

# ATOMS® Adjustable Transobturator Male System

Salvador Arlandis, PhD MD



## Disclosure of Conflict of Interest

---

### Dr Salvador Arlandis

Dr Salvador Arlandis declared on the 23 January 2016 that they had the following existing or known future financial relationships or commercial affiliations:

#### **Astellas**

- Consultant
- Speaker Honorarium
- Trial participation

#### **Pfizer**

- Speaker Honorarium
- Research grant

#### **Allergan**

- Consultant
- Speaker Honorarium

#### **Medtronic**

- Consultant
- Speaker Honorarium

#### **Gebro**

- Consultant
- Speaker Honorarium

#### **AMS**

- Consultant
- Speaker Honorarium

# Male slings classification

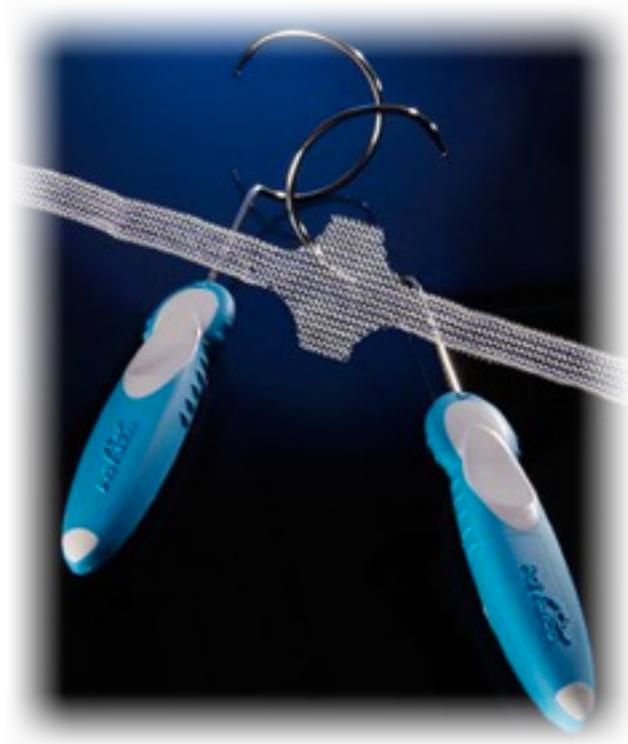
**Fixed**

**Adjustable**

# Male slings classification

**Fixed**

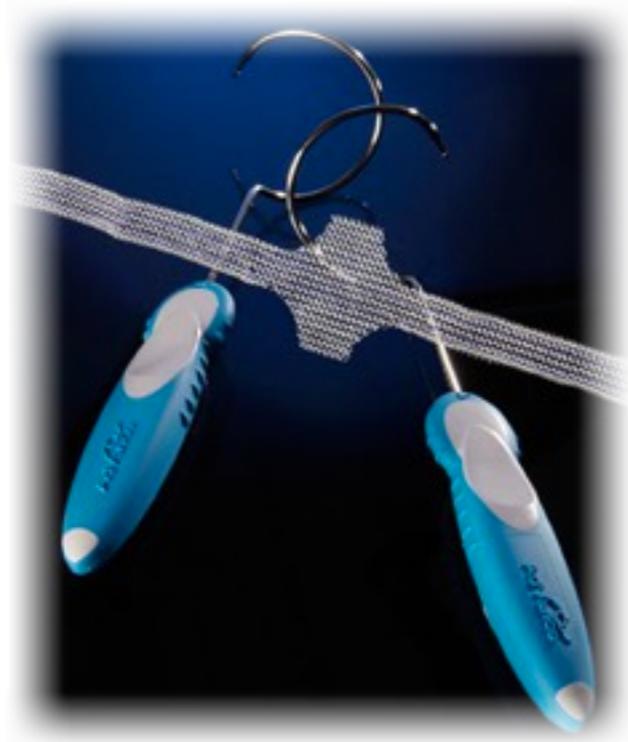
**Adjustable**



# Male slings classification

**Fixed**

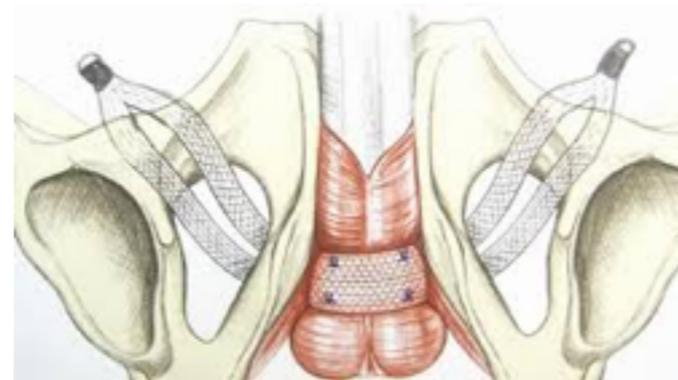
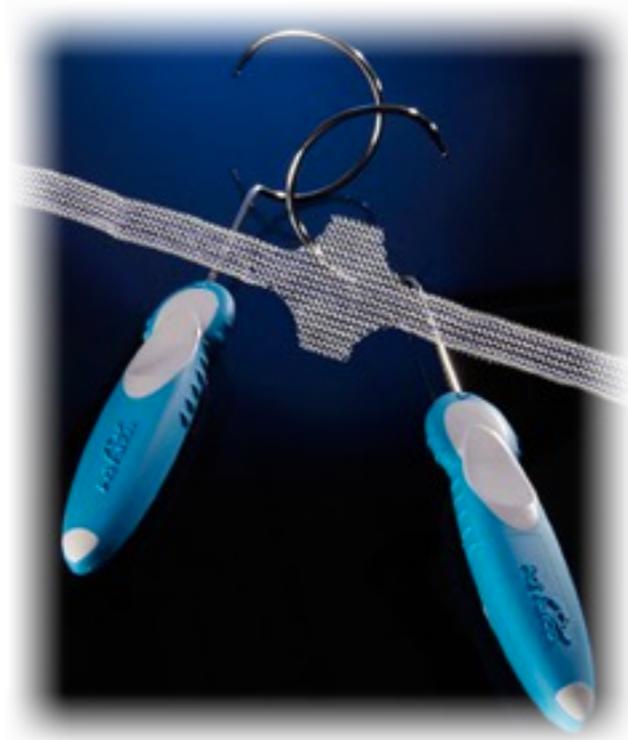
**Adjustable**



# Male slings classification

**Fixed**

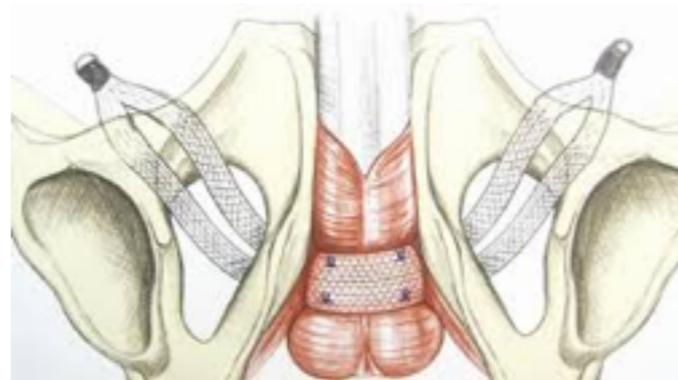
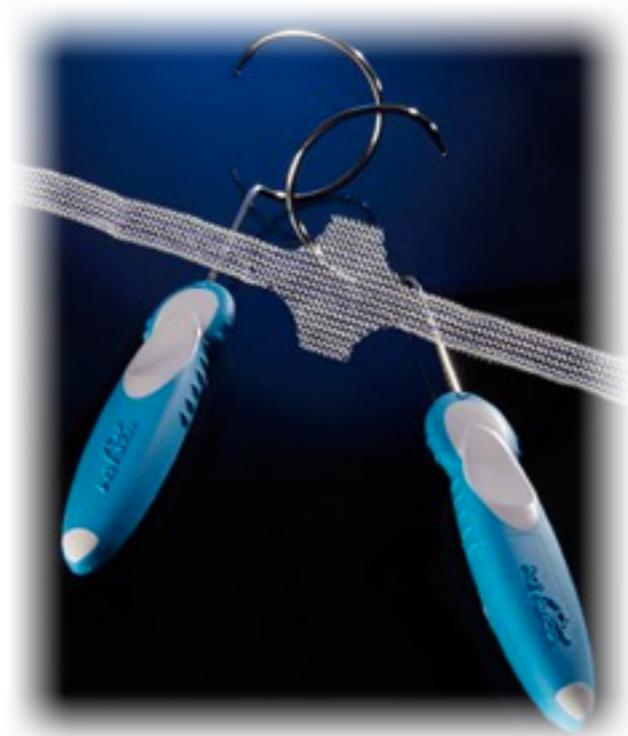
**Adjustable**



# Male slings classification

## Fixed

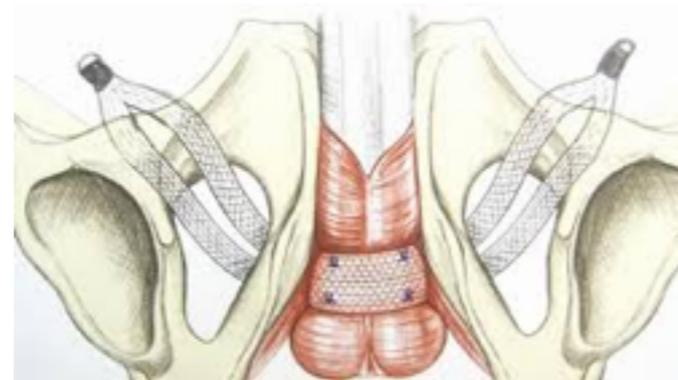
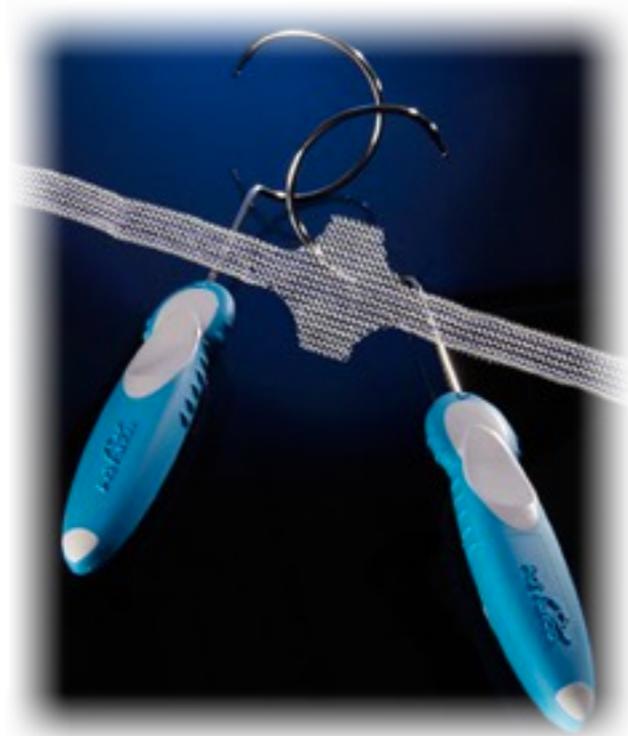
## Adjustable



# Male slings classification

**Fixed**

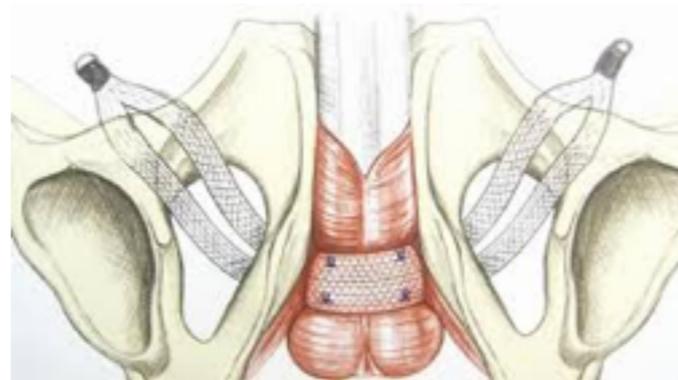
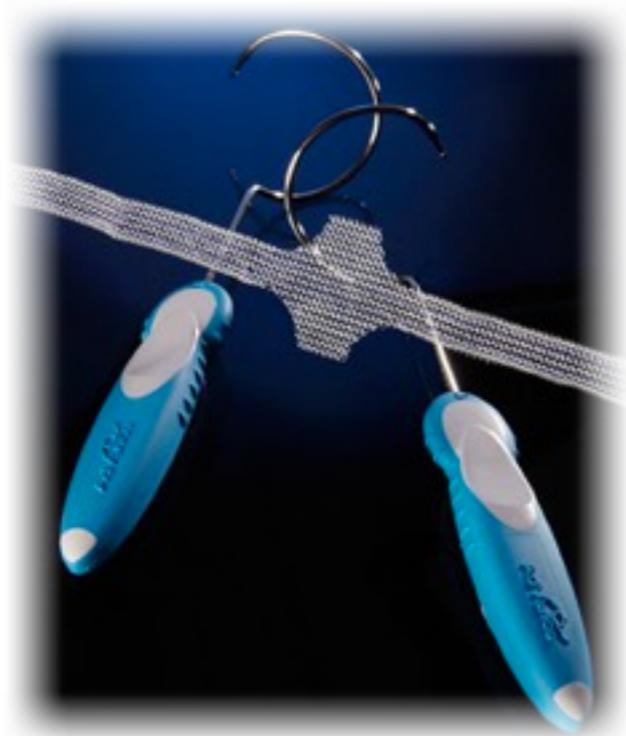
**Adjustable**



