

I-STOP Suburethral Sling: Outcomes of a Non-Deformable Sling for Intrinsic Sphincter Deficiency

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SUI: Spectrum of disease

- › Spectrum of urethral dysfunction in SUI patients



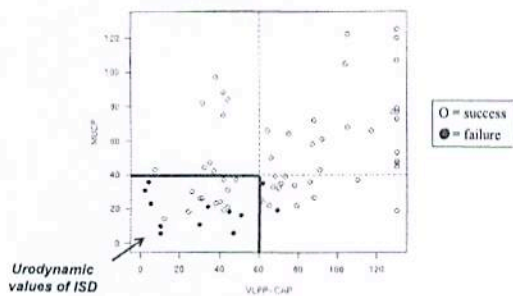
- › ISD patients:

- › More severe incontinence & urgency symptoms
- › Greater incidence of associated voiding dysfunction
- › More scarring from previous anti-incontinence procedures
- › Lower chance for surgical success
- › Higher rate of sling-related complications

Rezapour M, Falconer C Int Urogyn J 2001



TOT slings for ISD have inferior results



Guerrite, Davila Int Urogyn J 2008



RCT: TOT vs. TVT

- › RCT comparing TVT vs TOT for ISD

- › 6 month follow-up
 - › 21% TOT vs 45% TVT urodynamic SUI (p=0.004)
 - › 9.7% TOT vs no TVT had repeat SUI surgery
- › 3 year follow-up (IUGA/ICS 8/2010):
 - › 18.3% TOT vs 1.2% TVT underwent additional SUI surgery due to sling failure (p<0.001)
 - › Performing TVT over TOT avoids 1 in 6 failures

Schierlitz L, Dwyer P et al. Obstet Gynecol 2008



Biomechanical properties of sling types

- › Softness ↔ Hardness
- › Shrinkage ↔ Stability
- › Elasticity ↔ Stiffness

Alternative sling types and tensioning techniques may be of benefit to patients with severe SUI such as those with ISD



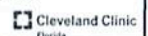
I-STOP* Sling

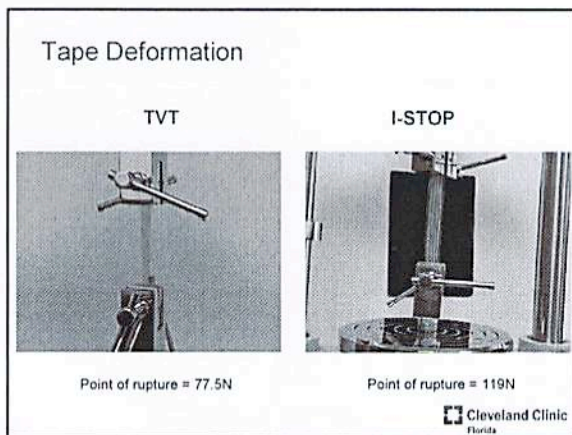
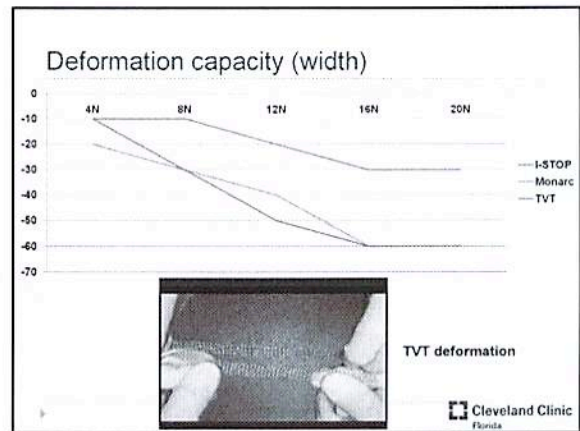
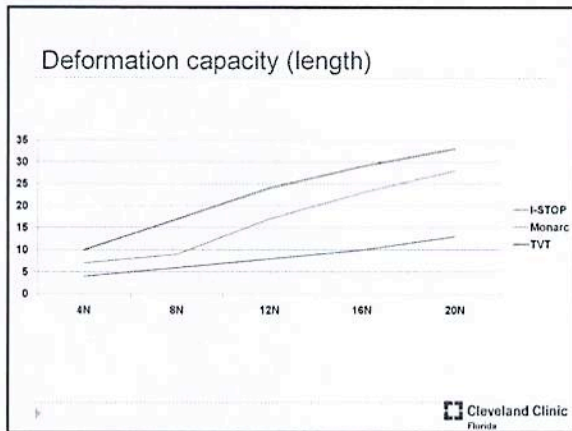
- › Monofilament, macroporous
- › Looped mesh edges
- › Maintains rigidity across width
- › Fibrous ingrowth
- › Low erosion risk
- › Minimal tape shrinkage & migration



More predictable urethral support & less postoperative voiding difficulties?

