

REZUM and HoLEP



MR. HRISHI JOSHI

**CONSULTANT UROLOGICAL SURGEON AND
HONORARY LECTURER**

**UNIVERSITY HOSPITAL OF WALES AND
SCHOOL OF MEDICINE**



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Treatment Options for BPH



- Watchful waiting
- Pharmacologic therapy
 - Alpha 1-adrenergic blockers
 - PDE-5 inhibitor (tadalafil)
 - 5-ARIs
 - Combination therapy
- Surgery
 - Open surgery (large prostate)
 - TURP(mono or bipolar)
 - Laser Vaporization & Enucleation - Water Jet
- Thermal Ablation
 - TUMT – TUNA
 - Steam (Rezum)
- Prostatic Urethral Lift (UroLift)

Convective water vapour treatment (Rezum)



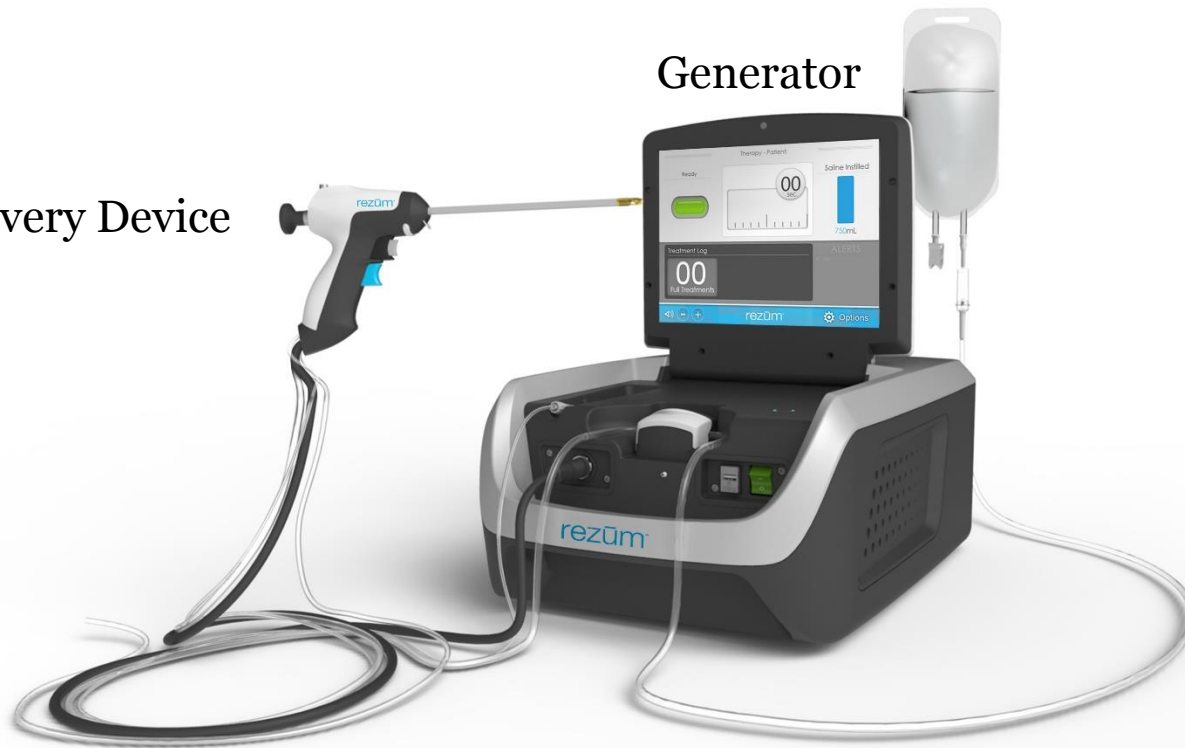
- The Rezum - convective water vapour energy (WAVE) to ablate prostatic tissue.
- Performed in an office or hospital setting using oral pain medication
- Shown to be safe and efficacious in both Phase I and II studies
- MRI study: convective WAVE technology created thermal lesions in the prostate tissue, which then underwent near complete resolution by 3 and 6 months after treatment.
- Associated with a one-third reduction in overall prostate and transition zone volumes