# Male slings classification

## Fixed

## Adjustable



**Mesh  
arms**

**Titanium  
port**

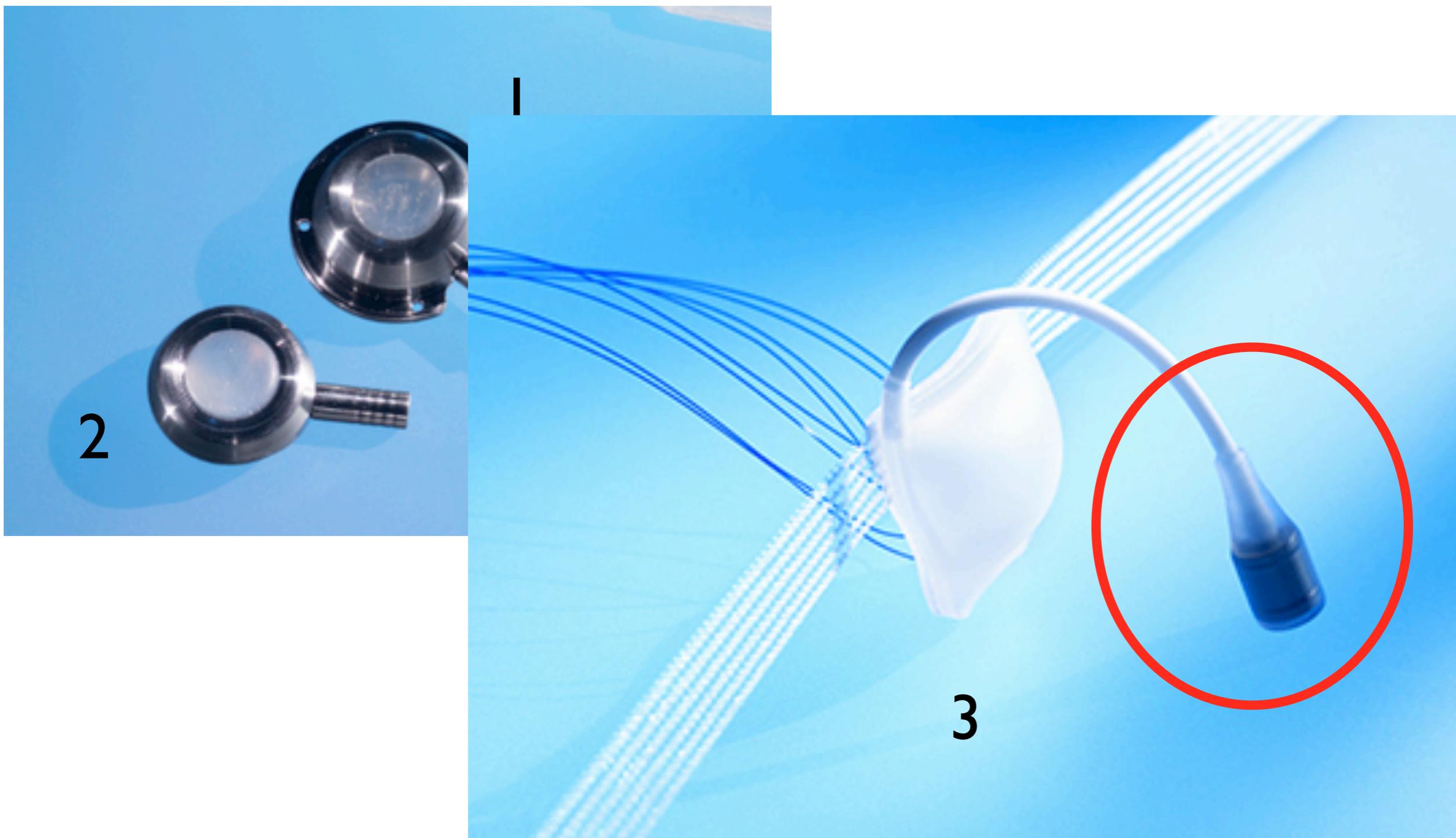
**Central  
cushion**

**Sutures for  
mesh arm  
fixation**

# ATOMS evolution

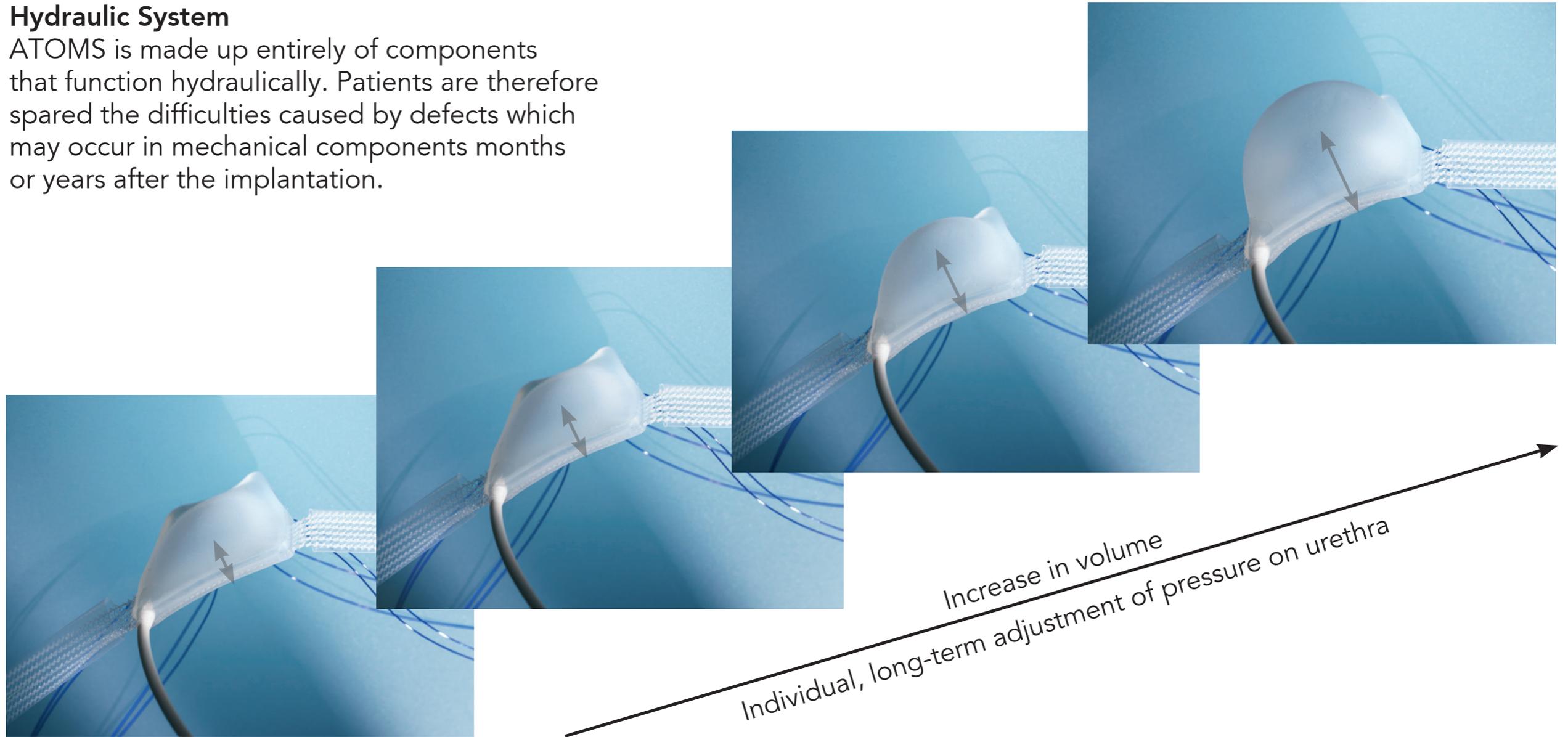


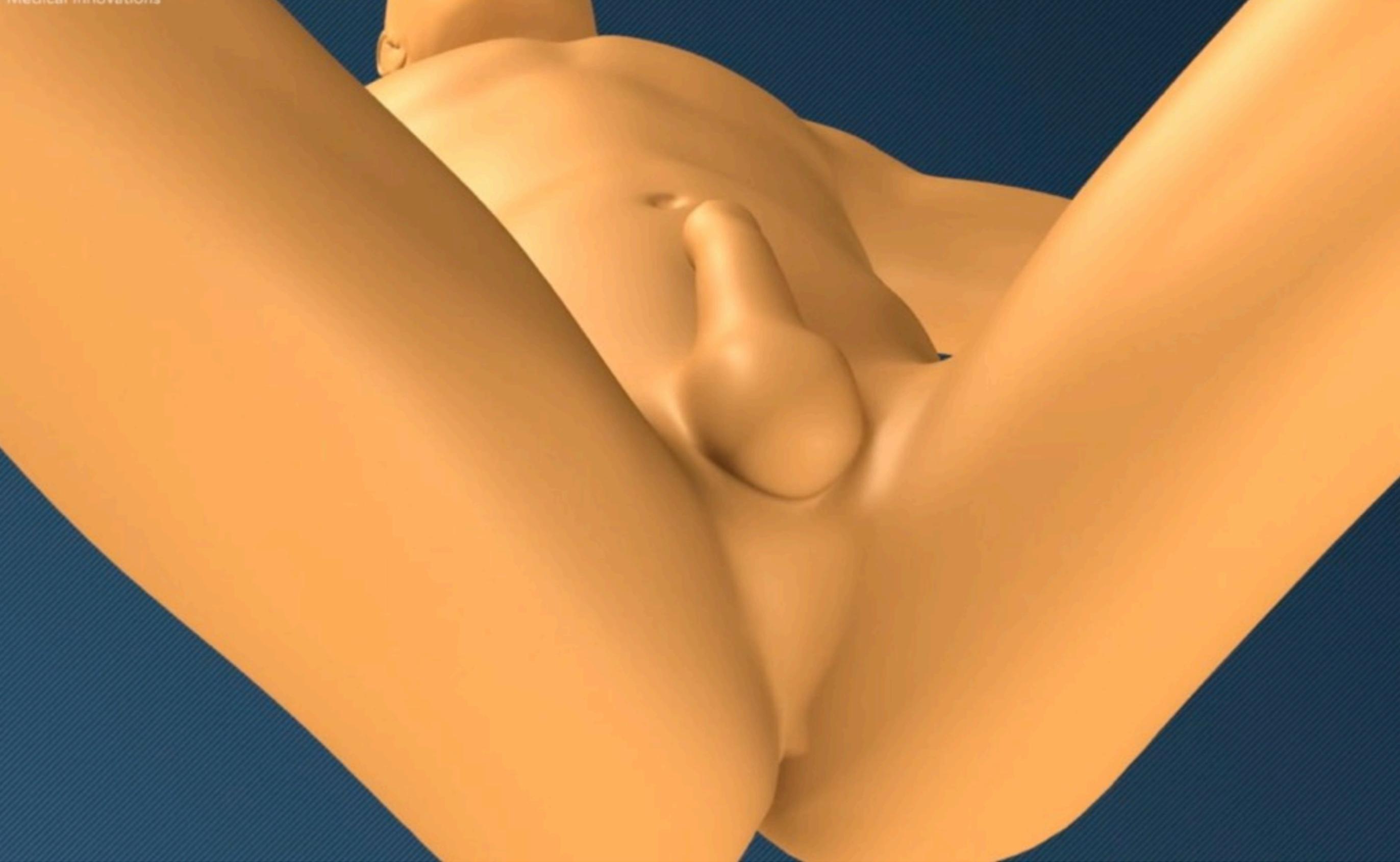
# ATOMS evolution



## Hydraulic System

ATOMS is made up entirely of components that function hydraulically. Patients are therefore spared the difficulties caused by defects which may occur in mechanical components months or years after the implantation.





# Video surgery



# Initial Experience and Results With a New Adjustable Transobturator Male System for the Treatment of Stress Urinary Incontinence

Jürgen Seweryn,\* Wilhelm Bauer,† Anton Ponholzer and Paul Schramek

*From the Department of Urology and Andrology, St John of God Hospital (JS, AP, PS), and Department of Urology, Göttlicher Heiland Hospital (WB), Teaching Hospital of the Medical University of Vienna, Vienna, Austria*

# Initial Experience and Results With a New Adjustable Transobturator Male System for the Treatment of Stress Urinary Incontinence

Jürgen Seweryn,\* Wilhelm Bauer,† Anton Ponholzer and Paul Schramek

*From the Department of Urology and Andrology, St John of God Hospital (JS, AP, PS), and Department of Urology, Göttlicher Heiland Hospital (WB), Teaching Hospital of the Medical University of Vienna, Vienna, Austria*

**Table 1.** *Functional outcomes of ATOMS*

	Preop		Postop
Mean daily pad use (range)	6.78	(2–10)	1.36 (0–10)
% Daily pad use:			
Greater than 5	57.89		5.26
3–5	34.21		10.52
2	7.89		7.89
1	0		34.21
No pads	0		42.10
Mean gm 24-hr pad test (range)	747	(230–1,600)	115 (0–1,500)

# Initial Experience and Results With a New Adjustable Transobturator Male System for the Treatment of Stress Urinary Incontinence

Jürgen Seweryn,\* Wilhelm Bauer,† Anton Ponholzer and Paul Schramek

*From the Department of Urology and Andrology, St John of God Hospital (JS, AP, PS), and Department of Urology, Göttlicher Heiland Hospital (WB), Teaching Hospital of the Medical University of Vienna, Vienna, Austria*

## Conclusions

- "Safe" and effective
- First or second line
- Mild to moderate UI
- Even after RT

# Initial Experience and Results With a New Adjustable Transobturator Male System for the Treatment of Stress Urinary Incontinence

Jürgen Seweryn,\* Wilhelm Bauer,† Anton Ponholzer and Paul Schramek

*From the Department of Urology and Andrology, St John of God Hospital (JS, AP, PS), and Department of Urology, Göttlicher Heiland Hospital (WB), Teaching Hospital of the Medical University of Vienna, Vienna, Austria*

## Conclusions

- "Safe" and effective
- First or second line
- Mild to moderate UI
- Even after RT

- No intra-complications
- 1 AUR
- Transient pain 53%
- 10% port infection
- 1 urethral erosion

	Patient characteristics					
	Bad hand dexterity Cognitive impairment	RT	Need of future TUR or cystoscopy	Nocturnal UI No contraction ext. sphinc.	24h Pad test (gr)	Negative Repositioning test
	Candidate?					
Advance XP <sup>®</sup>	Yes	No	Yes	No	<300	No
Virtue <sup>®</sup>	Yes	?	Yes	No	<300	Yes
Atoms <sup>®</sup>	Yes	≈	Yes	≈	300-600	Yes
AMS 800 <sup>®</sup>	No	≈	No	Yes	>600	Yes

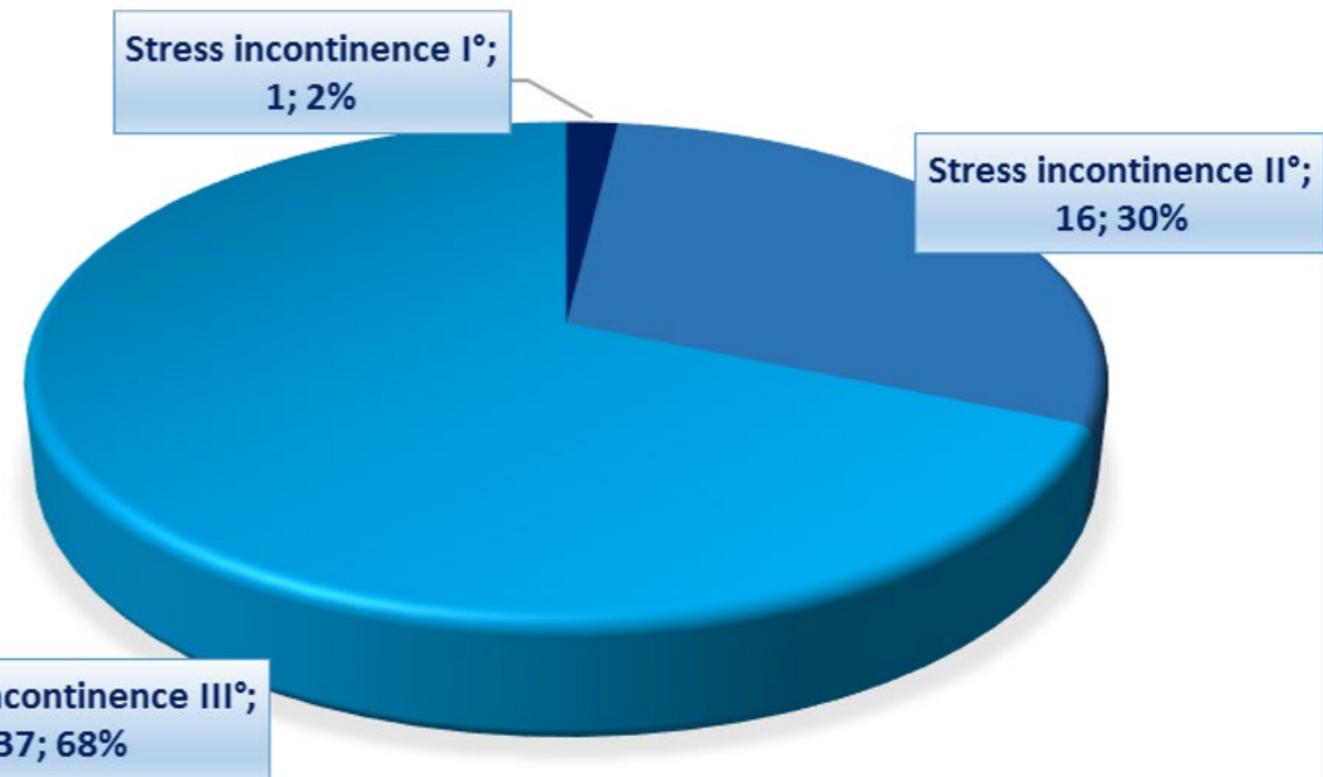


# Long term outcomes

# Five-year experience with the adjustable transobturator male system for the treatment of male stress urinary incontinence: a single-center evaluation

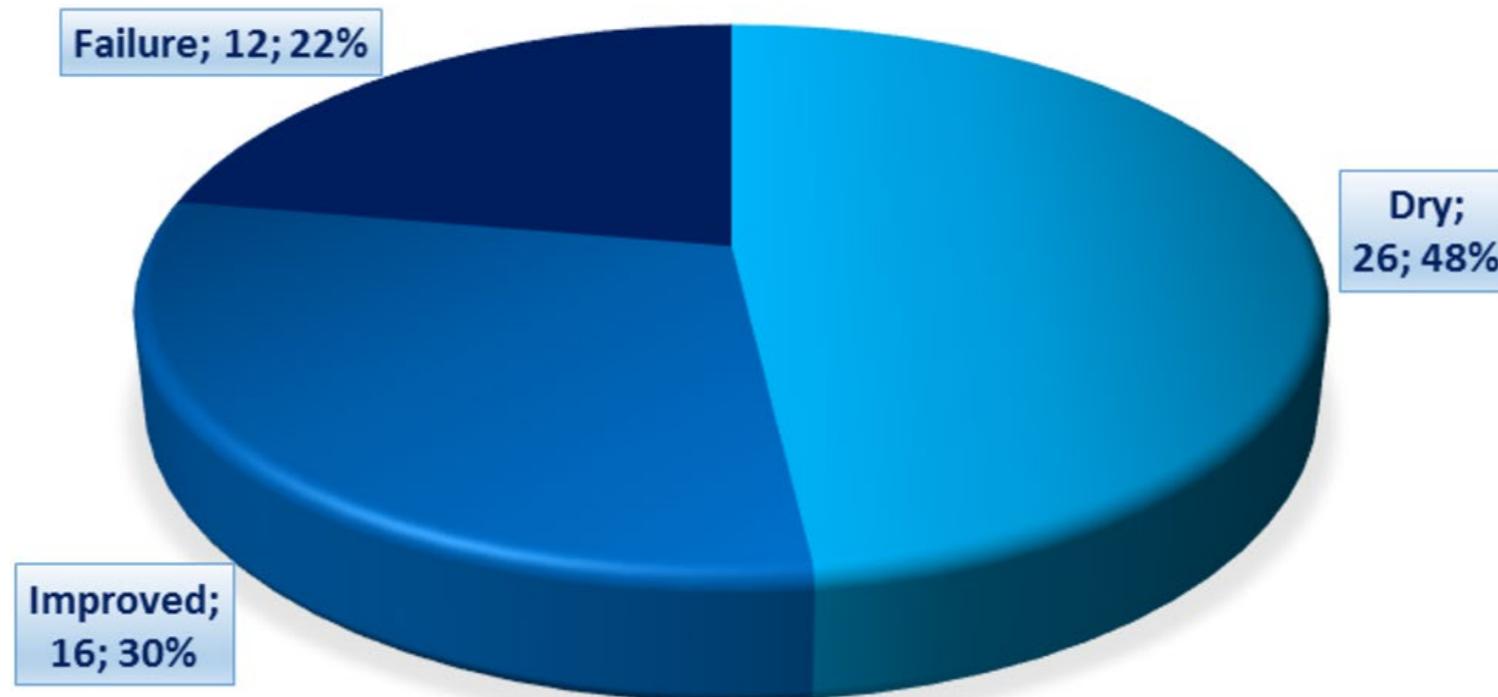
Sandra Mühlstädt<sup>1</sup> · Alexander Friedl<sup>2</sup> · Nasreldin Mohammed<sup>1</sup> · André Schumann<sup>1</sup> · Karl Weigand<sup>1</sup> · Felix Kawan<sup>1</sup> · Christian Göllert<sup>1</sup> · Christin Kahlert<sup>1</sup> · Gerit Theil<sup>1</sup> · Kersten Fischer<sup>1</sup> · Paolo Fornara<sup>1</sup>

- 54 patients
- Mean FU 26 m
- 38% RT
- Previous surgery 20%



>5 pads/day

# Results



**Table 3** Continence outcome of the patient population ( $n = 54$  patients, mFU  $27.5 \pm 18.4$  months), mean  $\pm$  SD (range),  $p < 0.05$

Category	Overall population	Former SUI I° and II°	Former SUI III°	$p$ value (comparison SUI I° and II° vs. SUI III°)
24-h Pad count [pads/24-h]	$1.6 \pm 1.7$ (0–8)	$0.4 \pm 0.6$ (0–2)	$2.2 \pm 1.7$ (0–8)	0.002

# Complications

**Table 4** Postoperative complications of the patient population ( $n = 54$  patients, mFU  $27.5 \pm 18.4$  months), according to Clavien classification [15]

Clavien grade—postoperative complications	<i>n</i>	Treatment
<b>Clavien I</b>		
Scrotal hematoma	2 (3.7 %)	Conservative
Pain (scrotal/perineal)	3 (5.6 %)	Conservative
<b>Clavien IIIa</b>		
Urinary retention	1 (1.9 %)	Readjustment + suprapubic catheter for 14 days
<b>Clavien IIIb</b>		
Wound infection perineal	2 (3.7 %)	2× explantation
Wound infection port-sited	4 (7.4 %)	3× explantation, 1× open wound management + secondary suture
Erosion of the port (no infection)	1 (1.9 %)	Immediately replacement of the port
Incipient erosion of the port	2 (3.7 %)	Elective replacement of the port

## **Long-term outcome of the adjustable transobturator male system (ATOMS): results of a European multicentre study**

Alexander Friedl<sup>\*</sup>, Sandra Mühlstädt<sup>†</sup>, Roman Zachoval<sup>‡</sup>, Alessandro Giammò<sup>§</sup>, Danijel Kivaranovic<sup>¶</sup>, Maximilian Rom<sup>\*\*</sup>, Paolo Fornara<sup>†</sup> and Clemens Brössner<sup>\*</sup>

- 287 patients
- Multicentre study (5)
- Contraindications: UTI, tumor progression and resistant UUI
- Median follow-up 31 months

# Results

**Table 2** Baseline and <12 months/full follow-up values. Wilcoxon signed-rank test was used to test for differences in baseline and follow-up measurements.

