The gap in the care for glaucoma patients

Noncompliance with drugs versus invasive surgery

?

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What is the ideal solution for chronic disease management?

- **Effectively and significantly lowers eye pressure**
- **Gives physician control of therapy compliance**
- **Efficient**
- **Repeatable**
- **Leaves future options open**

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New Glaucoma Dedicated Laser System: CYCLO G6™

CYCLO G6™

Glaucoma Laser System

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CYCLO G6™ Glaucoma Laser System

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Glaucoma Laser System

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MicroPulse® P3

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MicroPulse® P3 – Innovative Cyclophotocoagulation with MicroPulse Technology

- Excellent Safety Profile
- Efficient & Straightforward for physician and patient
- Can be performed in the Office & OR
- Predictability

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Excellent Safety Profile

- Non-incisional
- Minimal to no inflammation post-op
- Patient downtime is significantly low
- Repeatable

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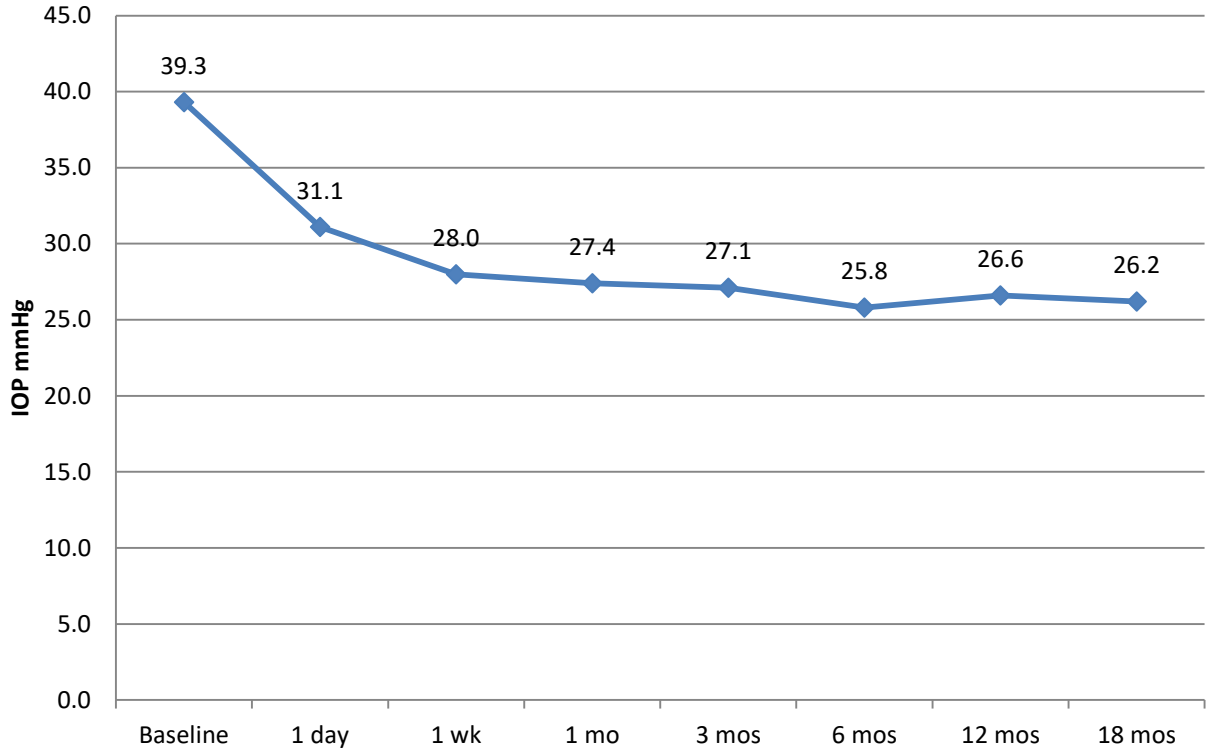
Long-term results from early work at NUHS
73% success rate @ 18 months



- 33% IOP reduction at 18 mos
- Med reduction from mean of 2.1 to 1.3
- 1.3 sessions

Chew Study		20.9%	28.8%	30.3%	31.0%	34.4%	32.3%	33.3%
# of Patients	38							38

Tan A, Chockalingam M, Aquino M, Lim Z, See J, Chew P. Micropulse transscleral diode laser cyclophotocoagulation in the treatment of refractory glaucoma. *Clin Experiment Ophthalmol 2010;38(3):266-72.*

