Clinical Summary

Holmium Laser Ablation of the Prostate

Boston Scientific

Dr. Ramsay Kuo, Volunteer Clinical Assistant Professor at Indiana University School of Medicine has compiled a summary of clinical data on Holmium Laser Ablation of the Prostate.

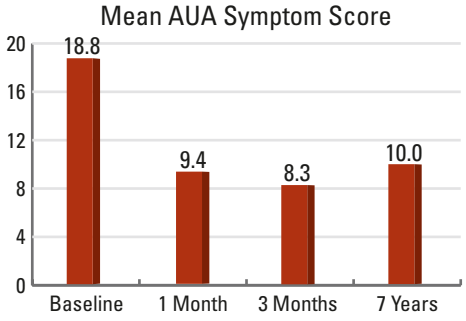
The following are a few selected series:

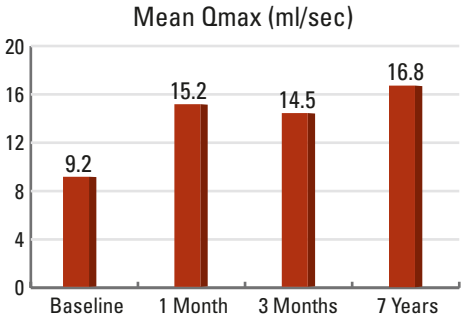
A Long-Term HoLAP Results

Long-term results of high-power holmium laser vaporization (ablation) of the prostate

Tan A, Gilling P, etal: BJU International 92:707-9, 2003

- 79 patients (mean age 67 years, mean TRUS volume 40.5 g) underwent HoLAP from 9/94 to 5/95
- 60 W unit utilized, settings of 2.4 J and 25 Hz
- 34 patients completed follow-up assessment (median 7.4 years)





5/34 pts (15%) required reoperation (1 BNI, 1 TURP, 2 HoLEP, 1 bladder stone removal)

Clinical Data Summary:

- 83% improvement in Qmax
- 47% decrease in AUA symptom score
- Durable outcomes over 7 years in some patients
- 15% reoperation rate, comparable to TURP

HOLAP

"Experience with holmium vaporization showed that the procedure was...simple to learn, and was effective in relieving the symptoms and improving flow rates in men with BPH."

B HoLAP Results vs. TURP

Randomized Comparison of Transurethral Electroresection and Holmium: YAG Laser Vaporization for Symptomatic Benign Prostatic Hyperplasia

Mottet, et al: J Endourol 13:127-130, Mar 1999

- Multi-center randomized trails
- 36 consecutive patients randomized in 2:1 fashion to HoLAP or TURP (23 HoLAP, 13 TURP)
- 60 to 80 watt holmium units utilized
- 6 patients treated with associated Nd:YAG

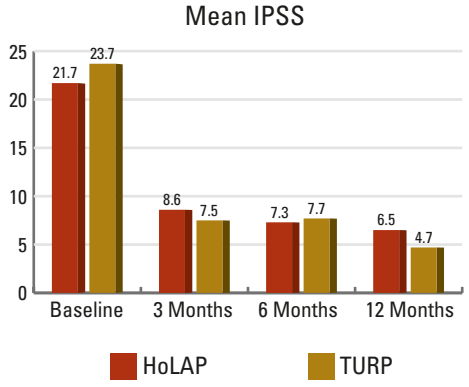
Baseline patient characteristics

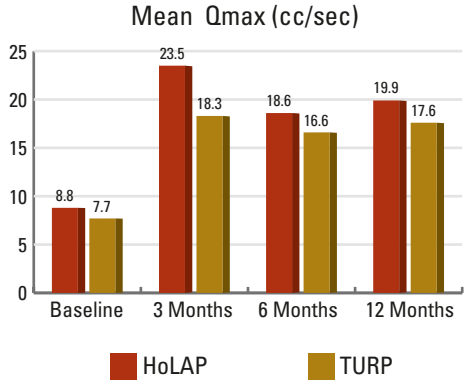
Mean	HoLAP (n=17)*	TURP (n=13)
Age (years)	67	64
Prostate volume (cc)	39	34

*not including 6 patients also treated with Nd:YAG.

Outcomes

Mean	HoLAP (n=17)	TURP (n=13)
Operative time (min)	75	40
Catheter time (days)	1.7	2.1
Hospital stay (days)	1.6	3.1





Clinical Data Summary:

- Outcomes between HoLAP and TURP patients equivalent at 12 month follow-up
- No post-operative irrigation required in HoLAP group
- Catheterization times for HoLAP only patients shorter
- Hospital stays for HoLAP patients shorter

"…holmium: YAG laser vaporization of BPH provides early results very similar to those of TURP with a shorter catheterization time and no initial dysuria or pain."