*CL Medical, Boston, MA





Why is non-deformability important in ISD?

- › Allows for a more precise individualized tensioning in order to optimize sphincteric function
- › More predictable support to the proximal and mid-urethra upon appropriate tensioning
- › Lack of deformation may reduce tape shrinkage and thus lead to less post-operative voiding difficulty and dysfunction

Pariente J, Villars F et al. Prog Urol 2005

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Objective

To determine the post-operative efficacy and safety of a non-deformable retropubic sling for the treatment of stress incontinence due to intrinsic sphincter deficiency

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Methods

- › Retrospective case-series of all patients who underwent an I-STOP suburethral sling at Cleveland Clinic Florida between 2007-2009
- › Inclusion criteria:
 - Symptomatic stress incontinence
 - Urodynamic diagnosis of ISD with urethral hypermobility
 - › Valsalva LPP ≤ 60
 - › MUCP ≤ 20

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Methods

Intraoperative

- › Complications
- › EBL
- › Bladder perforation

Postoperative outcomes

- › Subjective
 - › Complaint of SUI
 - › Incontinent events/ day
- › Objective
 - › Standardized cough stress test
 - › Postvoid residual

I-STOP Procedure

- › Similar technique to standard TVT or other retropubic sling
- › 3cm suburethral incision & 2 small suprapubic incisions
- › Full urethral mobilization is performed
- › 2 introducers guided through Space of Retzius, delivered through ipsilateral suprapubic incisions
- › Cystoscopy to confirm bladder integrity

Individualized Tensioning

- › Tape secured w/ suture suburethrally
- › Tensioned with a cystoscope in the urethra at a 45° angle (normalization without overcorrection)
- › Tape flat beneath urethra



Results: Baseline patient characteristics

	n=191
Age	66.5 (12.6)
Vaginal parity	2.4 (1.5)
BMI	29.8 (7.3)
Postmenopausal	161 (84)
Previous surgery	
Hysterectomy	84 (44)
Sling	19 (10)
Burch/MMK	7 (4)

Mean (standard deviation); n(%)

Results: Concomitant surgical procedures

ASSOCIATED PROCEDURES	N	%
I-STOP Alone	60	31.4%
+ VVS-A/P Repair	34	17.8%
+ Lefort Colpocleisis	27	14.1%
+ A/P Repair	23	12.0%
+ TVH-McCall-A/P Repair	20	10.5%
+ Post Repair	18	9.4%
+ ASC-A/P Repair	5	2.6%
+ Perigee- A/P Repair	3	1.2%
+ Elevate + Post Repair	1	0.5%

Results: Other intraoperative characteristics

Anesthesia	
General	108 (57)
Spinal	78 (41)
Combined	5 (3)
Estimated blood loss	125cc ± 54
Bladder perforation*	1 (0.5)

n(%); Mean ± standard deviation

* Requiring continuous bladder drainage

Results: Postoperative outcomes

	Postop
"Cure" or "Greatly improved"	174 (91)
Reported daily leakage	25 (13)
Negative cough stress test	185 (97)

• n(%)

• Mean follow-up: 30 weeks (range 6-50)

Results: Postoperative complaints

	Preop	Postop
Stress Incontinence	79 (41)	14 (7)
Mixed Incontinence	77 (40)	15 (8)
Urgency/ Urge Incontinence	35 (18)	40 (21)

n(%)

Denovo urgency: 5 (2.6%)

Results: Postoperative (other)

- › No significant voiding dysfunction postoperatively
 - Mean post-void residual (PVR) at first post-operative visit = 49ml
- › No sling revisions for BOO performed
- › No tape exposures/erosions

Conclusion

- › The I-STOP sling is a safe and effective treatment for ISD
- › Non-deformable tape construction
 - Individualized suburethral tensioning
 - Less risk of tape shrinkage
 - High continence rate → minimal risk of denovo urgency & voiding dysfunction
- › A non-deformable tape can be beneficial in the surgical treatment of severely incontinent patients with ISD