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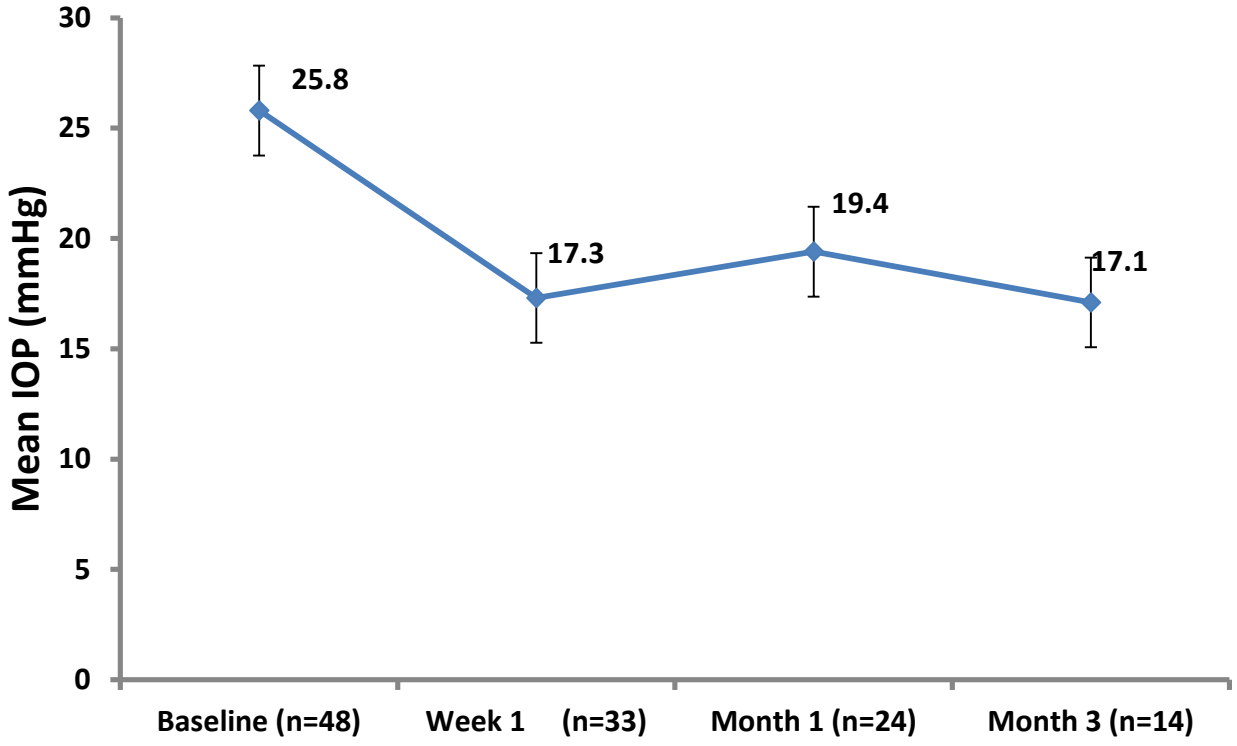
Early US work with Ahmed, Kammer, Khatana, Noecker, Parekh, Radcliffe, Vold also shows IOP reduction even with lower pre-op IOP starting point



Mean % Change in IOP		21.6%	30.0%	29.8%

- Ongoing patient case series
- 30% IOP reduction at 3 months
- Meds reduced from mean of 3.3 to 2.4

Radcliffe N, Vold S, Kammer J, Ahmed I, Parekh P, Noecker R, Khatana A. MicroPulse Trans-scleral Cyclophotocoagulation (mTSCPC) for the Treatment of Glaucoma Using the MicroPulse P3 Device. AGS, San Diego February 26 - March 1, 2015.

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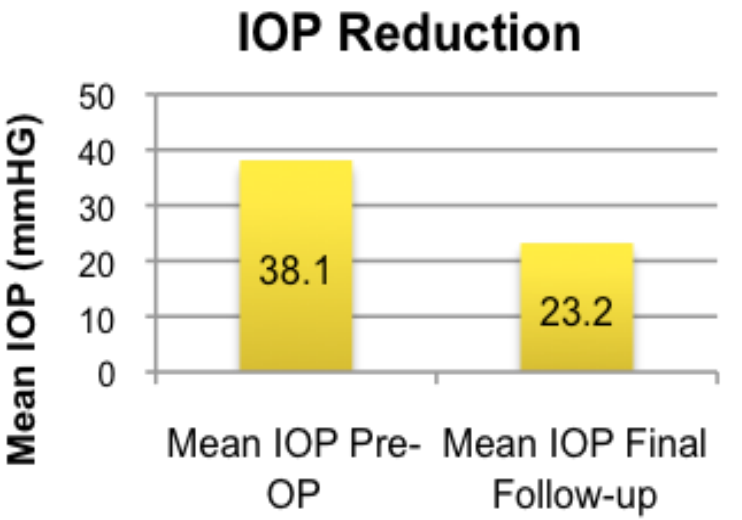
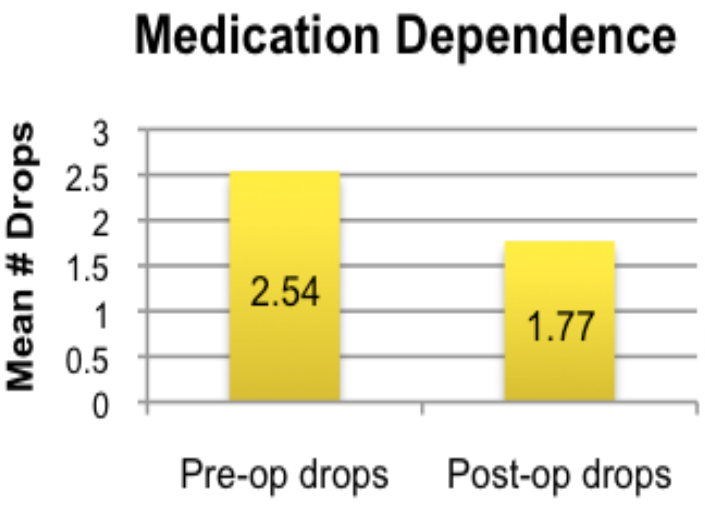
MicroPulse P3 Peer Reviewed Study by Wills Eye Hospital - Dr. Marlene Moster