	Baseline, median (IQR)	Follow-up, median (IQR)		P*
		<12 months	Full	
Pads use, pads/day	4 (3–5)	1 (0–2)	1 (0–2)	<0.001
Pad test, mL/day	400 (300–700)	10 (0–100)	18 (0–105)	<0.001
ICIQ-SF	17 (15–18)	5 (0–7)	5 (0–7)	<0.001
PGI-I	4 (4–4)	2 (1–2)	1 (1–2)	<0.001
Q <sub>max</sub> , mL/s	17 (15–19)	14 (13–15)	15 (13–16)	<0.001
Voiding volume, mL	155 (110–200)	190 (156–215)	192 (155–254)	<0.001
PVR, mL	0 (0–0)	0 (0–14)	0 (0–10)	<0.001
VAS	0 (0–0)	1 (0–2)	0 (0–1)	<0.001
LANSS	0 (0–0)	0 (0–3)	0 (0–0)	<0.001

\*Comparison between baseline and full follow-up.

# Results

**Table 2** Baseline and <12 months/full follow-up values. Wilcoxon signed-rank test was used to test for differences in baseline and follow-up measurements.

	Baseline, median (IQR)	Follow-up, median (IQR)		P*
		<12 months	Full	
Pads use, pads/day	4 (3–5)	1 (0–2)	1 (0–2)	<0.001
Pad test, mL/day	400 (300–700)	10 (0–100)	18 (0–105)	<0.001
ICIQ-SF	17 (15–18)	5 (0–7)	5 (0–7)	<0.001
PGI-I	4 (4–4)	2 (1–2)	1 (1–2)	<0.001
Q <sub>max</sub> , mL/s	17 (15–19)	14 (13–15)	15 (13–16)	<0.001
Voiding volume, mL	155 (110–200)	190 (156–215)	192 (155–254)	<0.001
PVR, mL	0 (0–0)	0 (0–14)	0 (0–10)	<0.001
VAS	0 (0–0)	1 (0–2)	0 (0–1)	<0.001
LANSS	0 (0–0)	0 (0–3)	0 (0–0)	<0.001

\*Comparison between baseline and full follow-up.

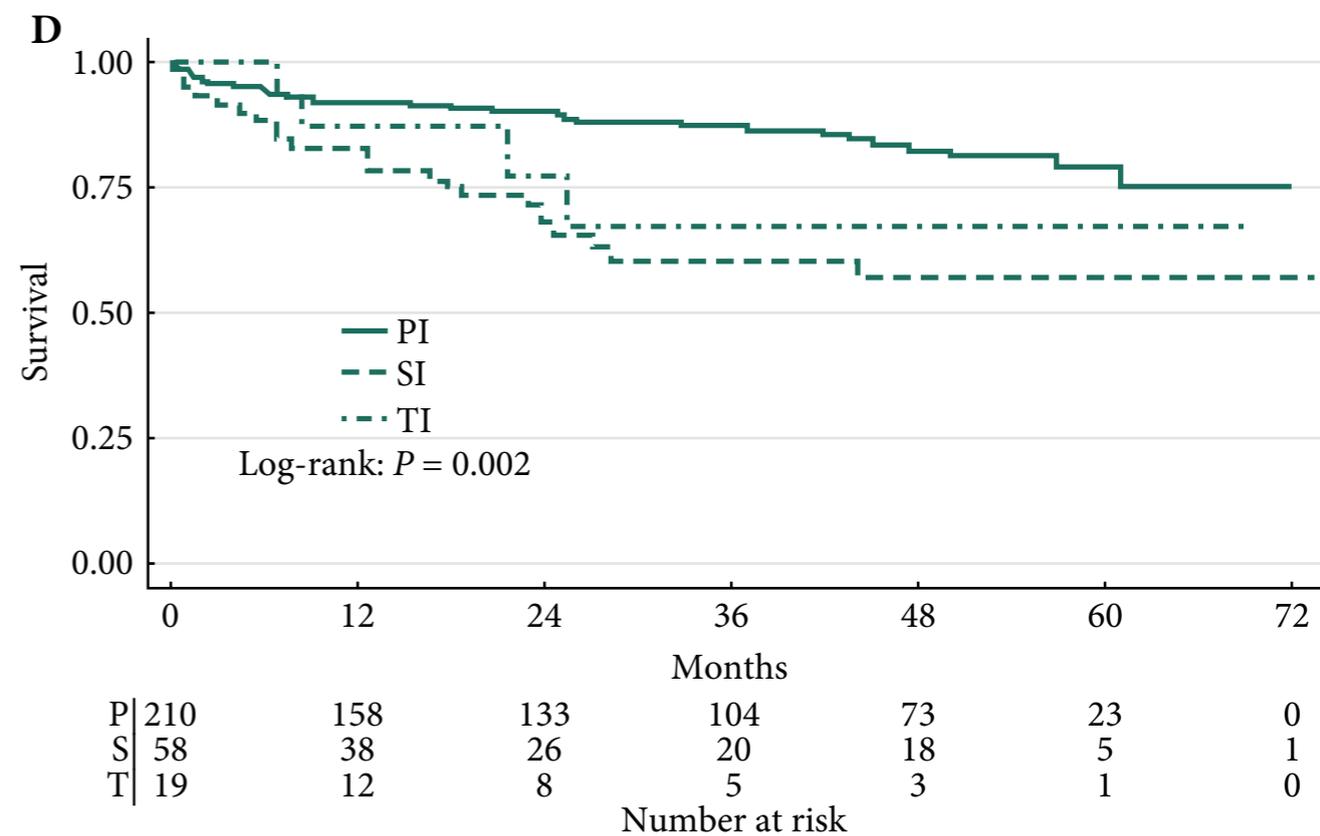
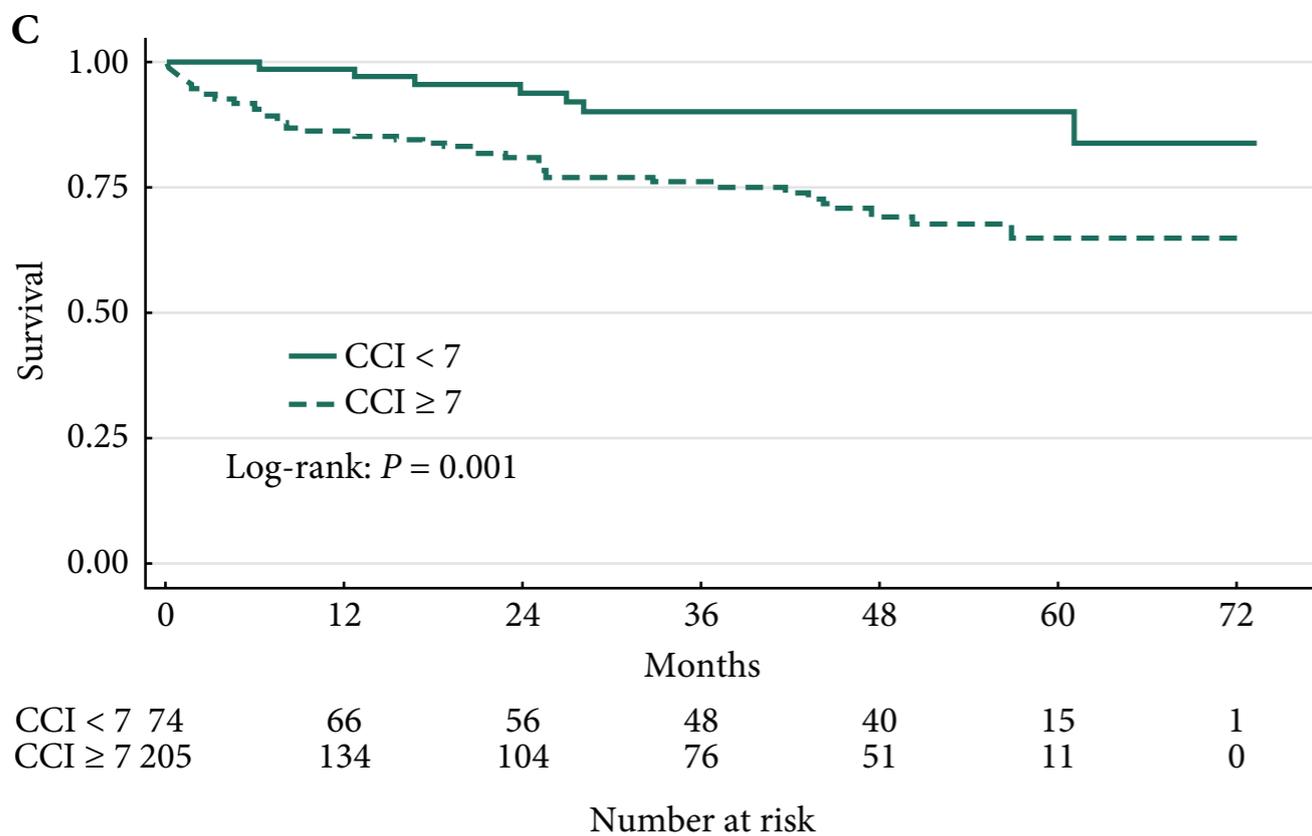
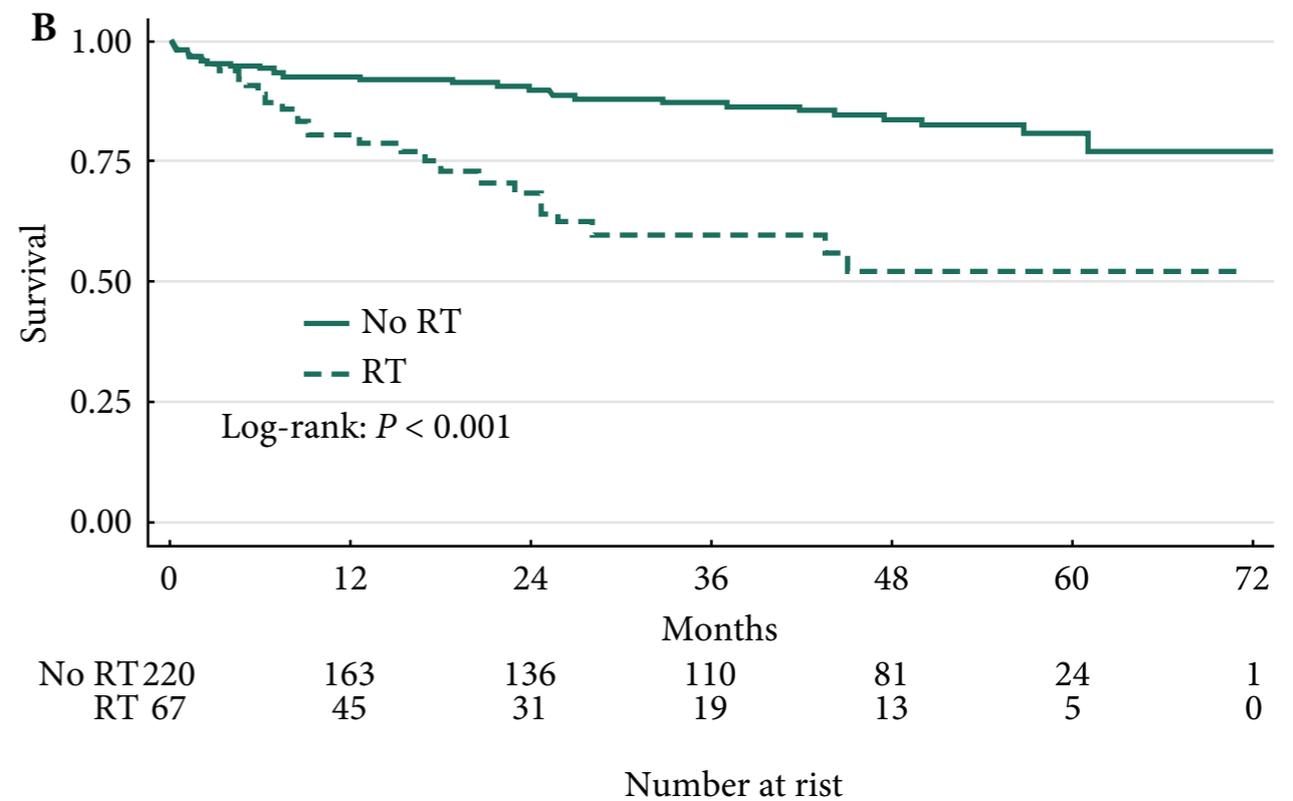
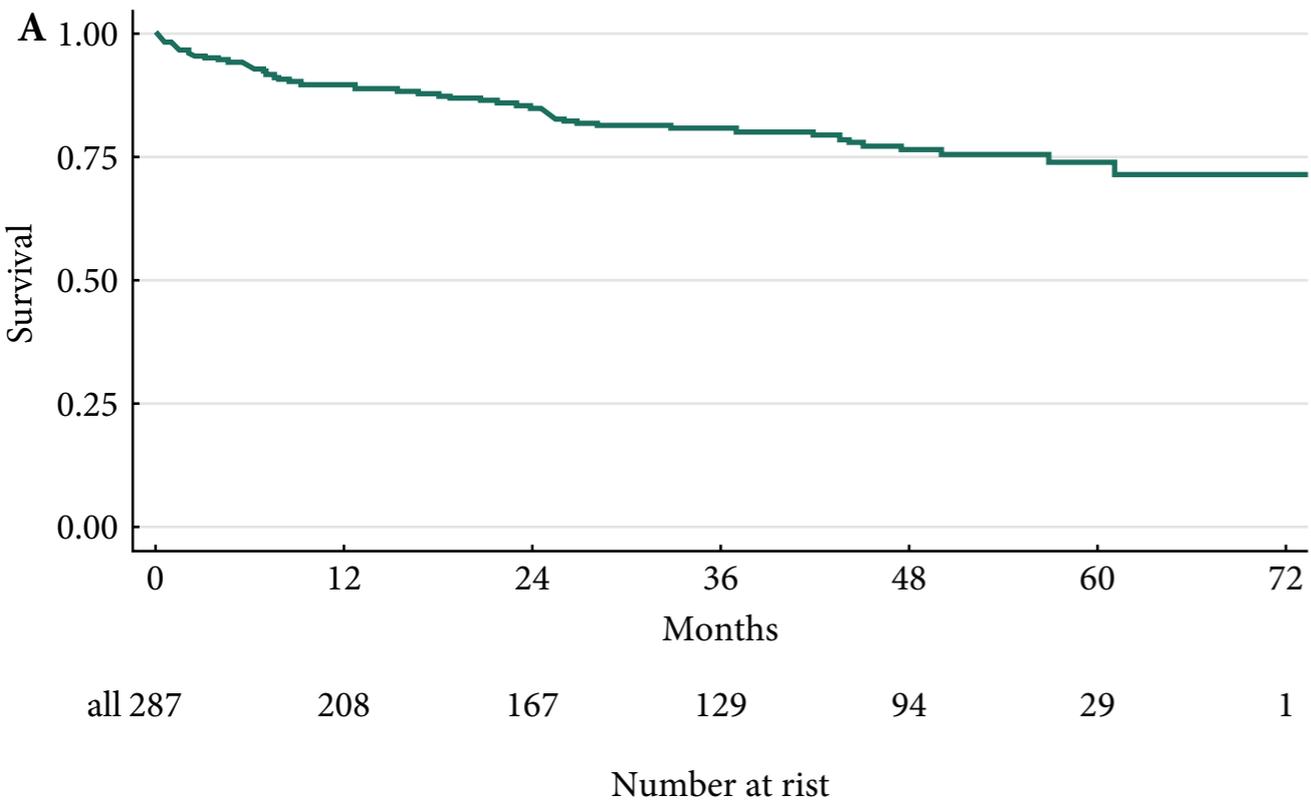
3 adjustments  
(2-4)