C HoLAP for Large Glands

Holmium Laser Ablation of Large Prostate Glands: An Endourologic Alternative to Open Simple Prostatectomy

Kumar, SM: Presented at 80th Annual Meeting of the North Central Section of the AUA

- 17 patients (mean age 68.2 years and TRUS volume > 80 cc)
- Mean laser time 77 minutes (range 43 to 203)
- Mean catheter time 2.12 days (range 1 to 5)
- Mean length of stay 1.34 days (range 1 to 3)
- No patients required continuous bladder irrigation
- 1 patient on clopidrogel had clot retention and required blood and platelets

	Pre-op	Post-op	% Change
AUA Symptom Score	20.4 ± 5.4	5.7 ± 2.2	**72%**
Post-void residual (cc)	121.8 ± 42.1	54.6 ± 20.7	**55%**
Qmax (cc/sec)	6.9 ± 5.7	15.1 ± 7.6	**217%**
Sodium	138.5 ± 2.5	138.0 ± 3.3	–
Hemoglobin	14.4 ± 1.2	13.6 ± 1.3	**6%**

Clinical Data Summary:

- 72%decrease in AUA symptom score
- 55% reduction in PVR
- 217% increase in Qmax

"Due to the excellent ablative and hemostatic properties of Holmium laser wavelength, large prostate glands can be safely vaporized with minimal morbidity and a short hospital stay."

D Holmium vs. KTP

Advantages of Holmium:

- Controlled depth of penetration
- Less necrosis beyond tissue surface
- "What you see is what you get" treatment effect

	Holmium	PVP
Wavelength	2140 nm	532 nm
Absorption medium	Water	Hemoglobin
Penetration depth	0.5 mm	1-2 mm
Laser fiber	550µ Duotome	600µ ADDStat
Effective for stones	Yes	No

Points for consideration:

- Consequences of differences in medium absorption by holmium and KTP energy
  - When holmium fiber tip held a few millimeters away from tissue, no tissue effect occurs secondary to water or saline absorption
  - KTP energy absorption by hemoglobin necessitates very careful use near the bladder neck to prevent vaporization near trigone
  - Decrease in vascularity in deeper adenoma may translate to decreased treatment efficacy of KTP later in procedure and incomplete treatments

E Holmium Reference Article List

Comprehensive studies show that holmium laser is excellent for treating BPH. Holmium laser treatments have been among the most rigorously investigated BPH techniques. Over **90** articles have been published from 8 randomized clinical trials and over 30 case studies and comparative series.

Below is a abbreviated list of selected articles. A full listing is available upon request.

Gilling PJ, et al. *Combination Holmium an ND: YAG Laser Ablation of the Prostate: Initial Clinical Experience.* J Endo, 9:151-153, Apr 1995.

Gilling PJ, et al. *The Use of Holmium Laser in the Treatment of Benign Prostatic Hyperplasia.* J EndoUrol, 10(5): 459-461, Oct 1996.

Fraundorfer M, Gilling P. *Laser Prostatectomy Techniques: Holmium Laser Resection and Holmium Laser Enucleation with Intracavity Morcellation.* Current Surg Techniques in Urol, 11(2):1-7, 1998.

Mottet N, et al. *Randomized Comparison of Transurethral Electroresection and Holmium: YAG Laser Vaporization for Symptomatic Benign Prostatic Hyperplasia.* J Endourol, 13:127-130, Mar 1999.

Bagley D, Das A. *Endourologic Use of the Holmium Laser, Book Chapter 7, Teton New Media,* ISBN:1-83441-43-1, 2001.

Tan A, Gilling P, et al. *Long-term Results of High Power Holmium Laser Vaporization (Ablation) of the Prostate.* BJU International 92(7):707-709, Nov 2003

Kuo R, Lingeman J. *Use of the Holmium Laser for the Treatment of Benign Prostatic Hyperplasia.* Business Briefing: Global Surgery 2004 Extract, Nov 2004.

Kuo R, et al. *On the Cutting Edge: Holmium Laser Ablation for BPH.* Urol Times, 33(9):1-7, Sep 2005.

Wilson C, Gilling P. *Lasers for Prostate Surgery – An Update.* European Kidney and Urologic Disease 2006, Touch Briefing, Dec 2005

Kuntz, R. *Current Role of Lasers in the Treatment of Benign Prostatic Hyperplasia (BPH).* Eur Urol, 49:961-969, Jun 2006.

Elzayat E, Elhilali M. *Laser Treatment of Symptomatic Benign Prostatic Hyperplasia.* J Urol, Jul 2006.

Kumar SM, *Poster Presentation at 80th Annual Meeting of North Central Section of AUA, 2006.*

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