39.1% IOP reduction
Med reduction from mean of 2.54 to 1.77
Pilot case series of 19 consecutive patients with mean 50.1 day follow-up

1)Kuchar S, Moster M, Waisbourd M. Treatment Outcomes of MicroPulse Trans-scleral Cyclophotocoagulation in Advanced Glaucoma. AGS abstract, San Diego February 26 - March 1, 2015.
2) Kuchar S, Moster M, Waisbourd M. Treatment Outcomes of MicroPulse Trans-scleral Cyclophotocoagulation in Advanced Glaucoma. Lasers Medical Science ((2016)31:393-396, DOI 10.1007/s10103-015-1856-9.

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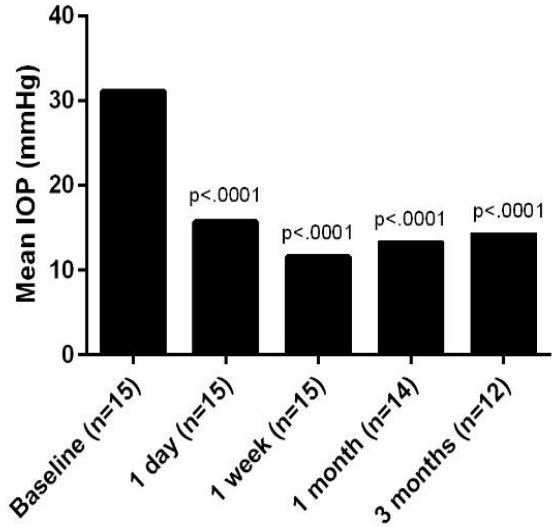
MicroPulse P3 AGS 2016 Prospective Study
Dr. Marlene Moster, Wills Eye Hospital



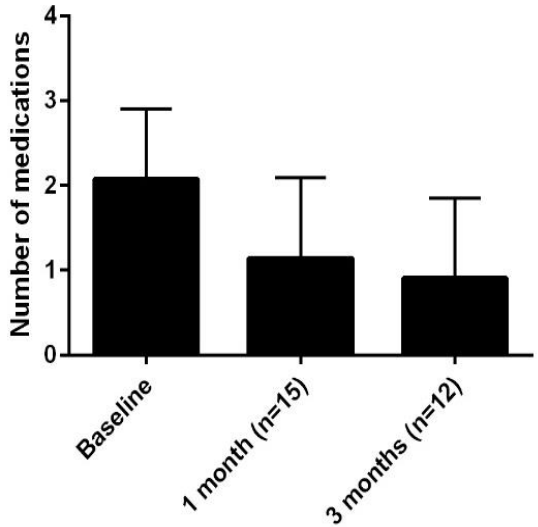


Figure 1. Intraocular pressure reduction and number of glaucoma medications distribution at study visits.

	Month 1	Month 3
IOP reduction	57%	54%
Mean # meds (baseline = 2.1)	1.1	0.9

93% success on first treatment @ 3 mo follow-up
15 patient study continuing for 1 year follow-up

Resende A, Moster M, Waisbourd M. A Prospective Pilot Study Evaluating the Novel Micropulse Transscleral Cyclophotocoagulation: Short-Term Results. AGS abstract, San Diego March 3-6, 2016

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MicroPulse vs normal TSCPC – 2014 controlled, randomized study showed similar IOP reduction as G-Probe with higher success rate and no hypotony

Clin Experiment Ophthalmol. 2014 May 9. doi: 10.1111/ceo.12360. [Epub ahead of print]

Micropulse versus continuous wave trans-scleral diode cyclophotocoagulation in refractory glaucoma: a randomised exploratory study.

Aquino MC[1], Barton K, Tan AM, Sng C, Li X, Loon SC, Chew PT.