# Complications

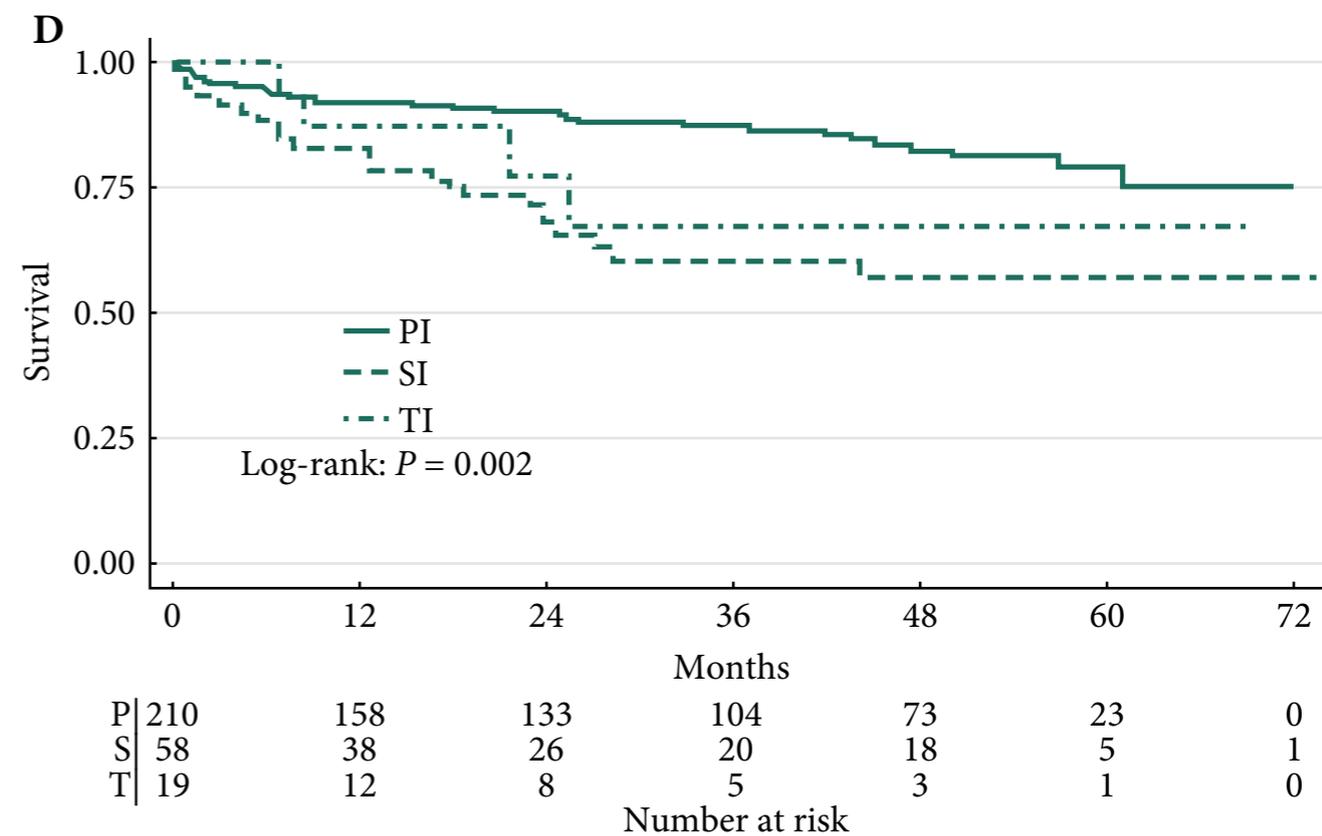
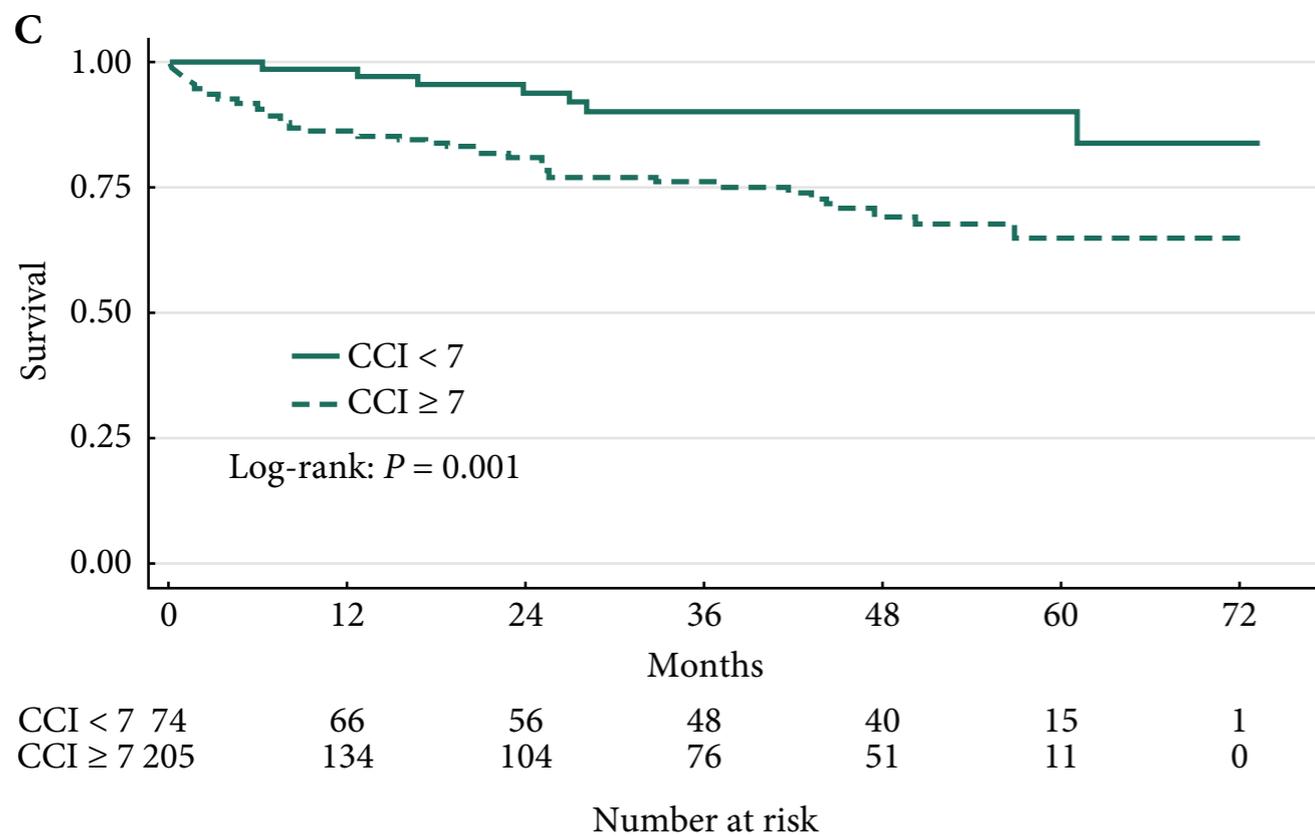
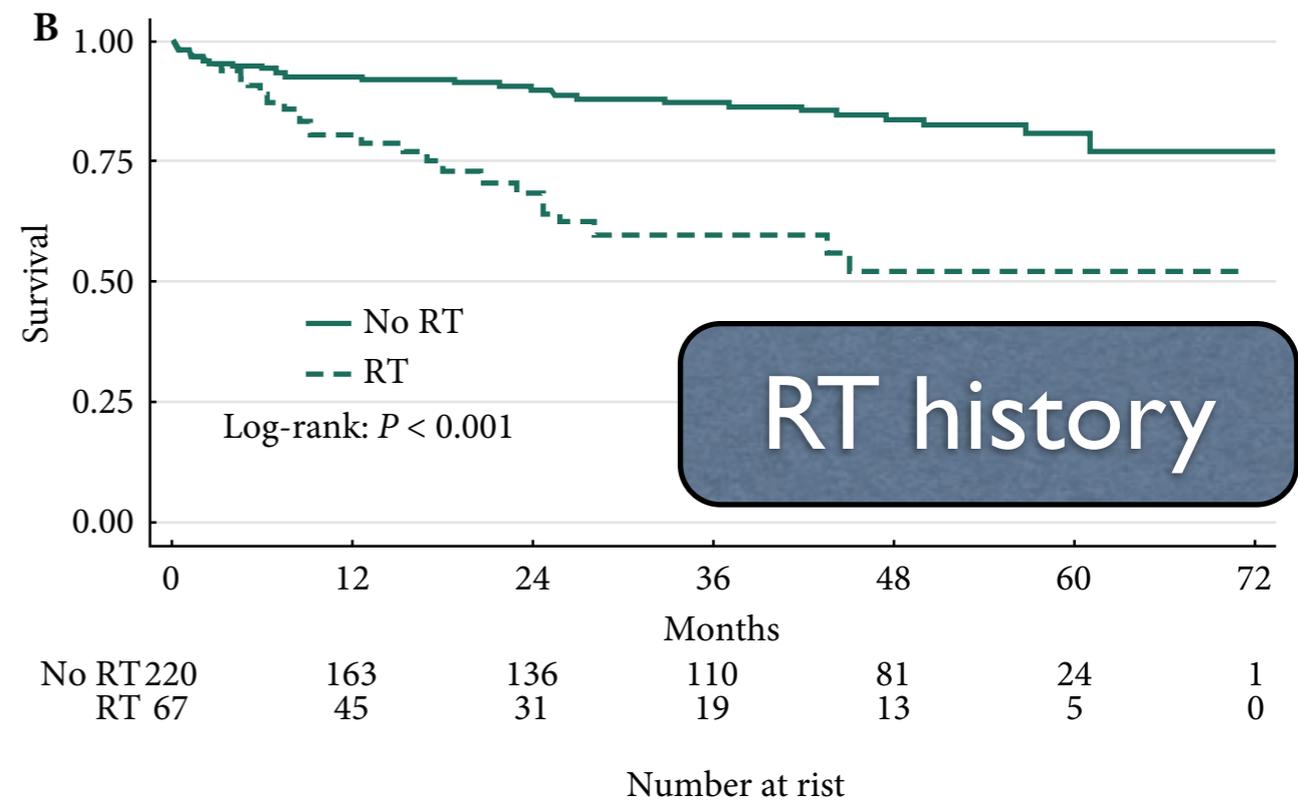
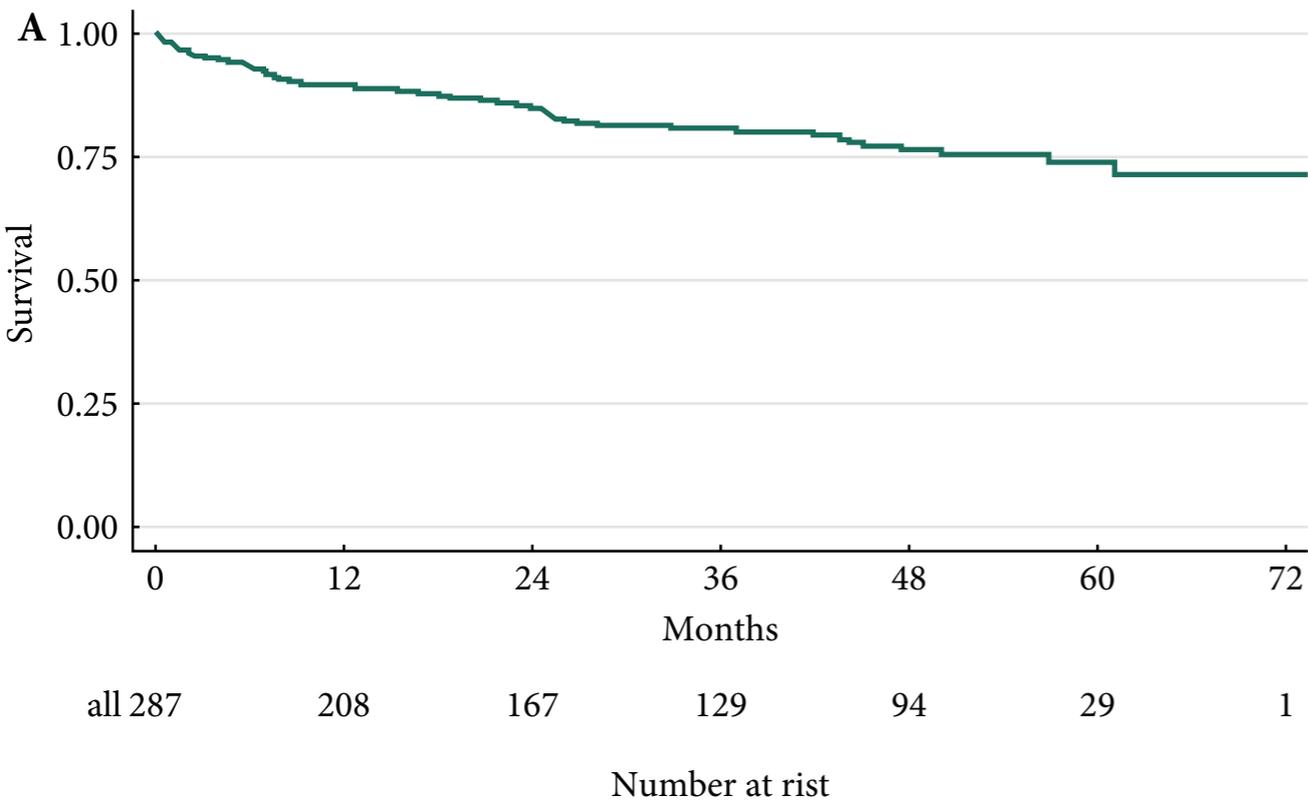
**Table 3** Side-effects and complication management of all devices using the Clavien–Dindo classification.

Complications	Clavien–Dindo grade	N (%)
Intraoperative complications	–	0
Early complications (<30 days)		
Minor complications	I	8 (3) urinary retention
	II	6 (2) early infections
Major complications	III	6 (2) haematoma
	IV	0
	V	0
Removals		56 (20)
Complications leading to removal		
Titanium intolerance		23 (41)
Leak (cushion, port)		12 (21)
Early infection (<30 day)		6 (11)
Late infection (>30 day)		6 (11)
Dysfunction		5 (9)
Dislocation		3 (5)
Persistent pain		1 (2)
Urethra erosion		0
Re-implantation		29 (52)
Solitary port change		14 (5)
AUS solution		11 (4)

