

#128 Long-term outcomes of the Ajust™ single-incision sling compared to the Align™ transobturator tape: a secondary analysis from a randomized controlled trial.

Introduction

- Single-incision midurethral slings (SIMS) were introduced with the aim of offering similar efficacy to transobturator suburethral tapes (TOT) with reduced morbidity for the treatment of female stress urinary incontinence (SUI).
- The effectiveness of SIMS in the long term is not well established.
- The aim of this study is to compare long term effectiveness and complications of the SIMS Ajust™ and Align-TO™ transobturator tape.

Methods and Materials

- Secondary analysis from a multicentre RCT¹.
- Patients attended at the coordinating centre.
- Non-inferiority design.
- Block randomization stratified by centre.
- Allocation ratio 1:1.
- Concealment: opaque and sealed envelopes.
- Eligibility: SUI or stress-predominant mixed UI.
- Exclusion: urgency predominant MUI, sphincter deficiency, urethral low mobility (Q-tip <30°), neurogenic bladder.
- Primary outcome: cure/improvement rate, defined by combined objective and subjective criteria.
- **Trial registration:** ClinicalTrials NCT01699425.

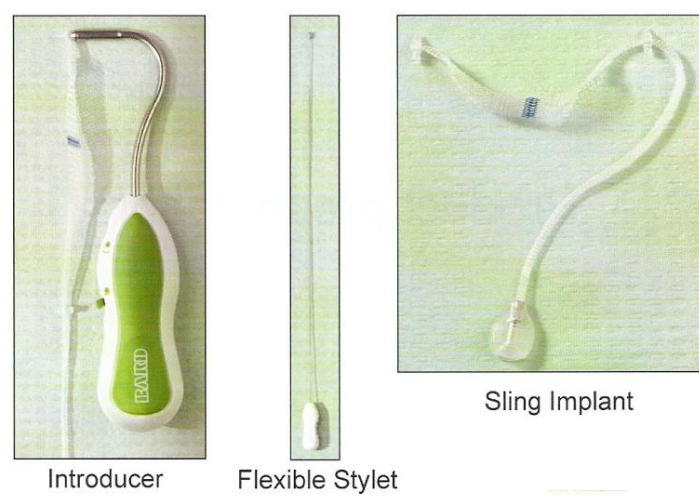


Table 1. Baseline characteristics

	Align™	Ajust™	p
Age (years) [†]	59.1 [47.4 – 78.9]	62.6 [44.8 – 73.7]	0.813
BMI [†]	28.4 [25.8 – 40.9]	29.7 [23.7 – 38.8]	0.949
Vaginal deliveries [†]	2 [1 - 3]	2 [1 - 6]	0.749
Menopause [†]	15 (78.9)	18 (90.0)	0.407
Smoking habit [†]	3 (15.8)	2 (10.0)	0.661
Previous surgery [†]	1 (5.3)	2 (10.0)	0.579
Associated POP [†]	7 (36.8)	6 (30.0)	0.651
Previous UUI [†]	13 (68.4)	10 (50.0)	0.242
Associated surgery [†]	8 (42.1)	7 (35.0)	0.648
Vaginal hysterectomy + anterior repair	2	3	
Manchester procedure	1	0	
Anterior repair	3	1	
Posterior repair	1	1	
Anterior and posterior repair	0	1	
Hysteroscopy	1	1	

BMI: Body mass index. POP: Pelvic organ prolapse. UUI: Urinary urge-incontinence.
[†]Data expressed in median [range]. [‡]Data expressed in n(%).

Results

- Present cohort: TOT Align™ n=19 and SIMS Ajust™ n=20.
- Similar initial characteristics (table 1).
- **Median follow-up:** Ajust™ = 48.5 and Align™=56.3 months.
- Failures:
 - Align™ = 0
 - Ajust™ = 5 → 2 IUE, 2 severe IUU, 1 MUI.

• Questionnaires:

	Median difference		p
	Align™	Ajust™	
ICIQ-SF	-14	-12	0.70
Sandvik	-8	-6.5	0.57

Figure. Kaplan-Meier survival functions for the effectiveness of the slings. The steps indicate failures.