	MicroPulse TSCPC	TSCPC
Pre-op IOP	36.5 mmHg	35.0 mmHg
N Total of 48	24 pts	24 pts
Average Followup	17.5 months	17.5 months
IOP reduction	45% reduction in IOP	45% reduction in IOP
Success Rate (≤21 mmHg at 12 months)	75%	29%
Prolonged Hypotony	0	5
Mean number of treatments	1.6	1.3

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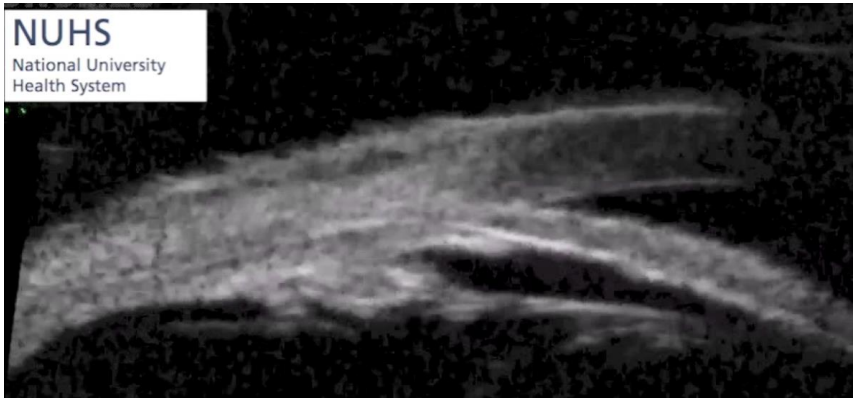
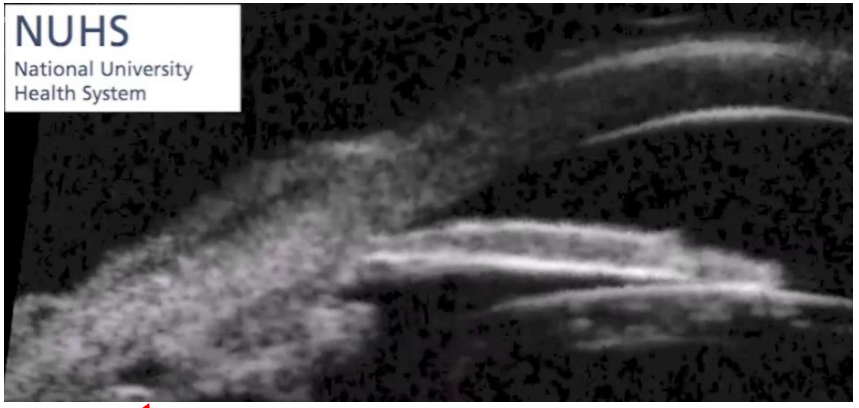
Standard TSCPC is Destructive

Pre TSCPC



Post TSCPC



Images courtesy of A/Professor Paul Chew, NUHS

Characteristic evidence of cyclo-destruction

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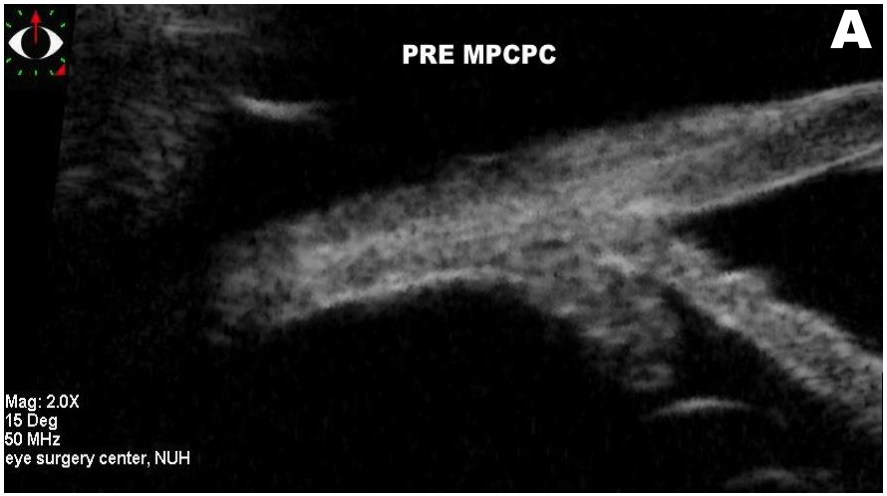
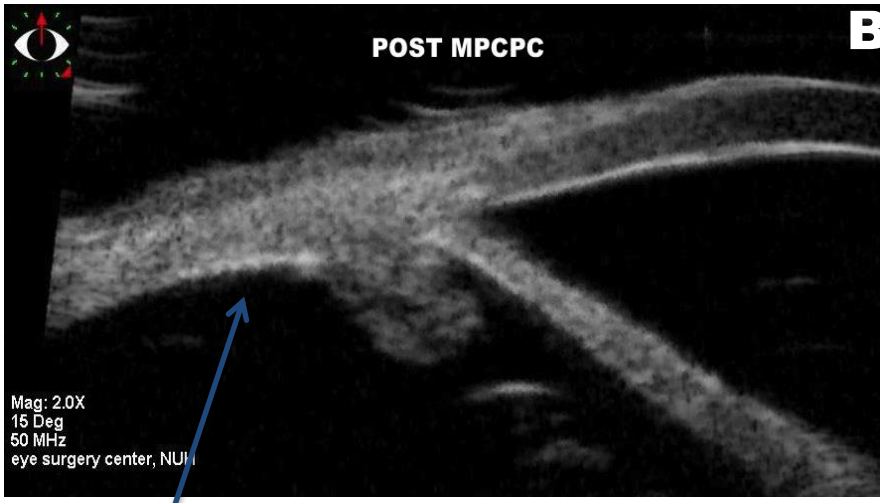
MicroPulse® TSCPC is Not Visibly Destructive