The Rezūm System



Delivery Device

Generator



REZUM animation



3D with Procedure No Loop.mp4

Rezüm - Results

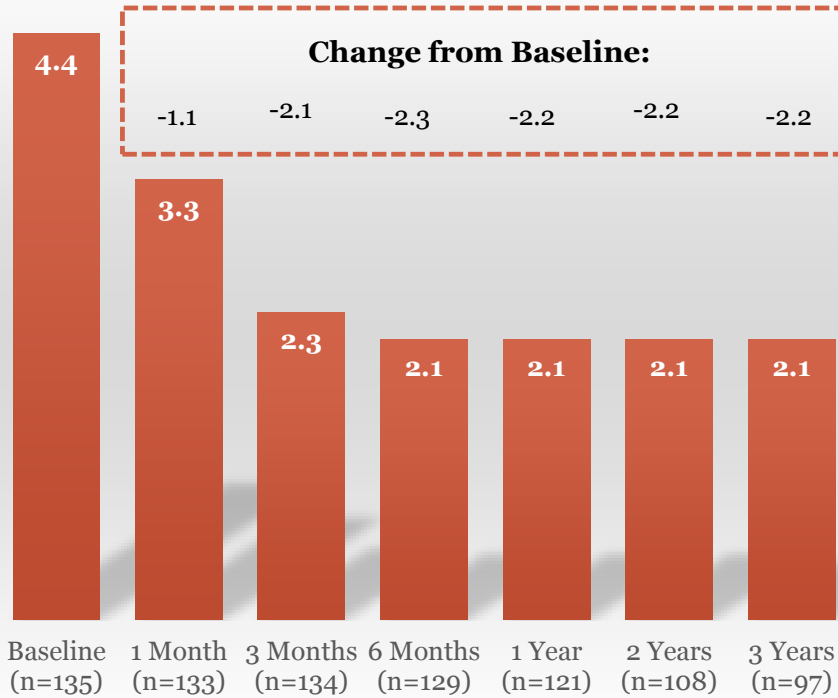


- Pilot studies (n=65) - significant clinical improvements at 1, 3, 6, and 12 months.
- IPSS (reduction of up to 13 points respectively) and
- Q_{\max} (increasing by up to 4.6 mL/s, respectively).
- At 12 months
 - 56% improvement in IPSS ,
 - 61% improvement in QoL and
 - 87% improvement in Q_{\max}
- Sexual function was maintained

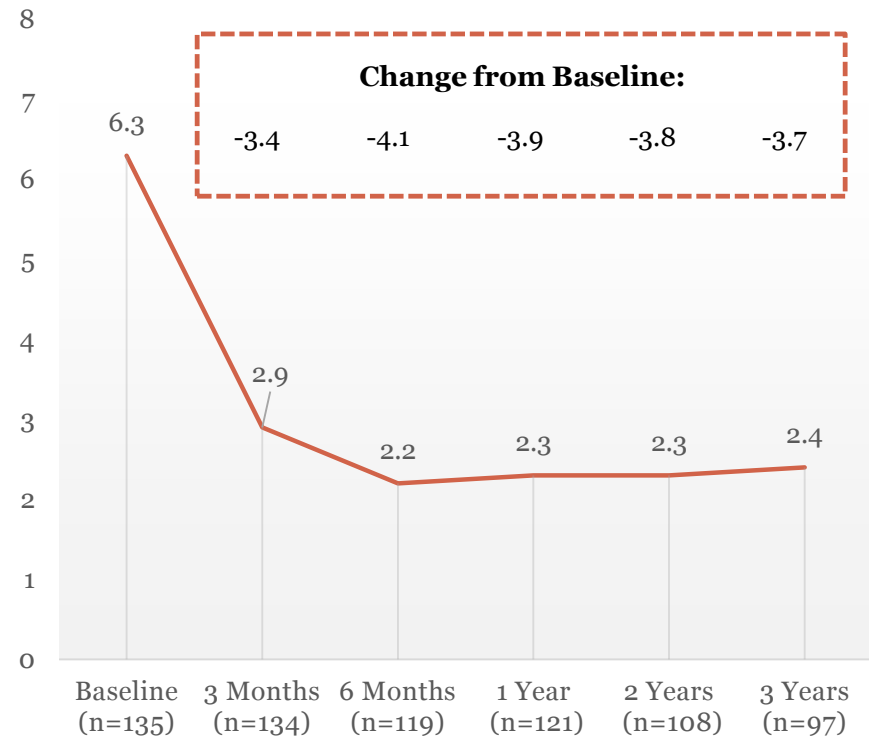
Rezūm Pivotal Study

Sustained Durability at 3 Years

QoL



BPH II



Outcomes with comparable treatments



How do they stack up?