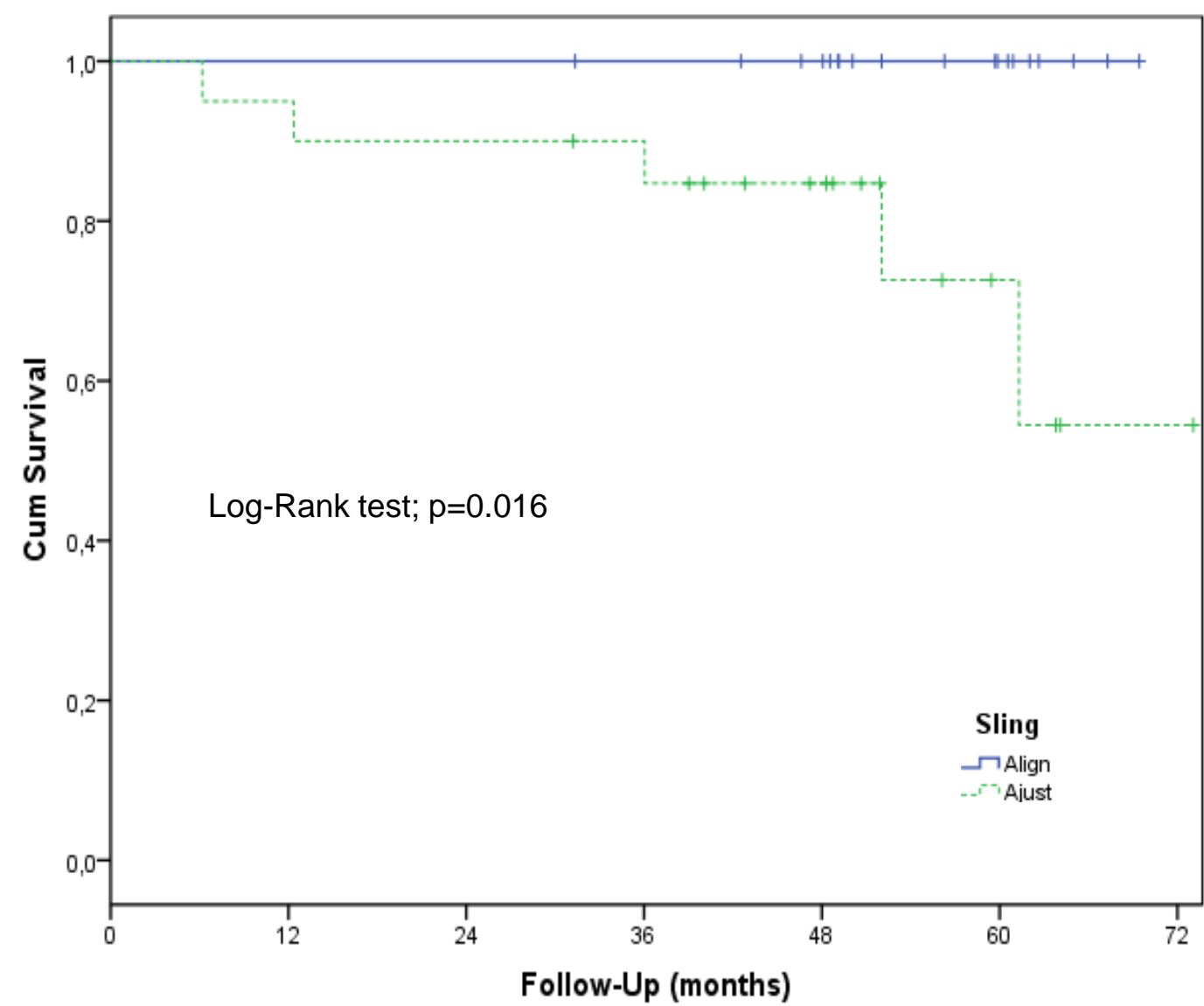


Table 2. Long-term adverse events

	Align™	Ajust™	p
Thigh pain	1 (5.3%)	4 (20%)	0.17
Dyspareunia	0	1 (5%)	0.32
Anchor displacement		1 (5%)	NA
Sling erosion	0	0	1
Sling division	1 (5.3%)	1 (5%)	0.97
New SUI surgery	0	2 (10%)	0.16

Interpretation of Results

- Effectiveness of SIMS Ajust™ seems to decrease over time more than that of standard TOTs.
- More cases of persistent pain in the Ajust™ group have been observed.



Concluding Message

- Effectiveness of SIMS over time is a major concern.
- Present results should be taken with caution (small sample / subset of patients).
- Long term effectiveness of SIMS should be evaluated accurately before to establish what their place in clinical practice is.
- The question of long term pain of SIMS Ajust™ should also be further investigated.

References

1. Sabadell J, Palau-Gené M, Huguet E, Montero-Armengol A, Salicrú S, Poza JL. Multicentre randomized trial of the Ajust™ single-incision sling compared to the Align™ transobturator tape sling. Int Urogynecol J 2017(28):1041-47.