Pre MicroPulse



Post MicroPulse



Images courtesy of A/Professor Paul Chew, NUHS

No detectable evidence of tissue damage

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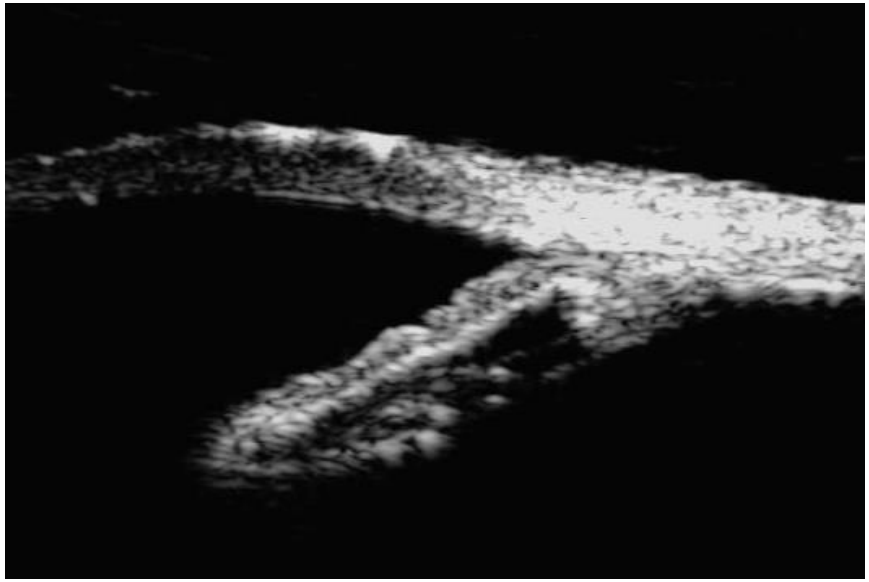
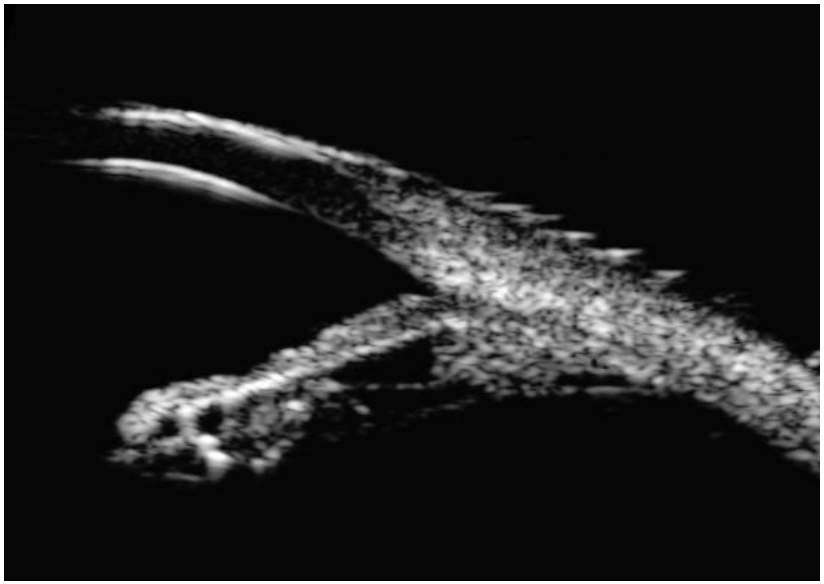
UCSF Study to assess anatomical effects of MP3
Dr. Shan Lin

Pre MicroPulse



Post MicroPulse



"No evidence of morphological changes or destruction of adjacent structures were observed."

Lin S, et al. Poster 23. Micropulse transscleral diode laser cyclophotocoagulation: Short-term results and anatomical effects. Presented at: American Glaucoma Society 26th Annual Meeting; March 36, 2016; Fort Lauderdale, Fla.

