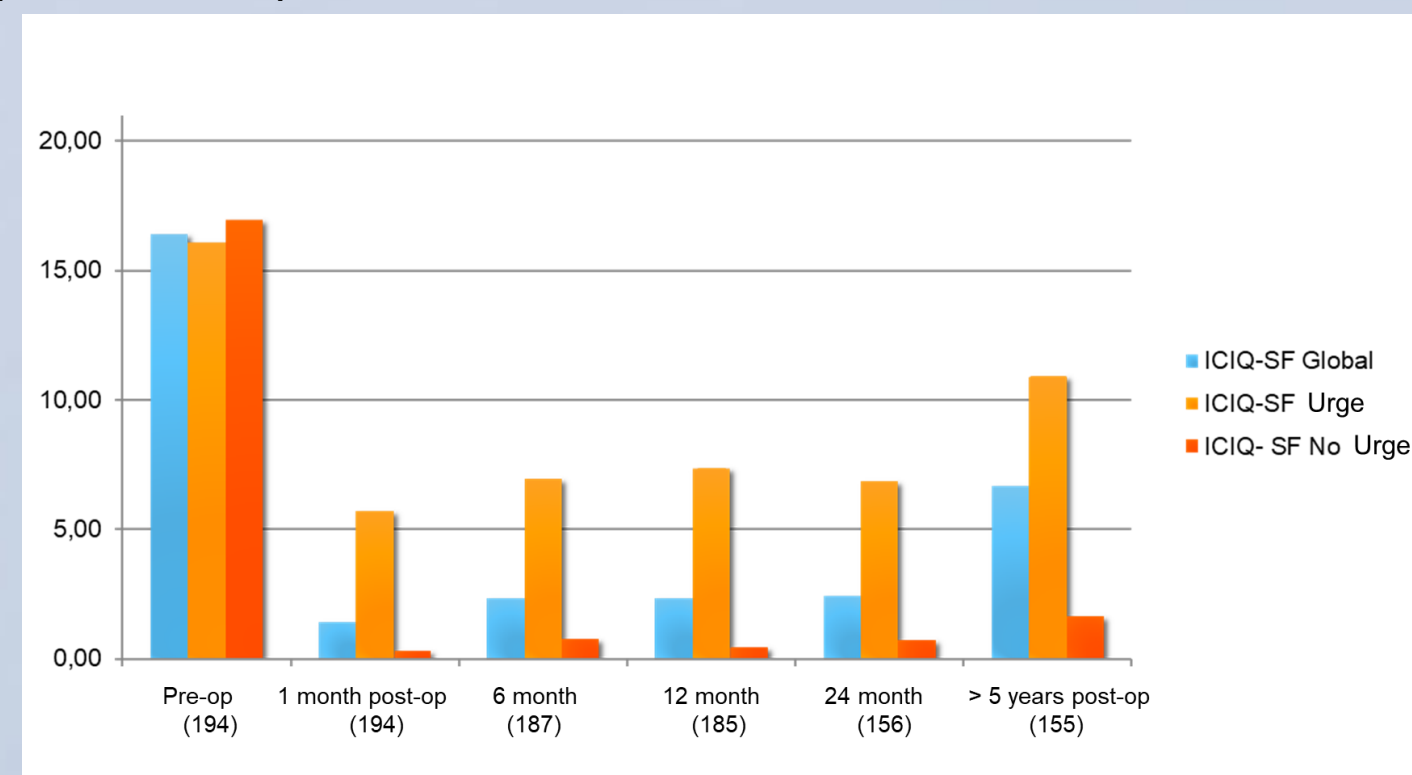


RESULTS

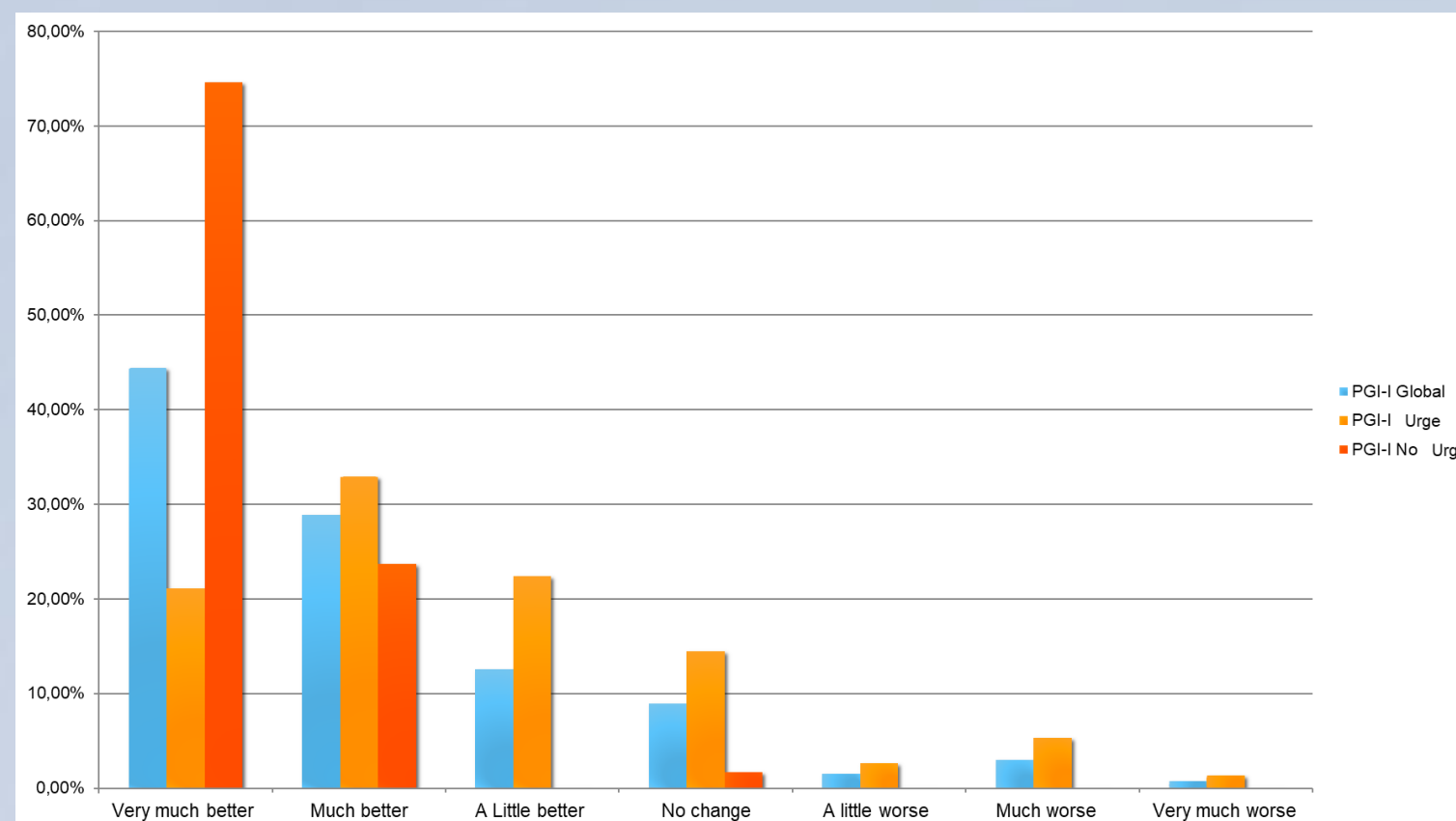
Patients analyzed: 197 (155 surveyed; 21% loss to follow-up). Mean follow-up time in 2023 was 7.1 years (6.9 - 7.3), with a maximum follow-up of 10.3 years. Mean age was 57.5 years (± 12.7). Simultaneous prolapse correction was performed in 30 patients and 28 patients (14.3%) had previous anti-incontinence surgery. Preoperative urgency was present in 118 patients (60.2%). Ninety-nine patients presented mixed incontinence (57%).

Continence rate was 92.4% at 2 years follow-up and was maintained over time, with 75.6% of patients surveyed in 2022-2023 having a negative cough stress test.

The evolution of the ICIQ-SF was analyzed and decreased by an average of 9.6 points (8.5-10.8). Although the overall value remained low, when analyzed according to the presence of OAB, the values for patients with pure SUI were much lower.



Patients' perception of improvement was also influenced by the presence of overactive bladder (OAB), being very high in patients with pure SUI (97.1%) and clearly lower in patients with OAB (75.3%).



Complications:

- Mesh erosion in 5 patients (3.22%)
- Mesh removal in 10 patients (5.1%): 4 recurrences of SUI, 3 erosions (3bT2S1, 3bT1S1 and 3bT2S2), one groin pain (6bT2S4), one urinary retention (4bT2S5) and one accidental section.
- High postvoiding residue, obstruction and partial excision of sling in two patients (4bT2S1).
- Nine patients developed chronic groin pain (1Be T2 S3 and 8Bd T2 S3).