Effectiveness

	UroLift ^{1,2}	Rezum ³
AUASI Improvement at 1 yr	-10.8 -11.4	-11.7
Qmax Improvement at 1 yr [mL/s]	4.0 4.0	5.1
QOL Improvement at 1 yr	-2.4 -2.8	-2.3
Retreatment Rate		
1 yr	5%	2.2%
2 yr	7.5%	4.4%
3 yr	10.5%	---
4 yr	13.6%	---
5 yr	13.6%	---

1. Roehrborn EAU2017, Urol Clin N Am 2016; 2. Sonksen Eur Urol 2015 and Gratzke BJUI 2016;
3. McVary J Urol 2015 and Roehrborn J Urol 2017.

Outcomes with comparable treatments



How do they stack up? Patient Experience

	UroLift ¹	Rezum ²
Local anesthesia compatible?		
Topical lidocaine / Oral Sedative	98%	69%
Prostate Block	2%	21%
IV Sedation	---	10%
Is it tolerable? [Pain VAS]		
Treatment	5.0 ± 3.0	6.4 ± 2.6
Rigid Cystoscopy Control	4.8 ± 2.9	3.8 ± 2.8
Difference	0.2 (4%)	2.6 (68%)

1.Roehrborn J Urol 2013; 2.McVary J Urol 2015.

Outcomes with comparable treatments



How do they stack up?



Patient Experience

	UroLift	Rezum
Can I avoid a catheter?		
No Post Op Catheter	68% ¹ to 80% ²	10% ³
Mean Duration [days]	0.9 ^{1,2}	3.4
Retention	0.7% ¹	3.7%
When can I get back to normal life?		
“Return to Pre-Op Activity” [days]	8.6 ± 7.5 ¹ 5.1 ± 5.8 ²	Median = 4 ³ [0-90]
“Return to Work” [days]	2.8 ± 3.7 ²	Not reported

1.Roehrborn J Urol 2013; 2.Shore Can J Urol 2013; 3.McVary J Urol 2015

Limitations



- Relatively new technology
- No long term data
- Heating technologies in the past have failed
- How to predict precise amount of heated tissue and size reduction - ? Unpredictability
- ? Work well for all sizes and median lobe?
- Limited data against competing technologies

- Current place – between medical and surgical treatment

HoLEP



Holmium Laser Enucleation of prostate (HoLEP)