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Histopathological changes after MicroPulse & CW TSCPC - Dr. Robert Noecker, Yale University

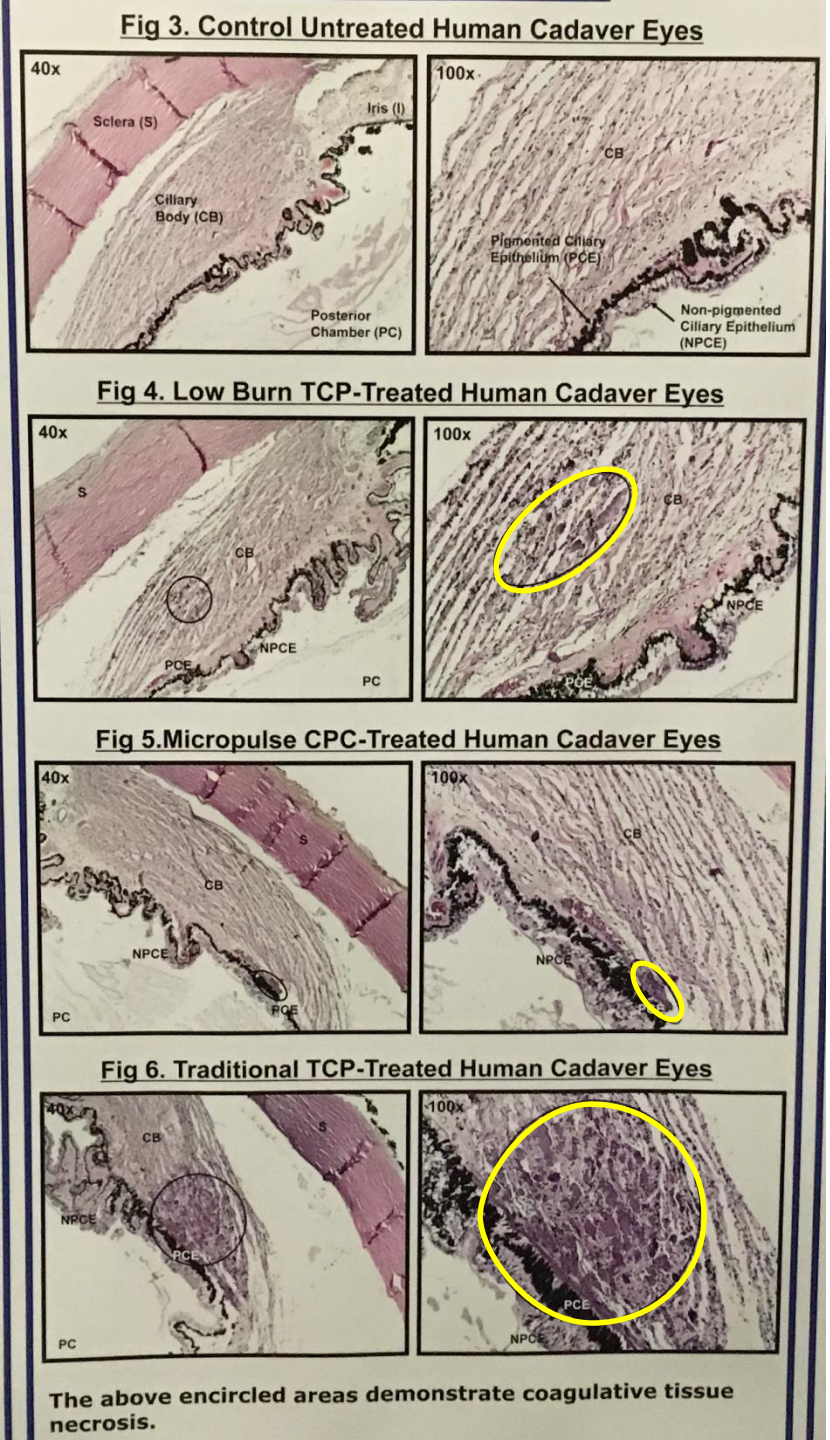
Control

Low-Burn

MicroPulse TCP

Traditional TCP

“In human cadaver eyes, MCP treatment caused less tissue disruption to the ciliary body compared with traditional and low burn TCP treatments.”



Noecker R, et al. Comparison of acute histopathological changes in human cadaver eyes after MicroPulse and continuous wave transscleral cyclophotocoagulation. Presented at: American Glaucoma Society 26th Annual Meeting; March 36, 2016; Fort Lauderdale, Fla.