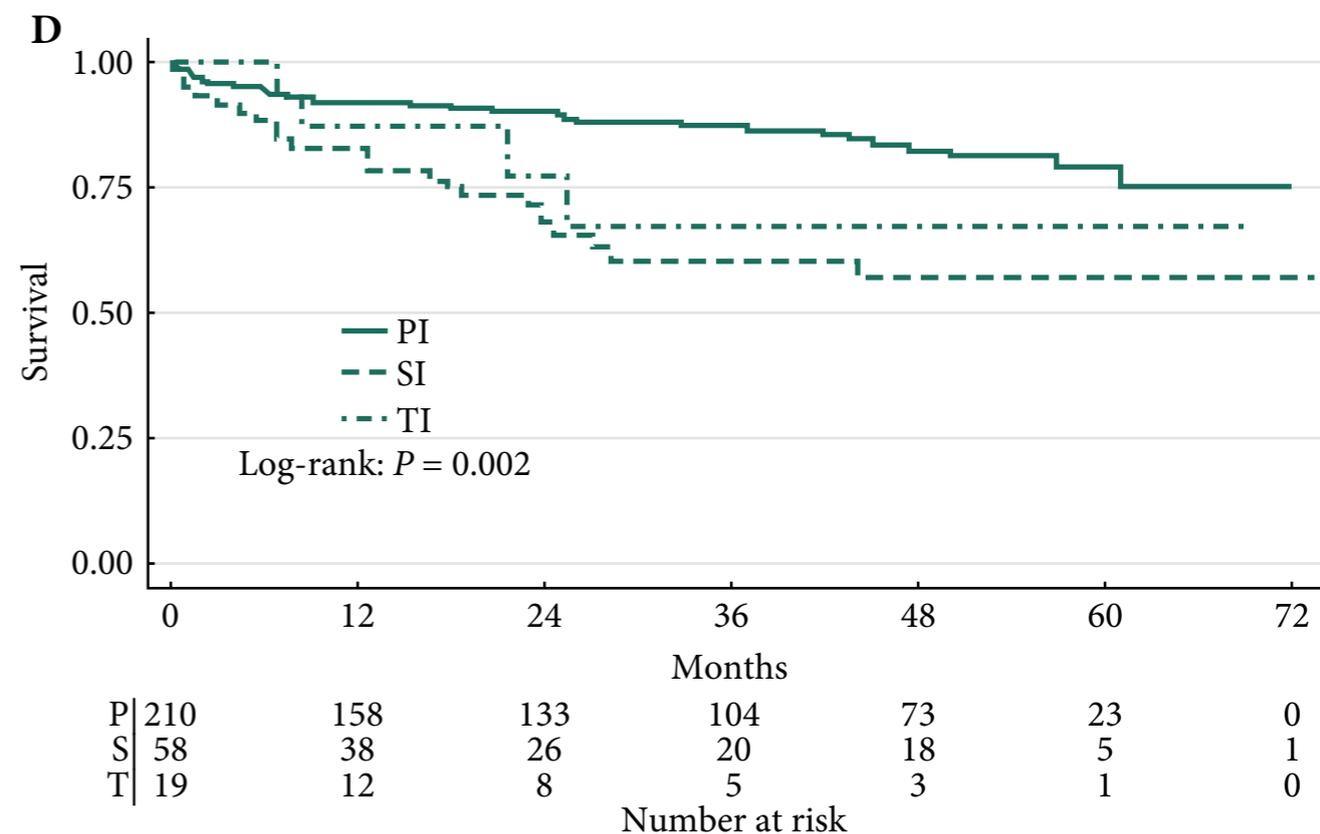
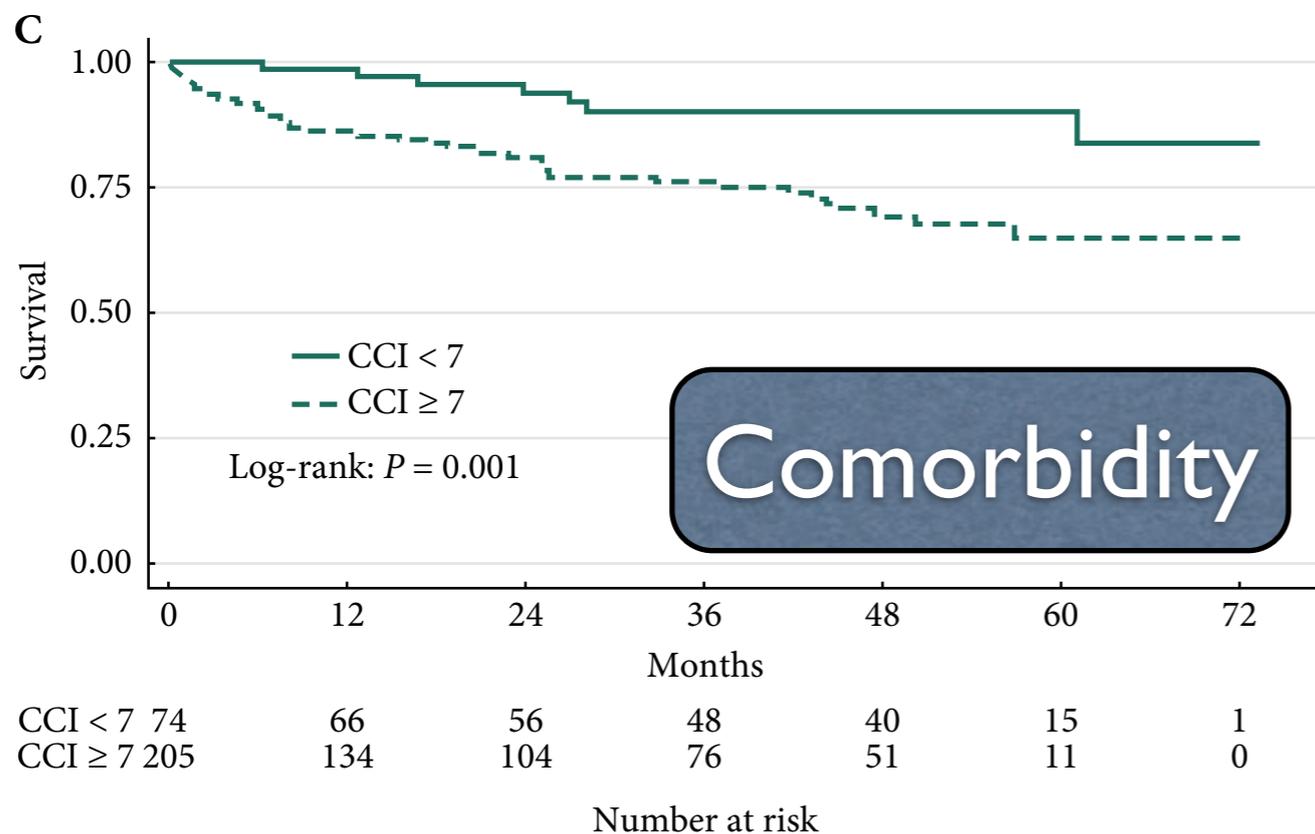
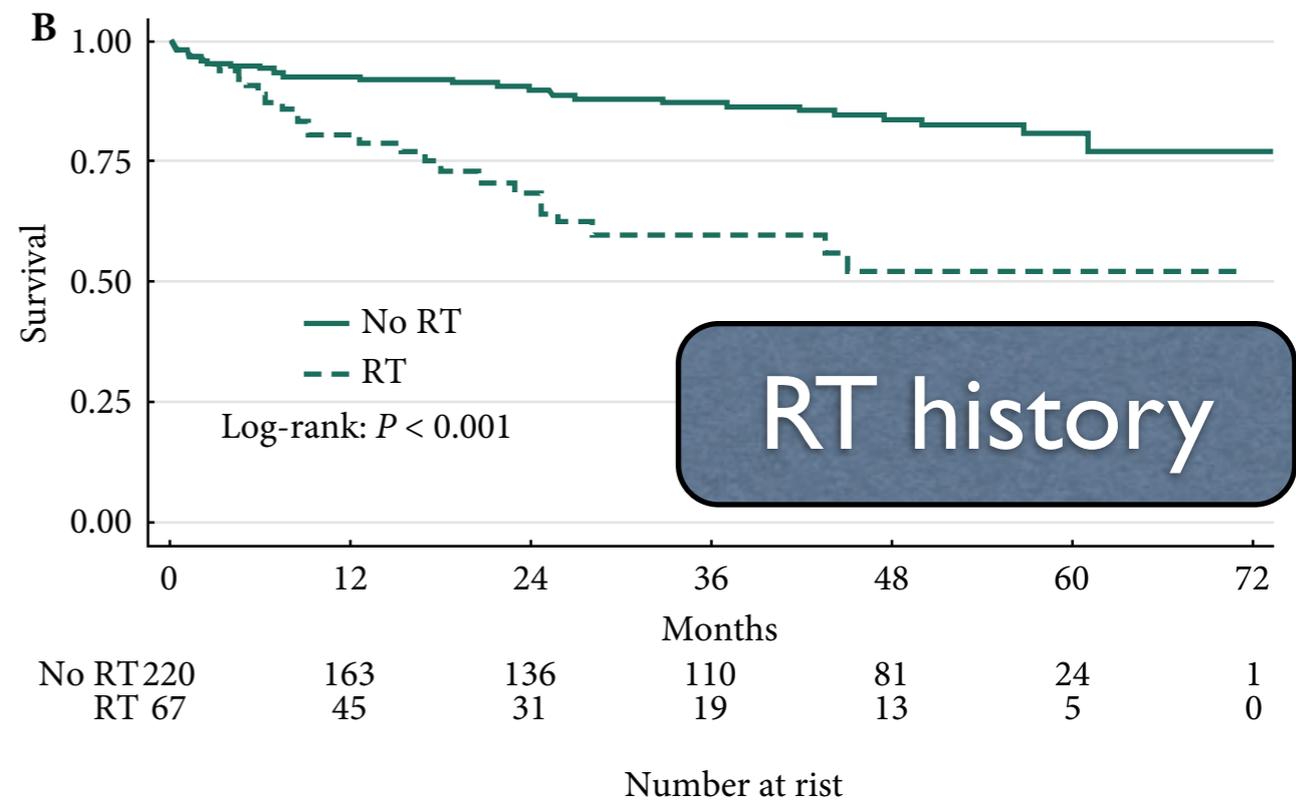
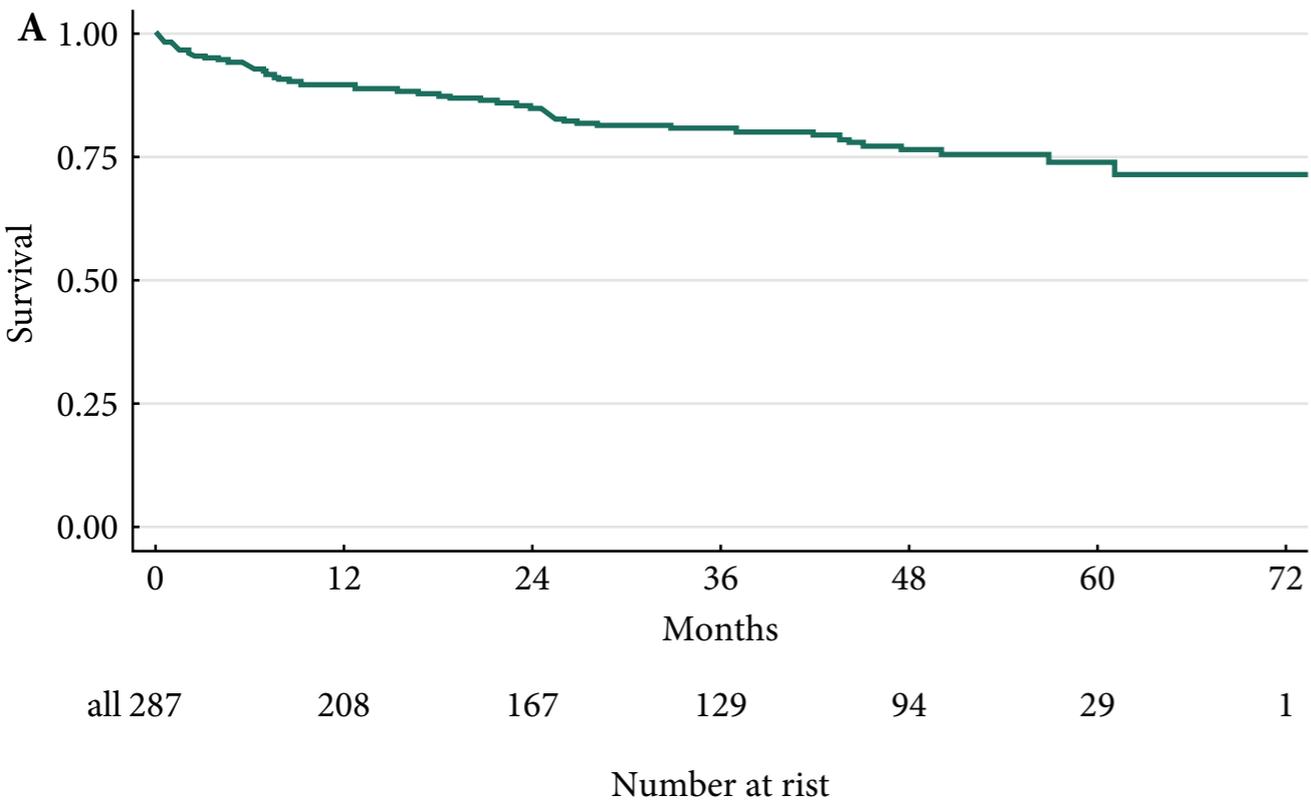
# Prognostic factors



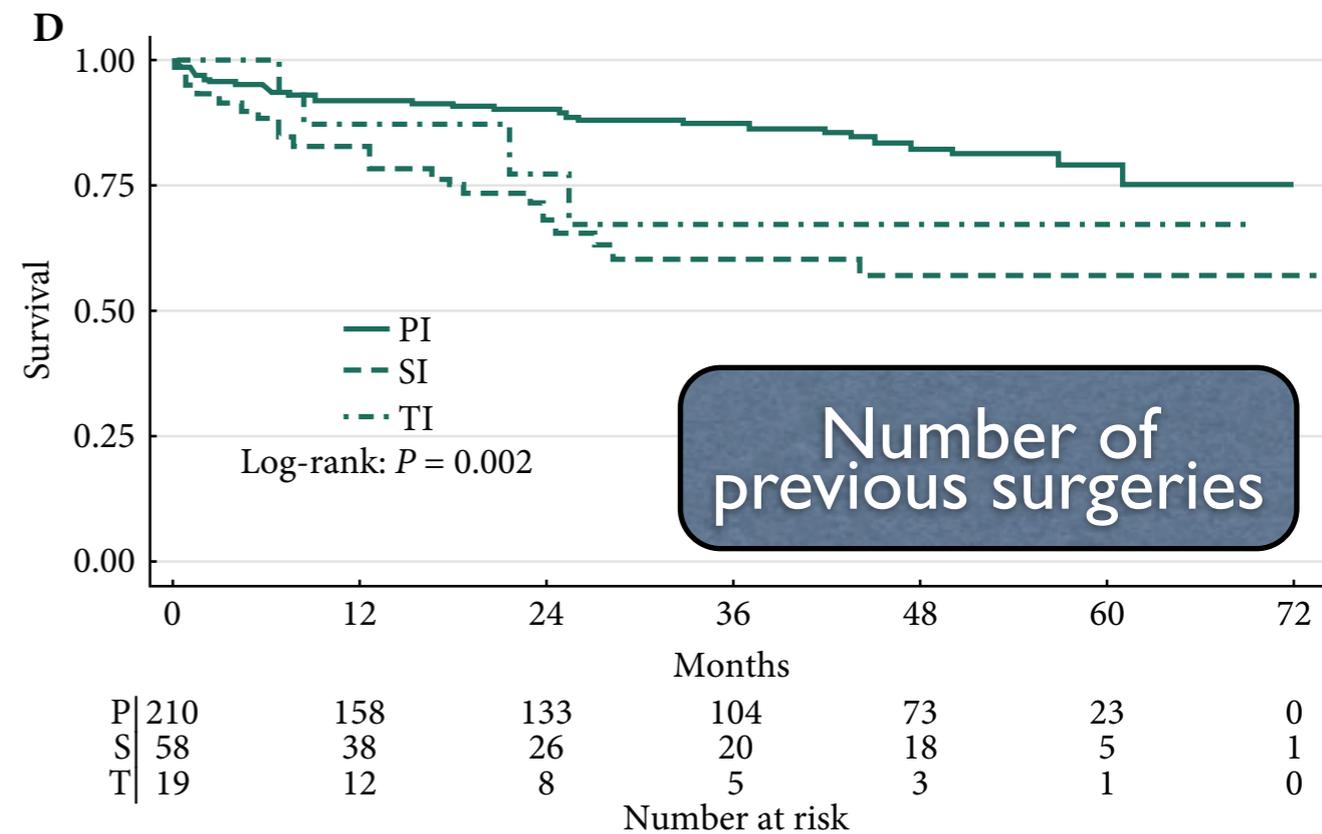
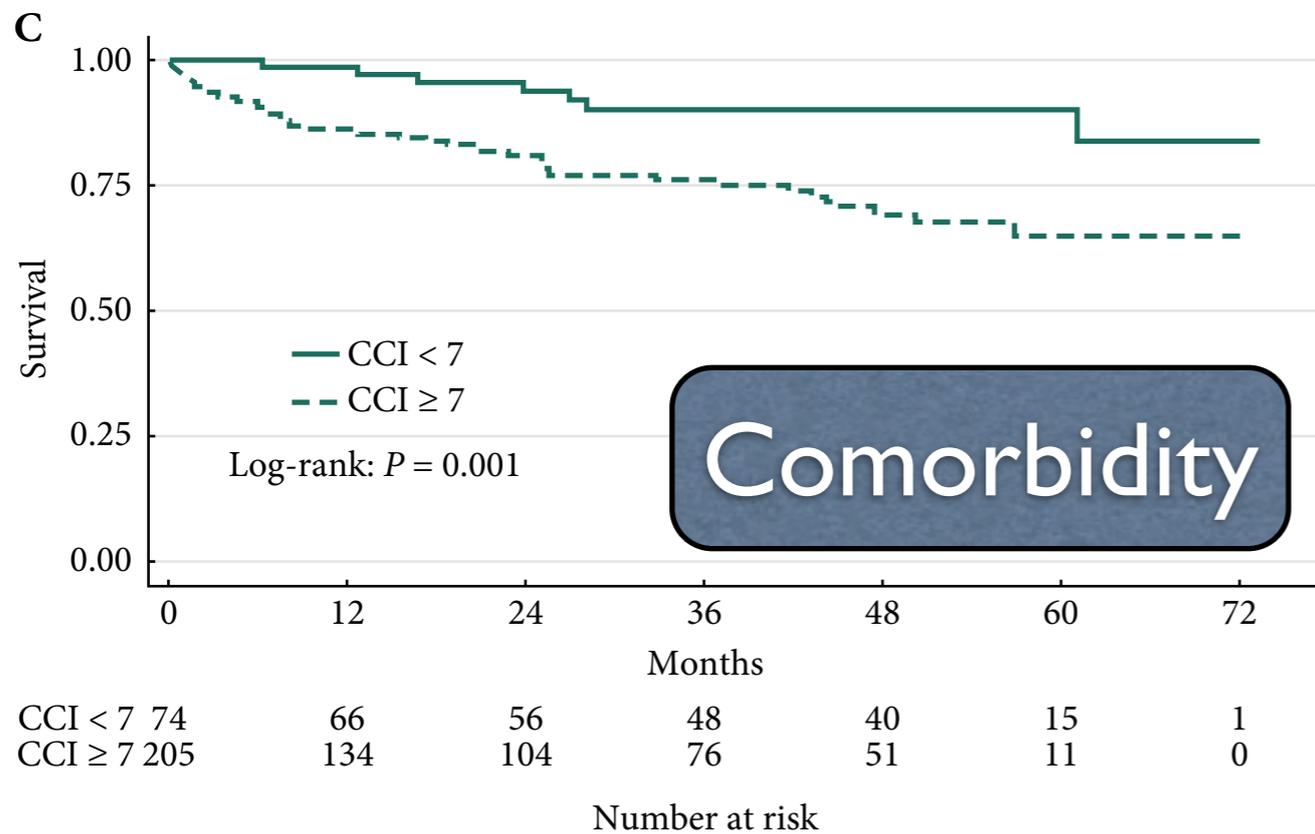
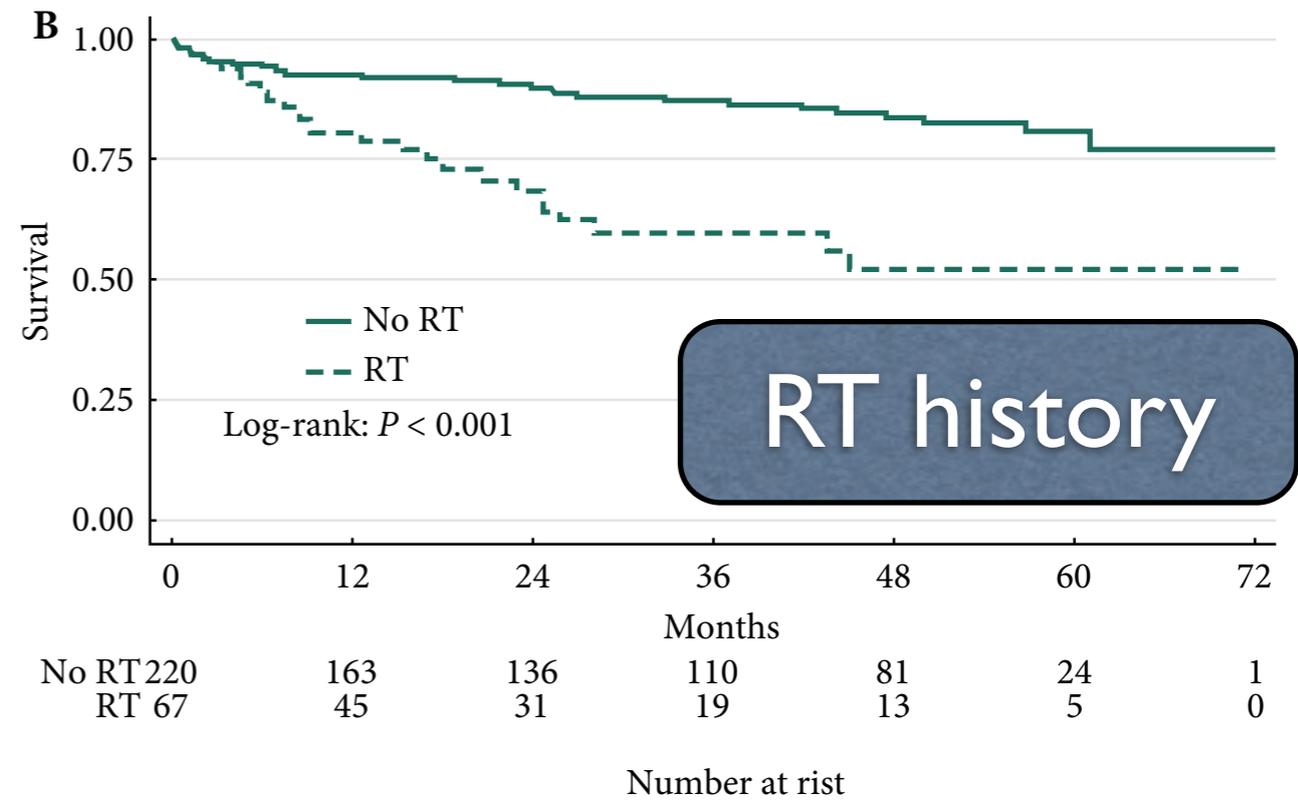
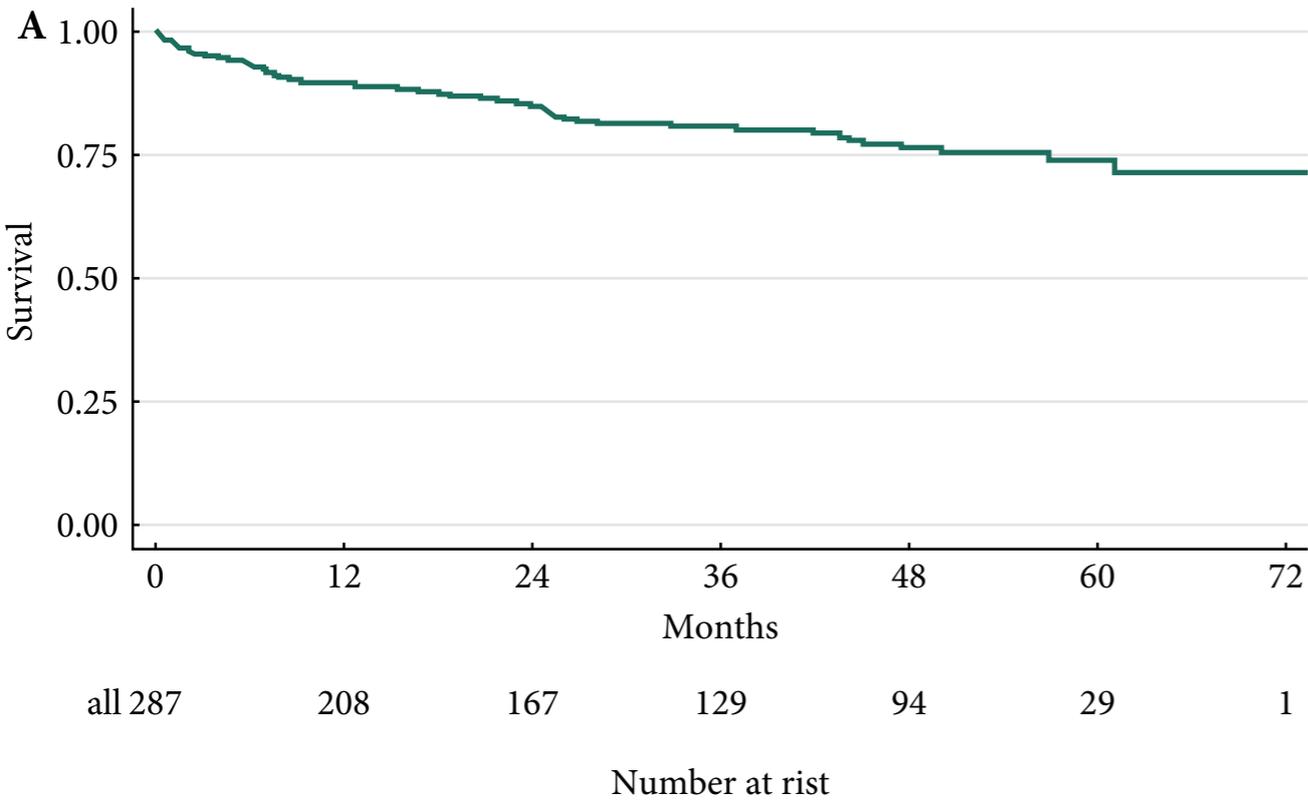
# Prognostic factors