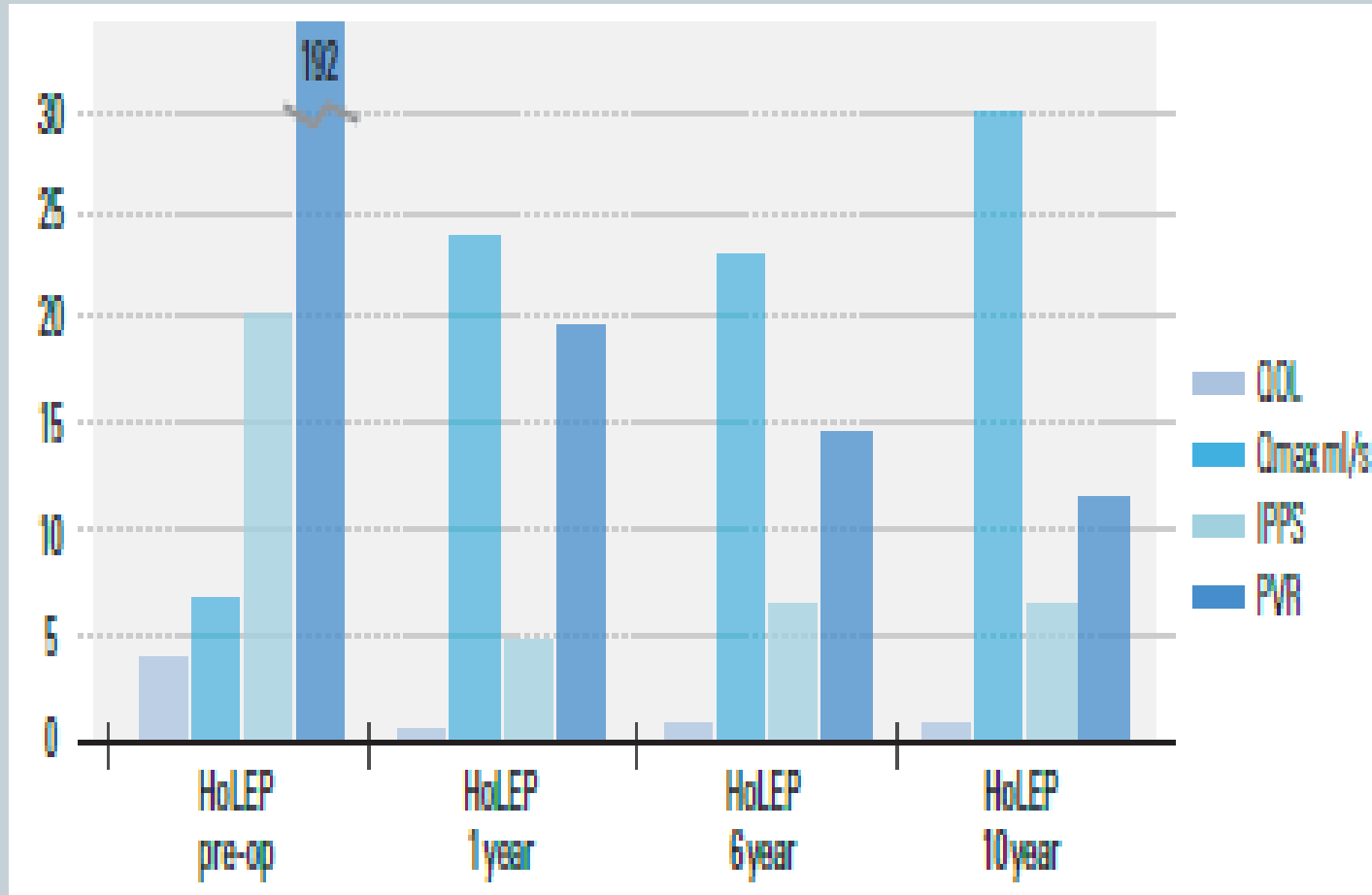


HoLEP results



	Number of patients	Mean patient age (years)	Mean operative time* (min)	Mean enucleated tissue weight (grams)	Mean length of hospital stay (days)	Mean pre-op Qmax (cc/sec)	Mean post-op Qmax (cc/sec)	Mean pre-op AUA SS	Mean post-op AUA SS
Fraundorfer, et al[22]	14	72.0	98	37.5	1.1	7.0	25.2	21.2	7.2
Gilling, et al[25]	64	70.2	59.2	35.5	1.3	8.9	23.4	23.0	8.6
Moody, et al[26]	61	71.3	117	48.0	1.2	7.7	-	20.4	6.7
Gilling, et al. [27]#	43	73.8	82.5	61.8	1.2	9.0	24.8	23.5	2.8
Moody, et al. [23]#	10	74.8	197	151.0	2.1	-	-	19.0	6.3
Kuntz and Lehrich[28]#	60	69.2	135.9	83.9	2.9	3.8	27.6	22.1	3.3

QOL, Qmax ml/s and IPSS outcomes at 10 years are comparable to outcomes at 1 year