Efficacy – Dr. Robert Noecker's Personal Experience @ 12 months follow-up – ARVO 2016

Dr. Noecker – MicroPulse P3 Patient Case Series	
Number of patients	46
Mean pre-op IOP	26.2 mm Hg
Mean 12 mo. post-op IOP	15.4 mm Hg
Mean IOP reduction	41%

- No IOPs lower than 8 mm Hg long term
- 12 cases retreated to achieve target

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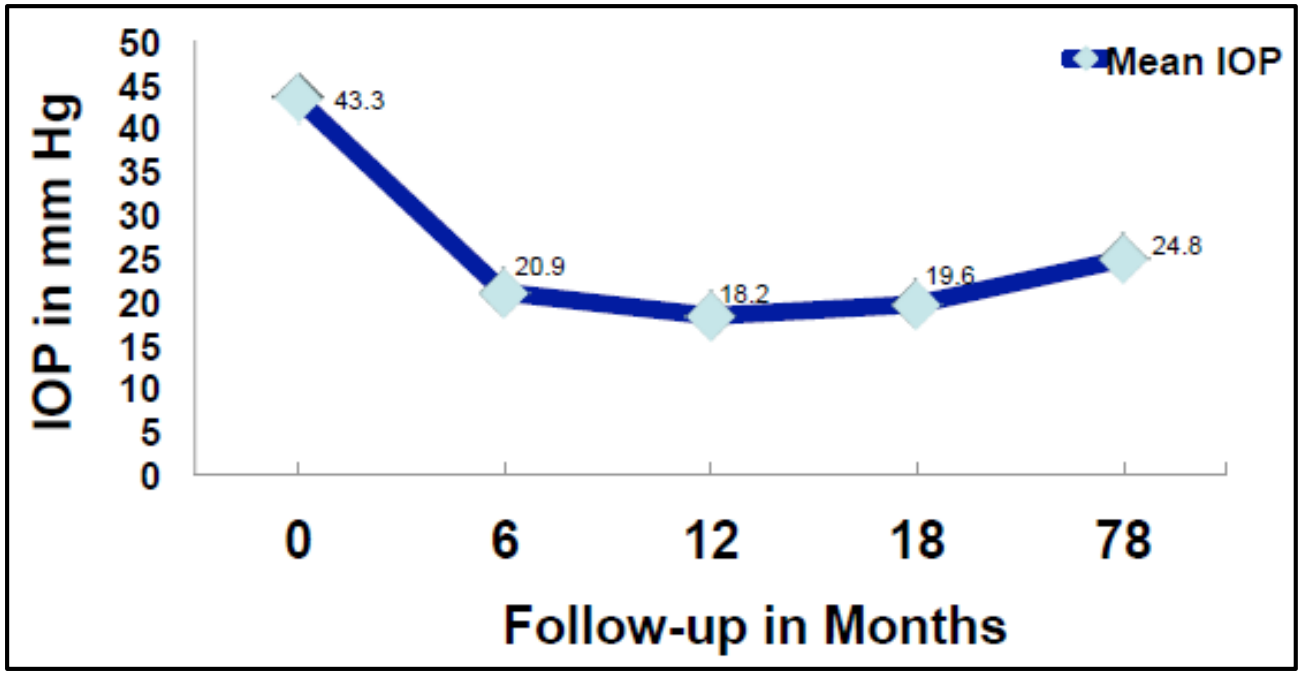
6½ Year Results Show Long-Term Efficacy & Durability
EGS 2016 - Dr. Paul Chew, NUHS



- 43% IOP reduction at 78 months (N=14)
- Meds reduced from mean of 1.8 to 1.1

Chew P, Aquino M. Long Term Efficacy of MicroPulse Diode Transscleral Cyclophotocoagulation in the Treatment of Refractory Glaucoma. EGS abstract, Prague, Czech Republic, June 19-22, 2016.

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G-Probe™ Illuminate

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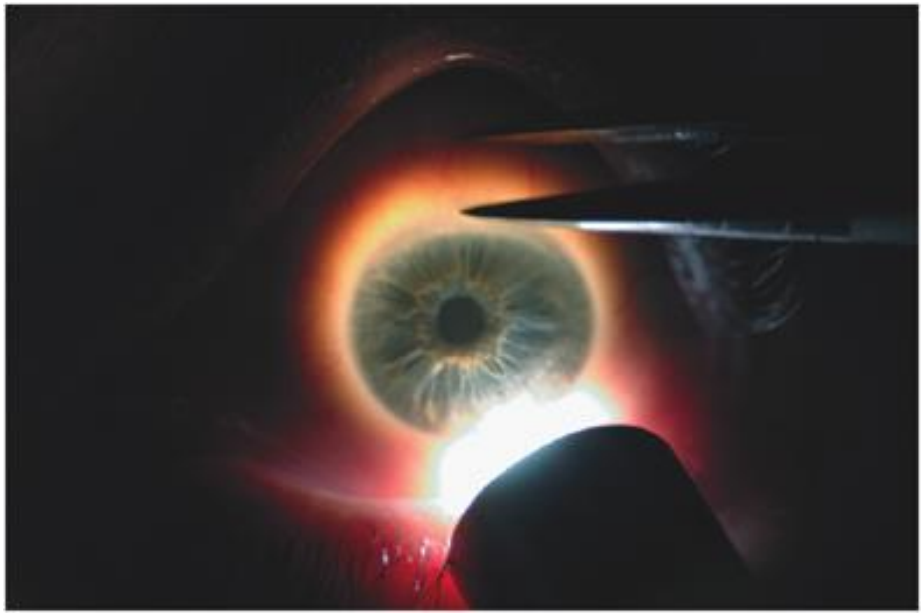
G-Probe™ Illuminate

Target Tissue Position Variability – Ciliary Body

- The location of the ciliary body varies
  - Among quadrants of the eye
  - Between patients with glaucoma



Agrawal P, Martin KR. Ciliary body position variability in glaucoma patients assessed by scleral transillumination. *Eye* (2008) 22, 1499-1503; doi:10.1038/eye.2008.79; published online 21 March 2008.