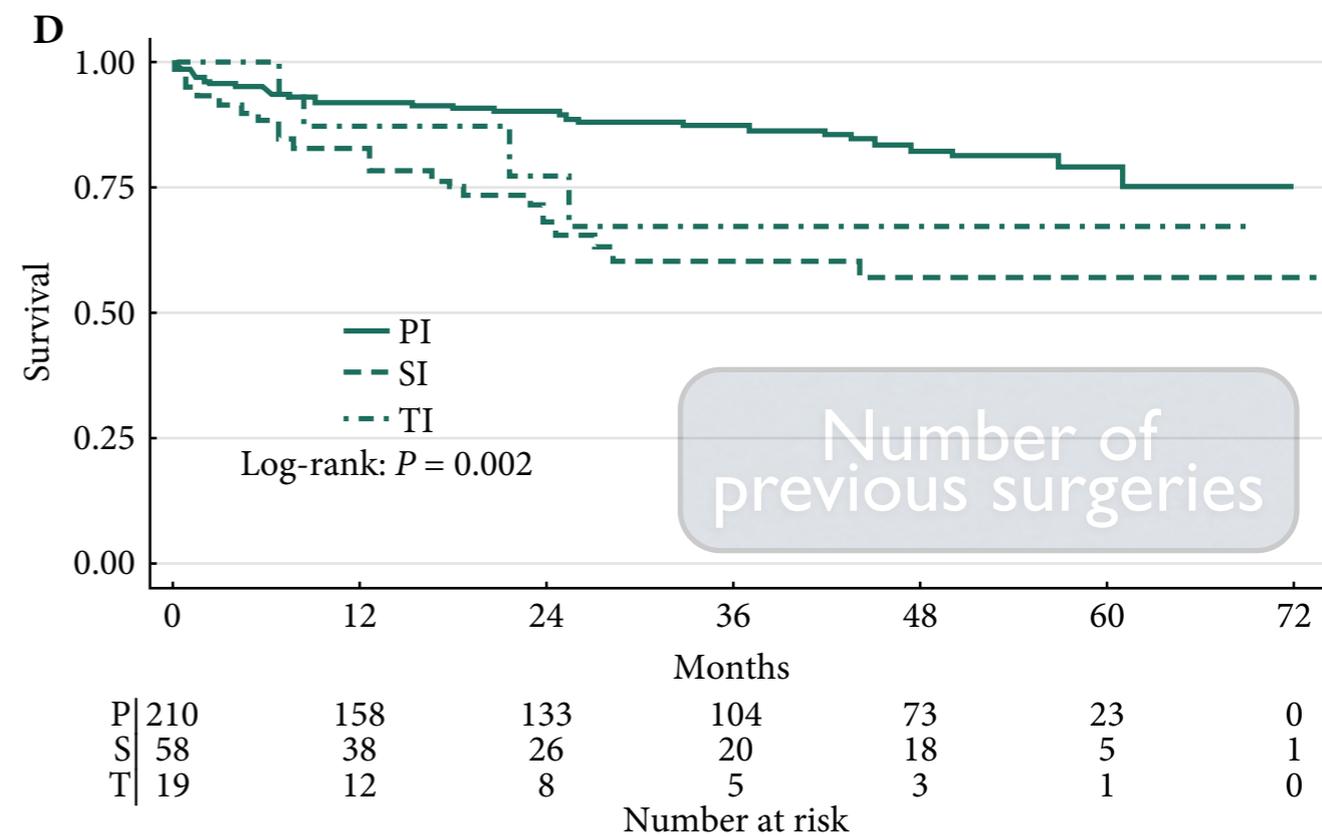
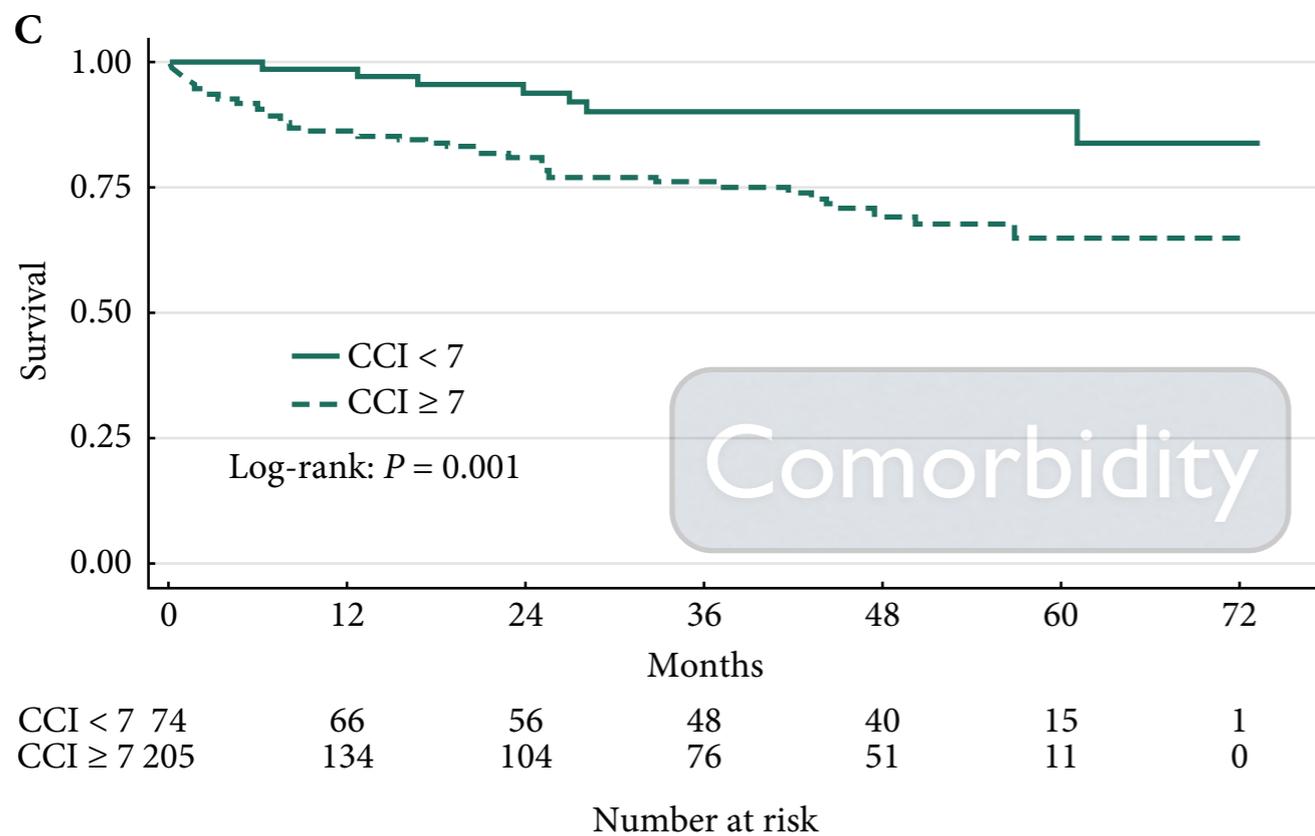
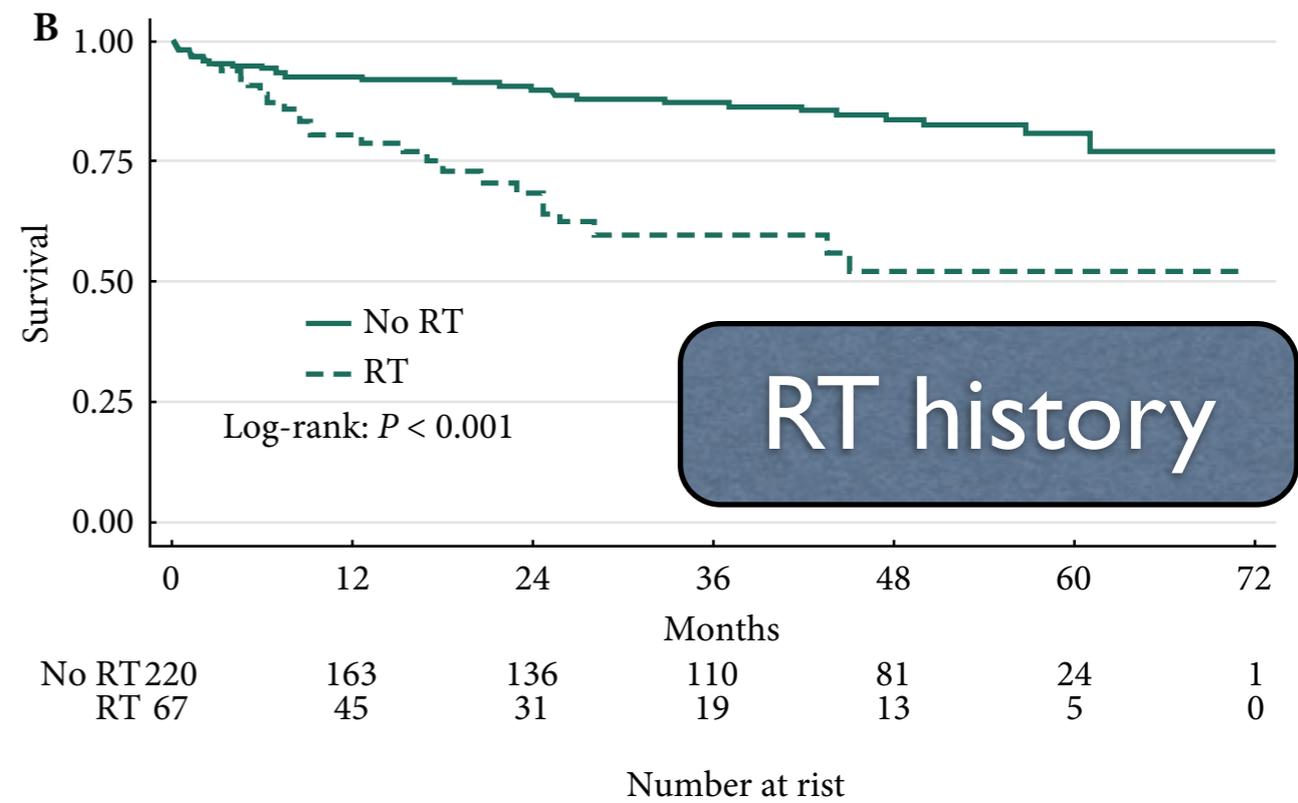
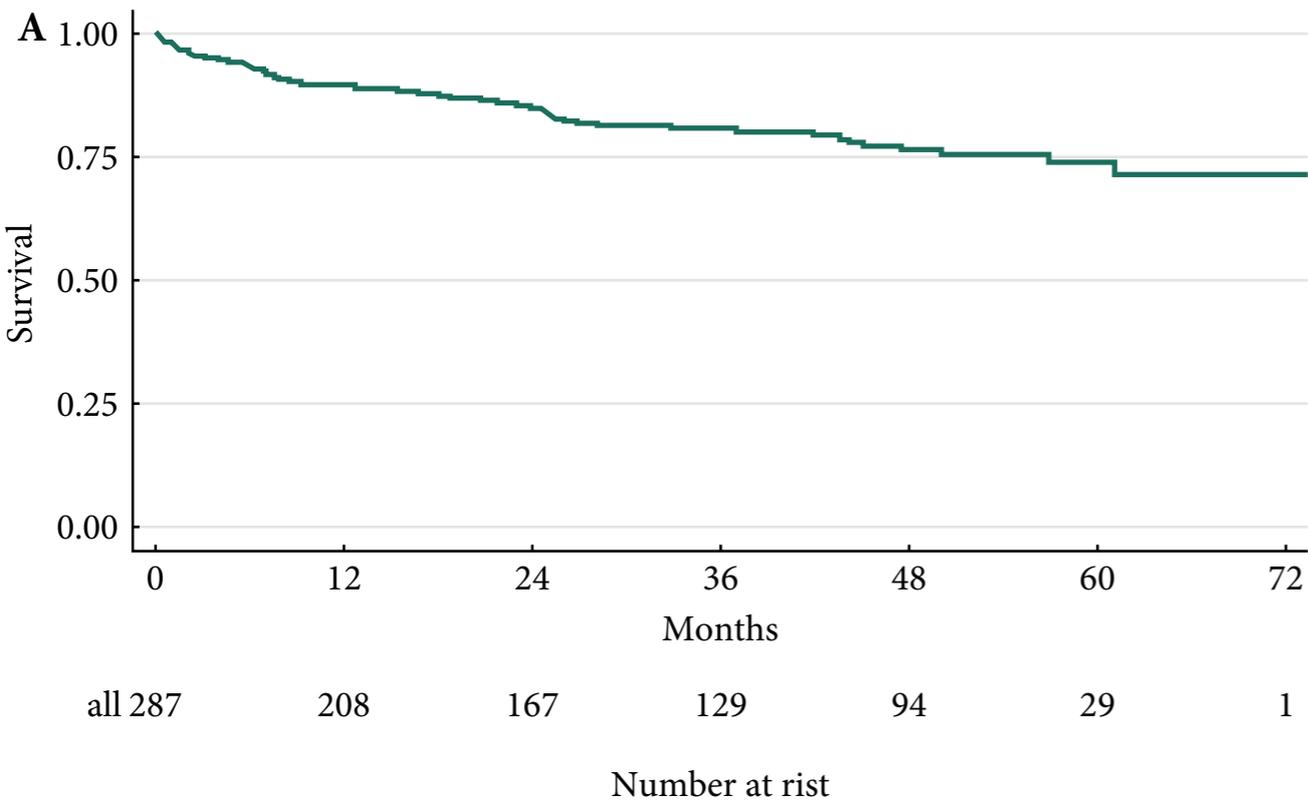
# Prognostic factors