Outcomes of HoLEP

HoLEP – 23 RCTs

2245 patients

- 14 Vs TURP/TUVP
- 1 Vs Gyrus
- 2 Vs Open
- 1 Vs Laser BNI
- 2 KTP laser

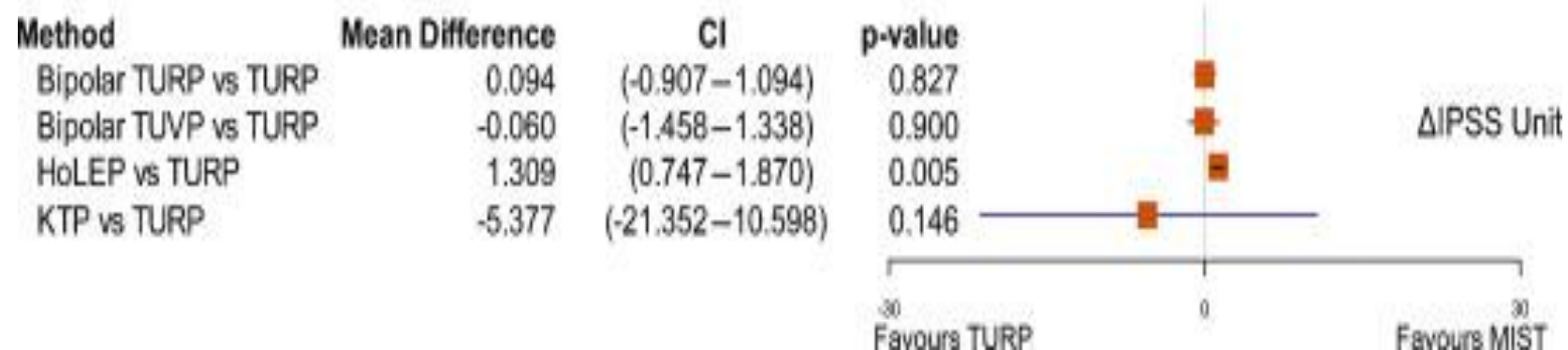
(Ahyai et al Eur Urology
2010)

Improvements:

- Max Flow rate – 300-600% @12 months
- Prostate volume reduction: 76-82%
- IPSS – 80-90% @12 months
- PSA reduction – 85%
- less blood loss and transfusion ($p = 0.001$),
- shorter catheterization time ($p < 0.001$),
- shorter hospital LOS ($p = 0.001$),

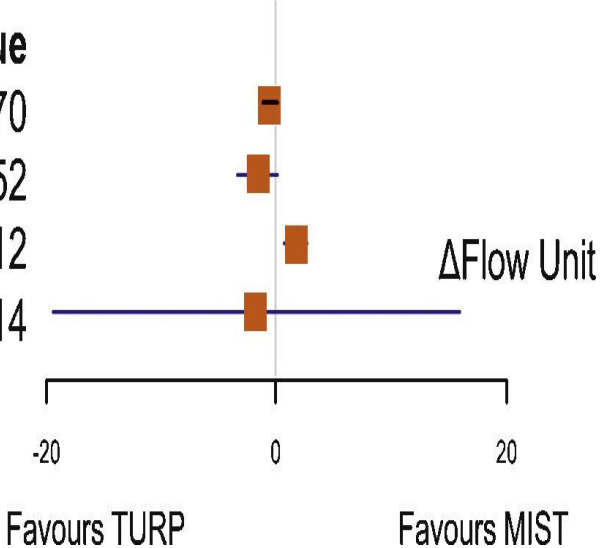
Meta-analyses of functional outcomes after prostatic tissue ablation: Comparison of different transurethral procedures and TURP

IPSS



Qmax

Method	Mean Difference	CI	p-value
Bipolar TURP vs TURP	-0.539	(-1.139–0.060)	0.070
Bipolar TUVF vs TURP	-1.696	(-3.416–0.024)	0.052
HoLEP vs TURP	1.687	(0.711–2.664)	0.012
KTP vs TURP	-1.826	(-19.466–15.814)	0.414



Complications



Common (>10%) - Mild burning, bleeding and frequency of urination after the procedure