- In 2023, 87% of patients (135/155) had no long-term complications. The most frequent complication was urinary tract infection (9.7%).

De novo OAB was described in 2.5% (2/78), 9.4% (7/74), 11% (8/73), 18.7% (12/64) and 38% (22/58) at 1, 6, 12, 24 months and at the time of the survey, respectively.

CONCLUSIONS

Single-incision slings have been proven to have high efficacy and good safety during follow-up (1). This is the largest cohort reported to date of patients treated with this single incision sling (2). The persistence or occurrence of OAB influences long-term satisfaction rates and patients with mixed urinary incontinence should be warned about this, prior to surgery. Development of de novo OAB, in line with the ageing population, may diminish the perception of improvement in these patients.

The Altis® single-incision sling is an efficacious and safe device for the treatment of SUI in females. Promising initial data has been confirmed during follow-up. Results on overall continence and satisfaction were high but were clearly influenced by the presence and development of OAB.

REFERENCES

1. Abdel-Fattah M, Cooper D, Davidson T, Kilonzo M, Hossain M, Boyers D, Bhal K, Wardle J, N'Dow J, MacLennan G, Norrie J. Single-Incision Mini-Slings for Stress Urinary Incontinence in Women. *N Engl J Med*. 2022 Mar 31;386(13):1230-1243. doi: 10.1056/NEJMoa2111815. PMID: 35353961.
2. Kocjancic E, Erickson T, Tu LM, Gheiler E, Van Drie D. Two-year outcomes for the Altis® adjustable single incision sling system for treatment of stress urinary incontinence. *Neurourol Urodyn*. 2017 Aug;36(6):1582-1587. doi: 10.1002/nau.23156.