# Prognostic factors



# Prognostic factors



# **Risk Factors for Treatment Failure With the Adjustable Transobturator Male System Incontinence Device: Who Will Succeed, Who Will Fail? Results of a Multicenter Study**

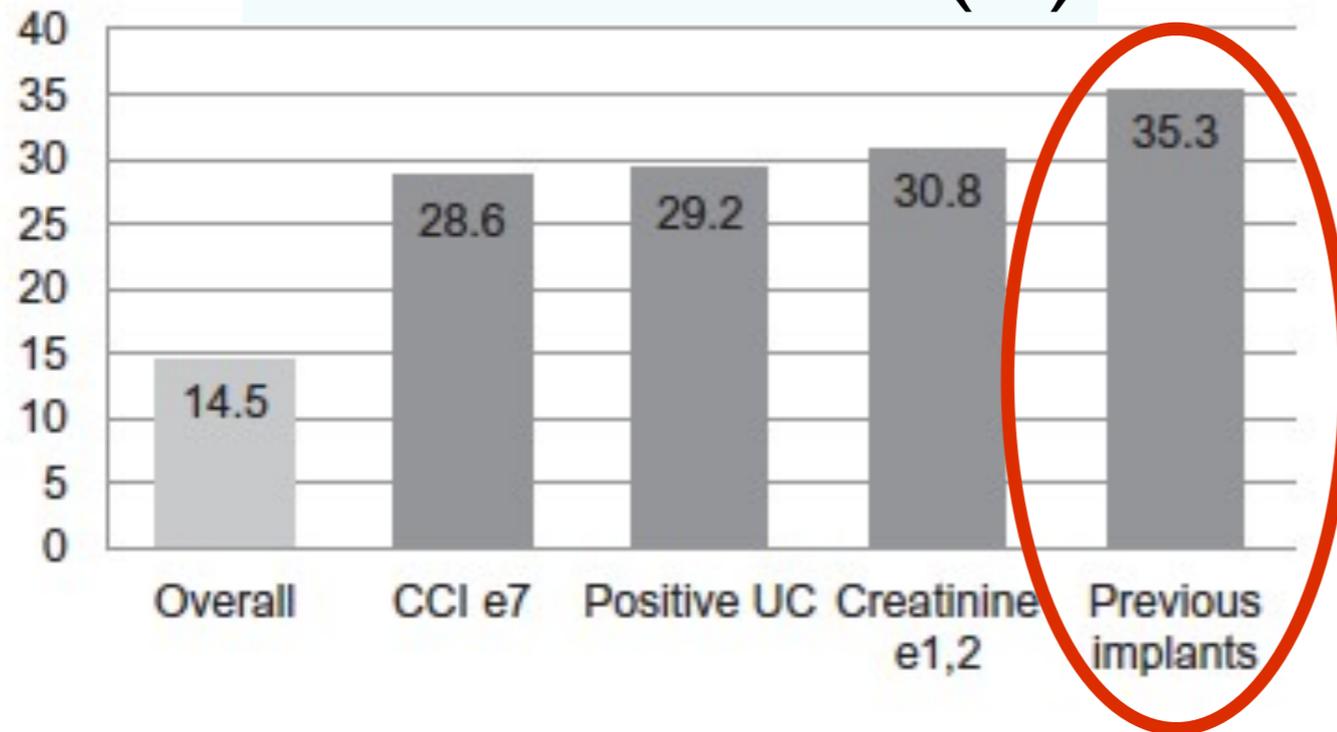
**Alexander Friedl, Sandra Mühlstädt, Maximilian Rom, Danijel Kivaranovic,  
Nasreldin Mohammed, Paolo Fornara, and Clemens Brössner**

## **Failure definition**

- **Implant removal**
- **no improvement**
- **$\geq 3$  pads/d or  $\geq 150$  mL/d**

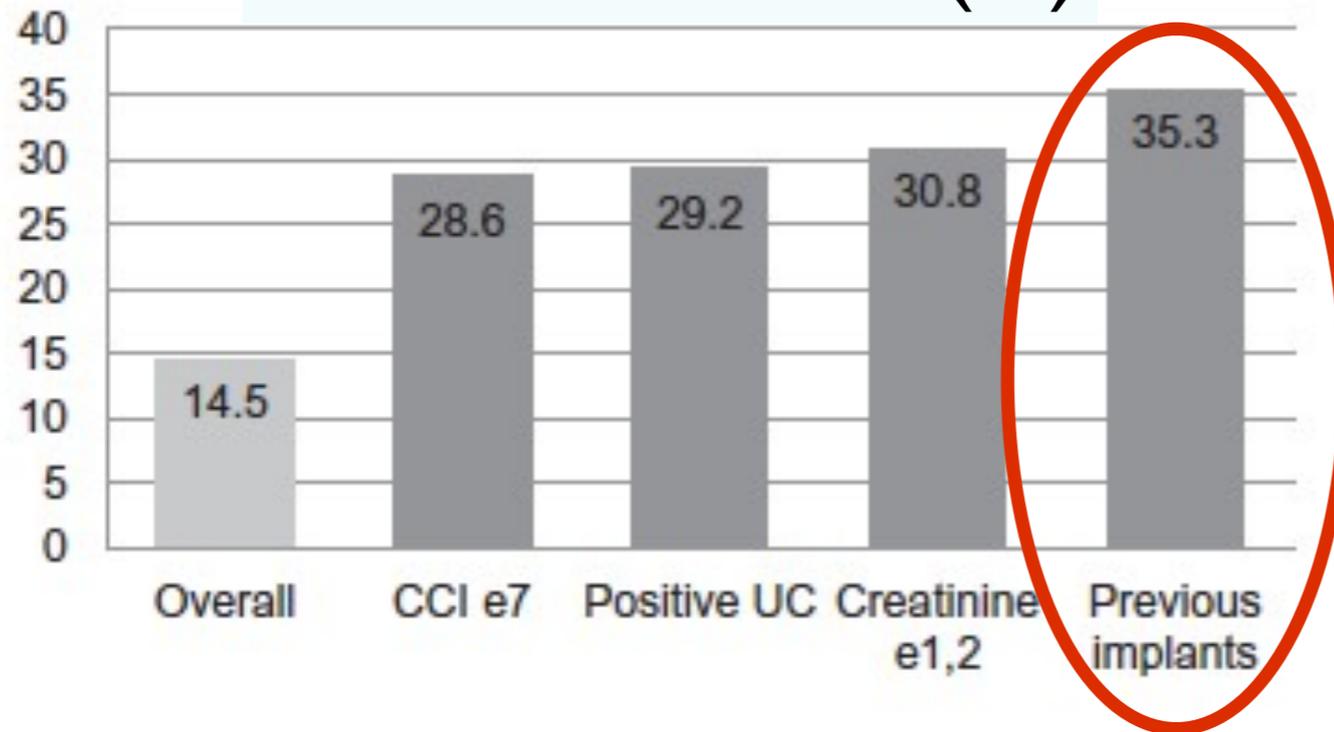
62 p

## Removal rates (%)



significant  
multivariate analysis

## Removal rates (%)



significant  
multivariate analysis

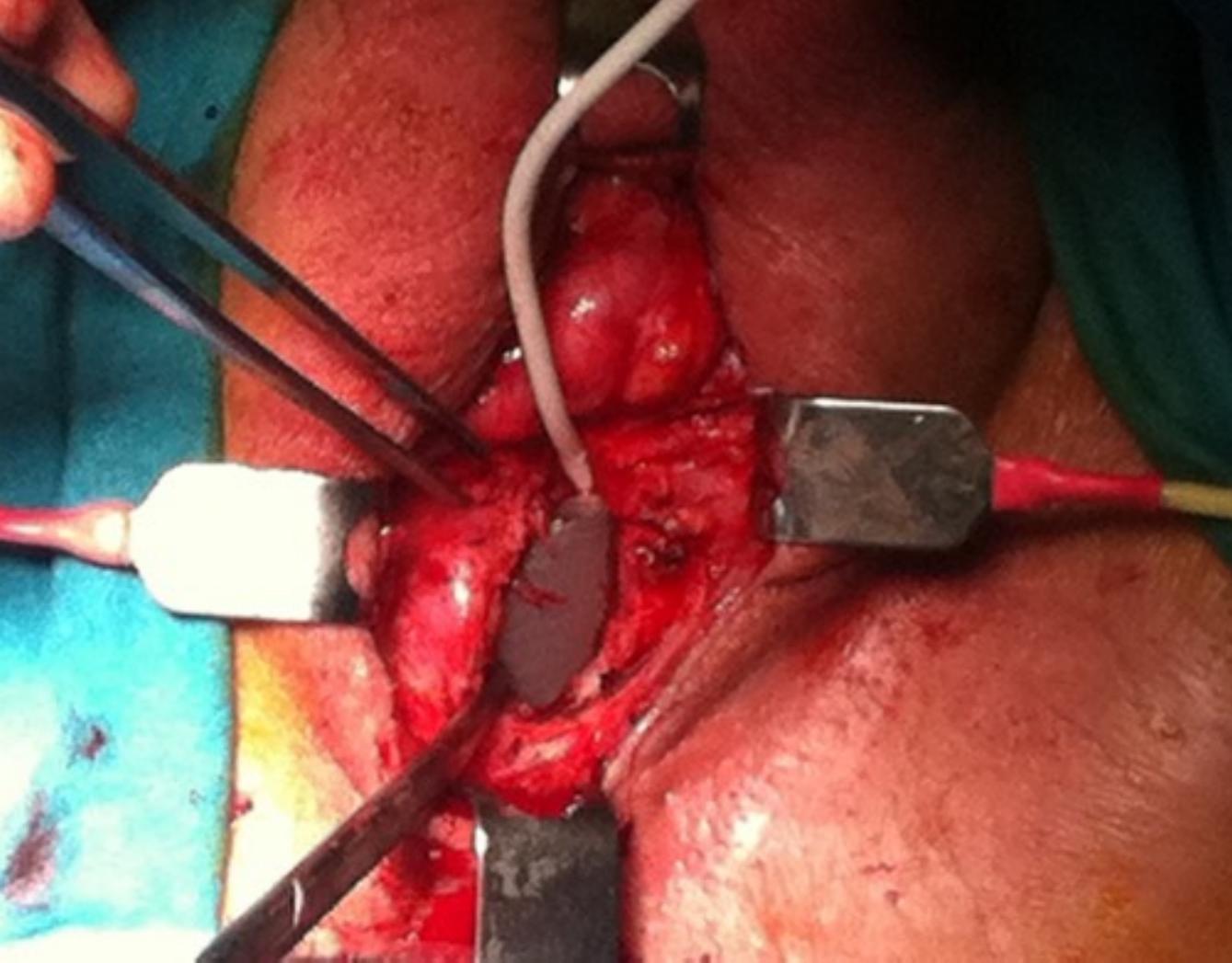
## Predictors of treatment failure

Urine culture +

High Charlson Comorbidity Index

Number of pads





# Results

	n	FU (m)	Dry rate %	Improvement %	Failure %	Complications %
<b>Seweryn et al 2012</b>	38	17	60	24	16	13
<b>Hoda MR et al 2013</b>	99	10	63	29	8	10
<b>Pérez S et al 2014</b>	13	16	92	8	0	23
<b>Krause et al 2014</b>	36	30	39	11	30	30
<b>Mühlstädt et al 2016</b>	54	26	48	30	22	28
<b>Friedl A et al 2016</b>	285	31	64	26	10	20

# Results

	n	FU (m)	Dry rate %	Improvement %	Failure %	Complications %
<b>Seweryn et al 2012</b>	38	17	60	24	16	13
<b>Hoda MR et al 2013</b>	99	10	63	29	8	10
<b>Pérez S et al 2014</b>	13	16	92	8	0	23
<b>Krause et al 2014</b>	36	30	39	11	30	30
<b>Mühlstädt et al 2016</b>	54	26	48	30	22	28
<b>Friedl A et al 2016</b>	285	31	64	26	10	20

# Results

	n	FU (m)	Dry rate %	Improvement %	Failure %	Complications %
<b>Seweryn et al 2012</b>	38	17	60	24	16	13
<b>Hoda MR et al 2013</b>	99	10	63	29	8	10
<b>Pérez S et al 2014</b>	13	16	92	8	0	23
<b>Krause et al 2014</b>	36	30	39	11	30	30
<b>Mühlstädt et al 2016</b>	54	26	48	30	22	28
<b>Friedl A et al 2016</b>	285	31	64	26	10	20

# Results

	n	FU (m)	Dry rate %	Improvement %	Failure %	Complications %
<b>Seweryn et al 2012</b>	38	17	60	24	16	13
<b>Hoda MR et al 2013</b>	99	10	63	29	8	10
<b>Pérez S et al 2014</b>	13	16	92	8	0	23
<b>Krause et al 2014</b>	36	30	39	11	30	30
<b>Mühlstädt et al 2016</b>	54	26	48	30	22	28
<b>Friedl A et al 2016</b>	285	31	64	26	10	20

# Results

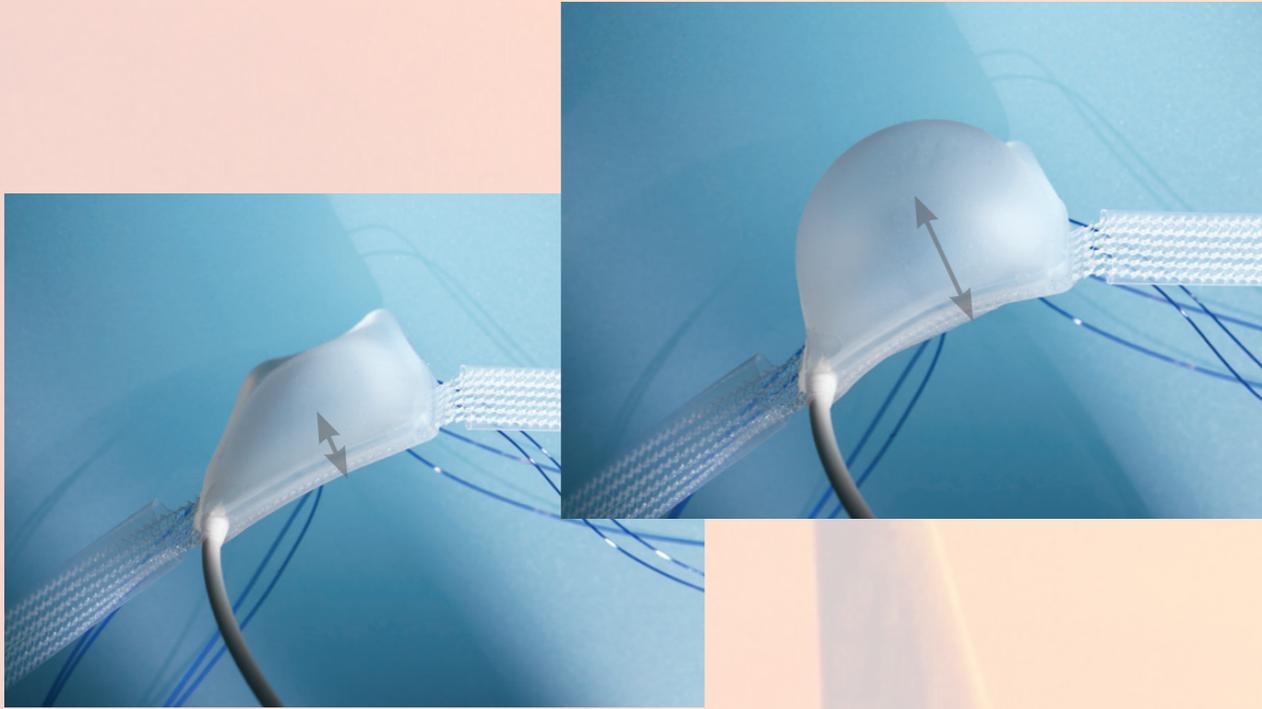
	n	FU (m)	Dry rate %	Improvement %	Failure %	Complications %
<b>Seweryn et al 2012</b>	38	17	60	24	16	13
<b>Hoda MR et al 2013</b>	99	10	63	29	8	10
<b>Pérez S et al 2014</b>	13	16	92	8	0	23
<b>Krause et al 2014</b>	36	30	39	11	30	30
<b>Mühlstädt et al 2016</b>	54	26	48	30	22	28
<b>Friedl A et al 2016</b>	285	31	64	26	10	20