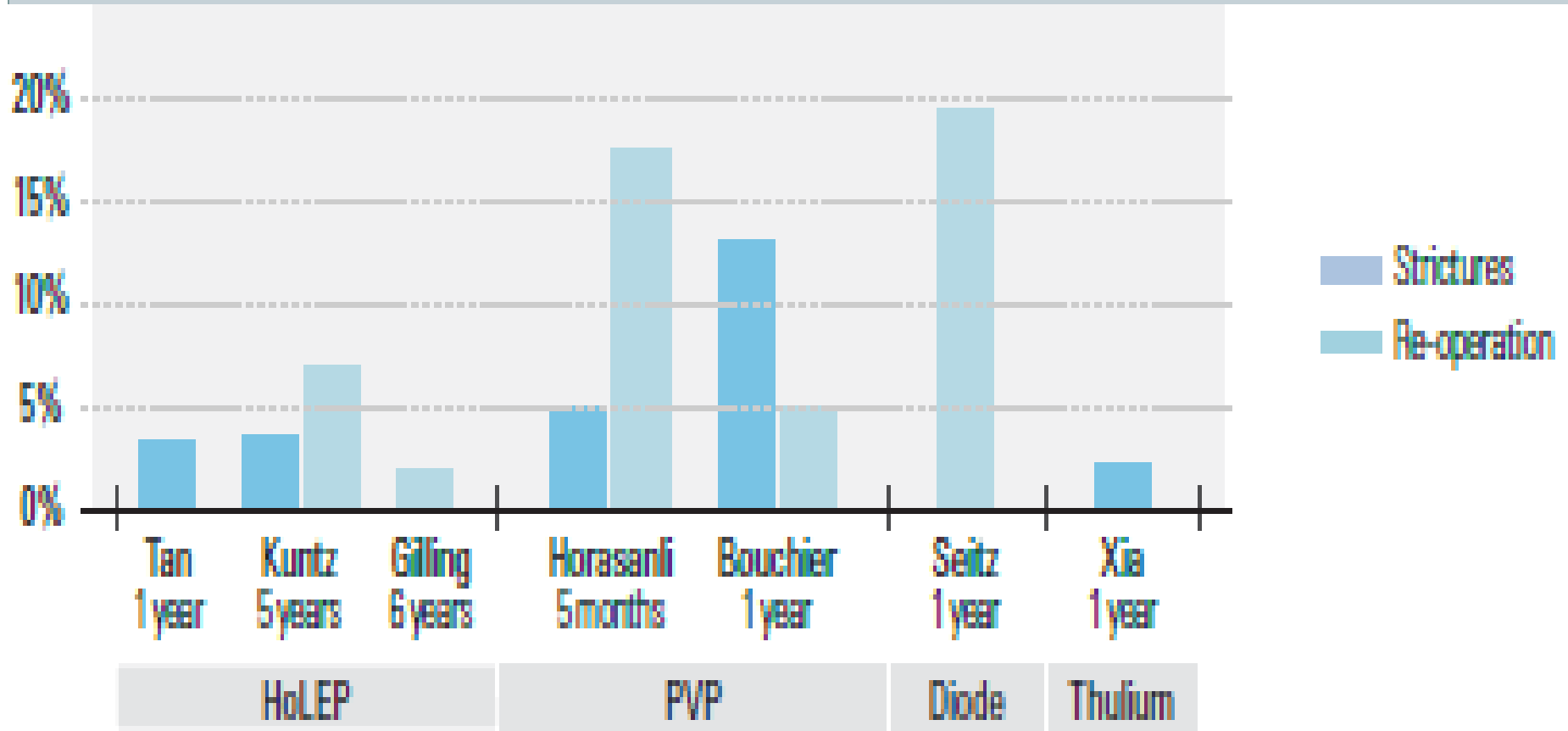
- -60=70% dry ejaculation
- Re-treatment - Possible need to repeat treatment later due to re-obstruction (approx 5-10%)
- Loss of urinary control (incontinence) which reduces within 6 weeks (10- 15%)

Occasional - Bleeding requiring return to theatre and/or blood transfusion (less than 2%)

Rare (<2%) - Retained tissue fragments which may require a second telescopic procedure for their removal

Very Rare - perforation of the bladder requiring treatment

HoLEP has fewer complications and lower re-operation rate^{1,2,3,7,8,9,10}



Post HoLEP incontinence



TUI, defined as any type of urine leakage, occurred after HoLEP in some patients, most of whom recovered within three months.

Stress urinary incontinence occurred in only 4% of patients after HoLEP.

Age and total operation time were associated with the occurrence of postoperative TUI. – **World Journal of Men's health 2015**

Incontinence



- Pelvic floor muscle re-education – pre and post operative, produces a quicker improvement of urinary symptoms and of quality of life in patients after TURP
- Intra-detrusor Botox injection and peri-urethral bulking agents in refractory
- Artificial sphincter <0.1%

Cost savings – Hospital stay alone

UHW audit



- Hospital stay: £536/ day
- Average cost for hospital stay per TURP: £1,286.40
- Average cost for hospital stay per HoLEP: £562.80
- £723.60
- Potential direct saving on hospital stay /100 patients: £72K or more
- Savings more – larger prostates

Indirect Cost Savings



- Other advantages with HoLEP (Difficult cost calculations):
 - Minimal/ no post operative irrigation
 - Hospital bed for other procedures (pre + post procedure)
 - Nursing care
 - Holmium laser + stones
- TURP cancellations – a significant bed impact ?



THANK YOU