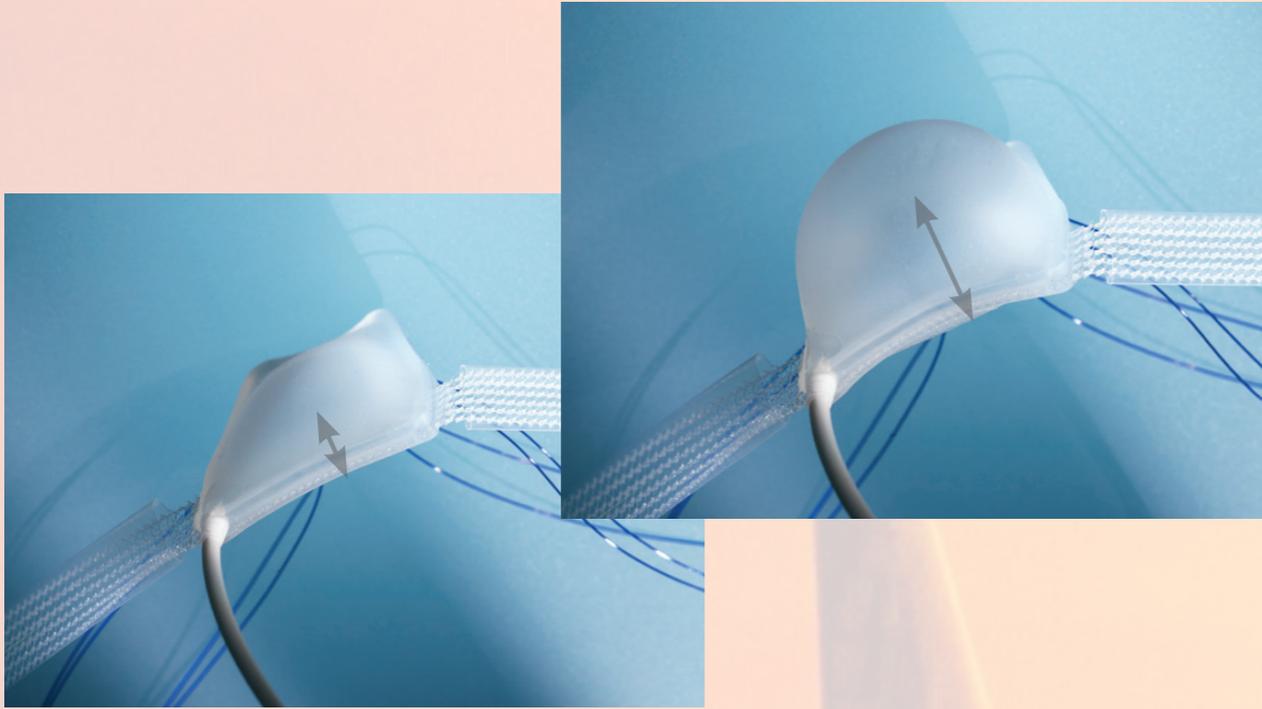
# Results

	n	FU (m)	Dry rate %	Improvement %	Failure %	Complications %
<b>Seweryn et al 2012</b>	38	17	60	24	16	13
<b>Hoda MR et al 2013</b>	99	10	63	29	8	10
<b>Pérez S et al 2014</b>	13	16	92	8	0	23
<b>Krause et al 2014</b>	36	30	39	11	30	30
<b>Mühlstädt et al 2016</b>	54	26	48	30	22	28
<b>Friedl A et al 2016</b>	285	31	64	26	10	20



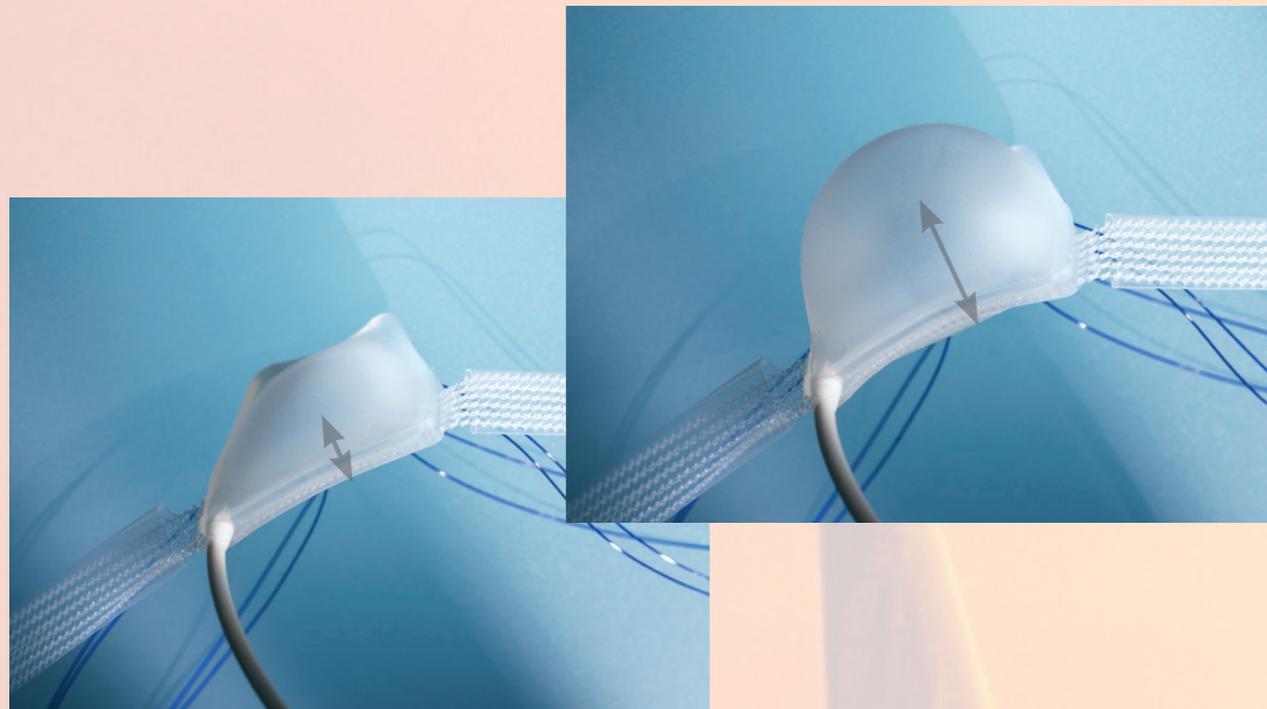






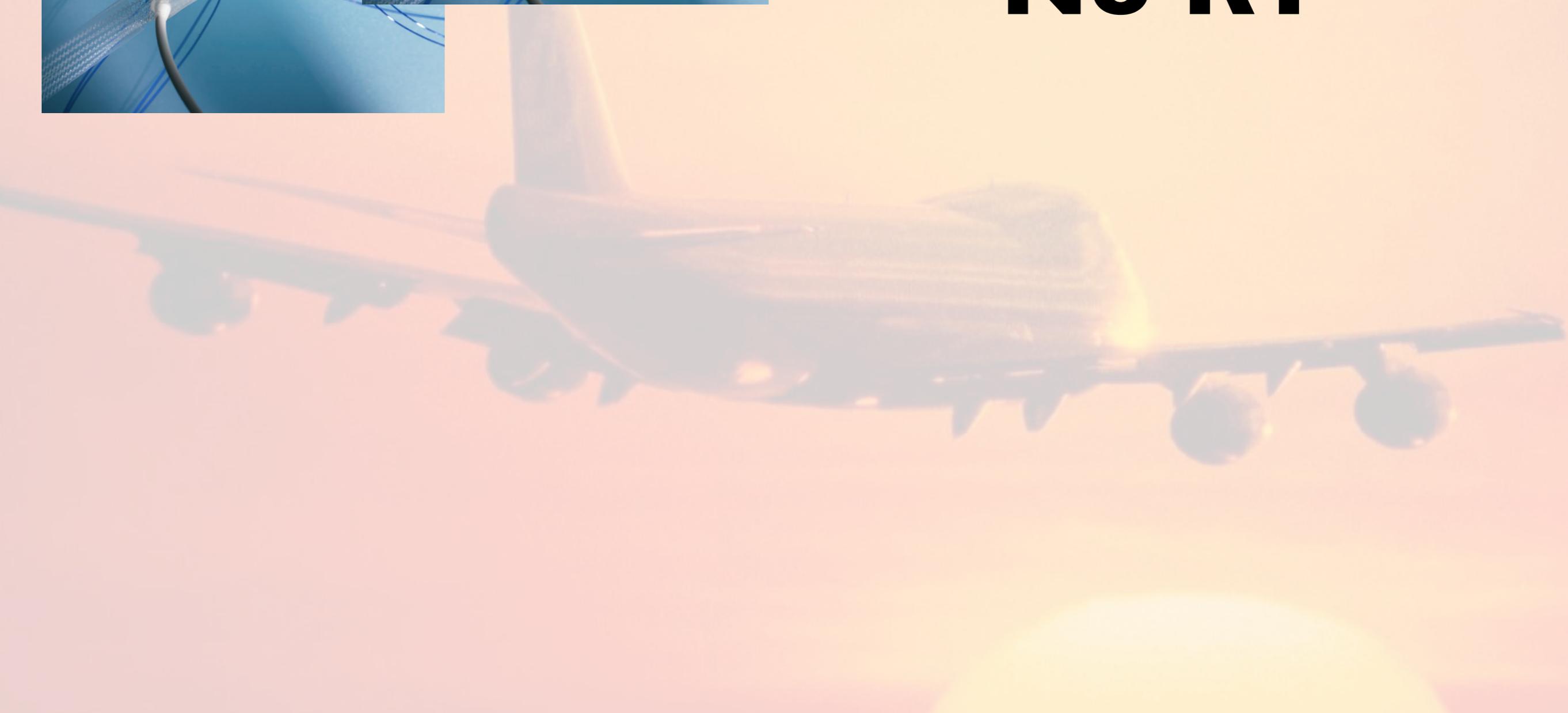
1<sup>st</sup>

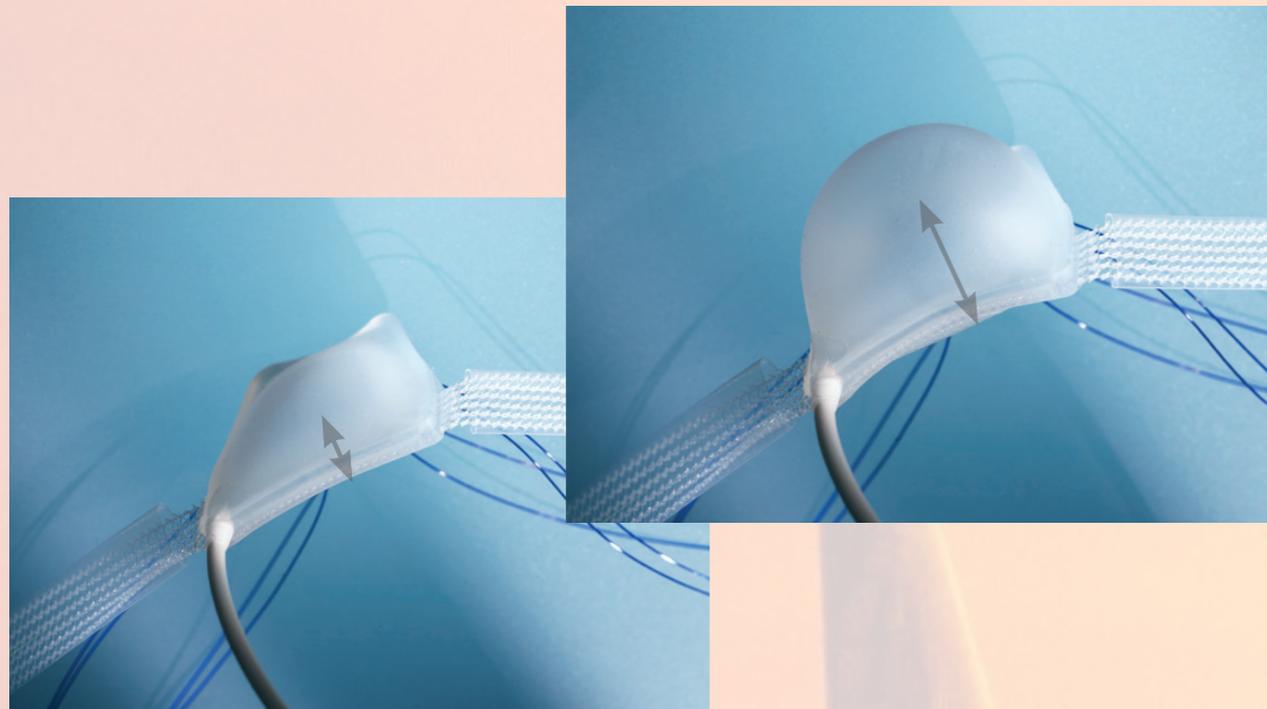




1<sup>st</sup>

**No RT**



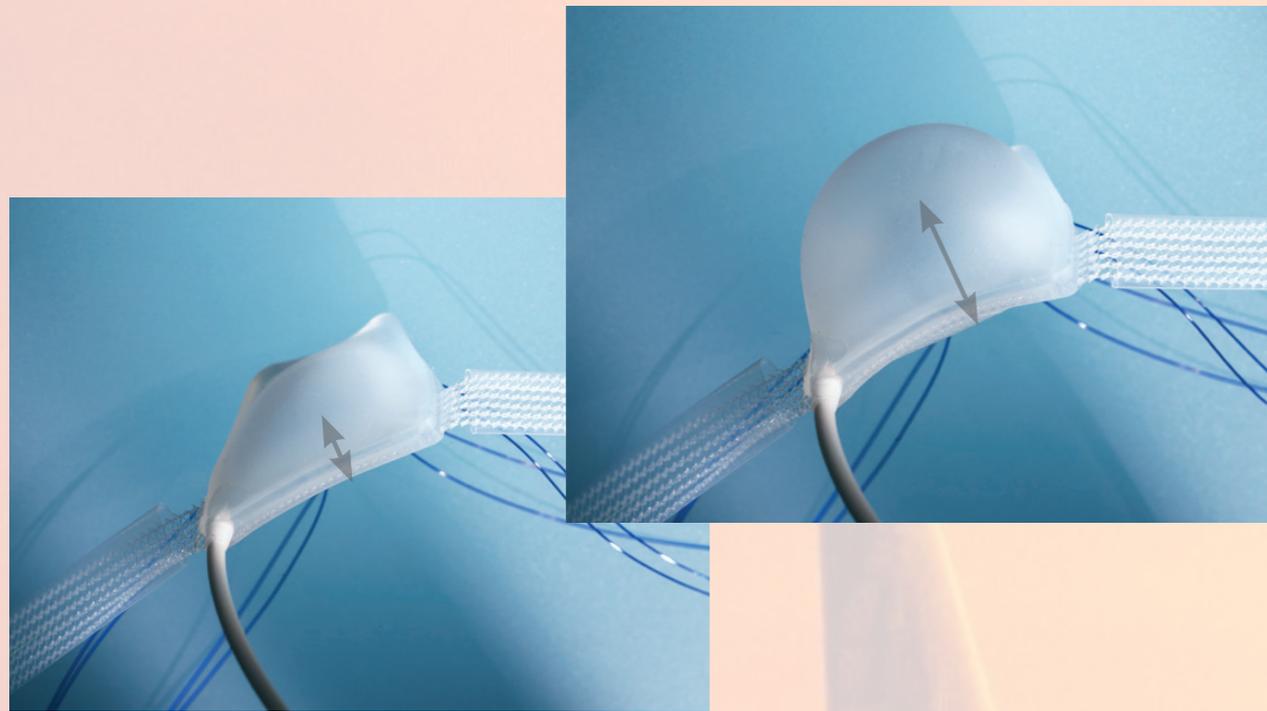


1<sup>st</sup>

**No RT**

Mild  
Moderate



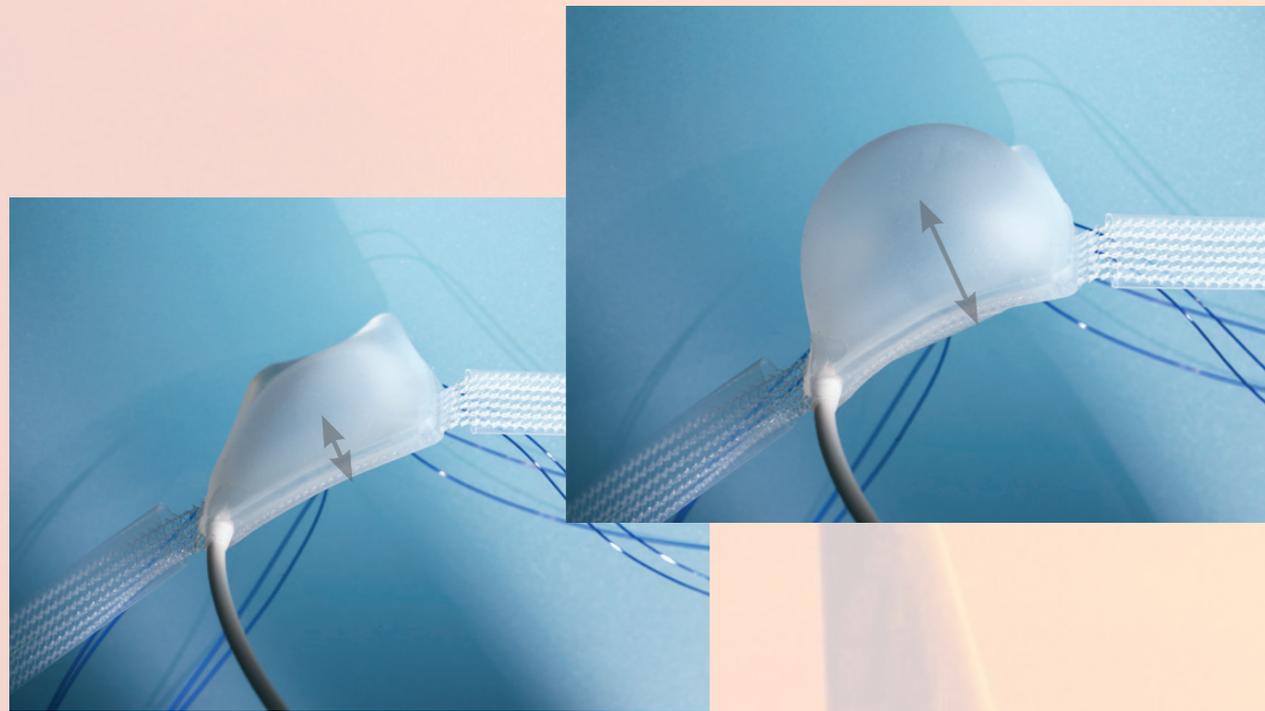


1<sup>st</sup>

**No RT**

Mild  
Moderate





1<sup>st</sup>

**No RT**

Mild  
Moderate



[salvador.arlandis@gmail.com](mailto:salvador.arlandis@gmail.com)