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Distance from limbus to anterior margin of the ciliary body as assessed by transscleral transillumination

Location	*Right eye* (n=*100*)				*Left eye* (n=*100*)			
	Mean	*SD*	*Range*	*95% CI*	*Mean*	*SD*	*Range*	*95% CI*
Superior	3.65	0.5	2.0–5.0	3.55–3.74	3.68	0.48	2.0–5.0	3.58–3.77
Nasal	2.6	0.45	1.5–4.0	2.51–2.68	2.53	0.4	1.5–3.5	2.45–2.61
Inferior	3.08	0.4	2.0–4.0	3.0–3.16	3.05	0.42	2.0–4.0	2.97–3.13
Temporal	2.65	0.43	1.5–3.5	2.56–2.73	2.62	0.48	1.0–3.5	2.53–2.72

Agrawal P, Martin KR. Ciliary body position variability in glaucoma patients assessed by scleral transillumination. *Eye* (2008) 22, 1499-1503; doi:10.1038/eye.2008.79; published online 21 March 2008.

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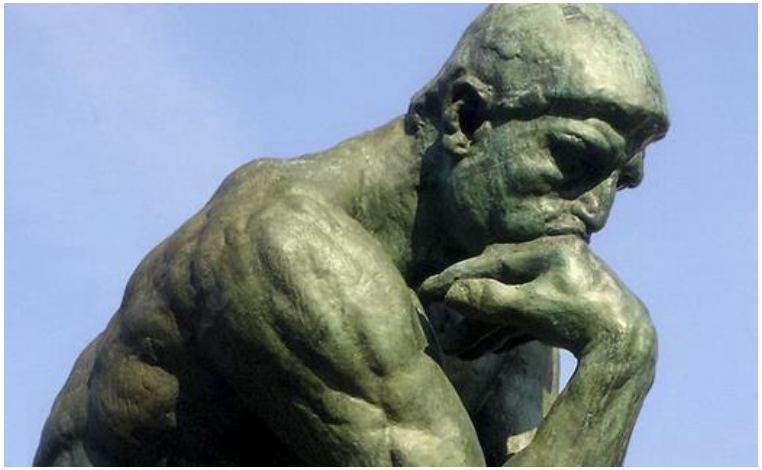
Challenging Patient Case Scenarios



- Conditions with abnormal ocular size
- Corneoscleral limbus difficult to visualize
- High myopes & post-corneal transplant patients (ciliary body may be more posterior)

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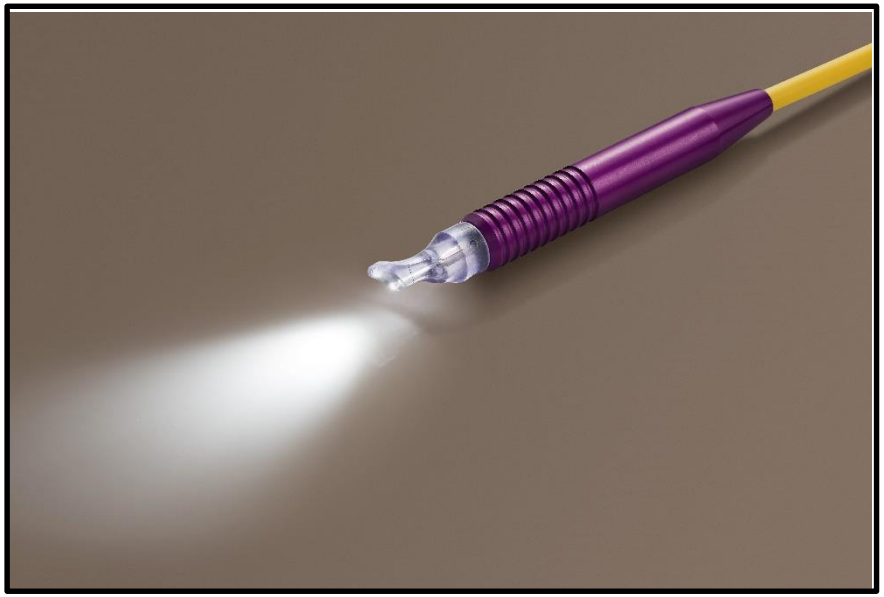
G-Probe™ Illuminate – Targeted CPC with Built-In Transillumination

- Optimized probe placement and therapeutic outcome
- Single-Handed procedure
- Non-Incisional
- Efficient & Straightforward
- Can be performed in the Office & OR



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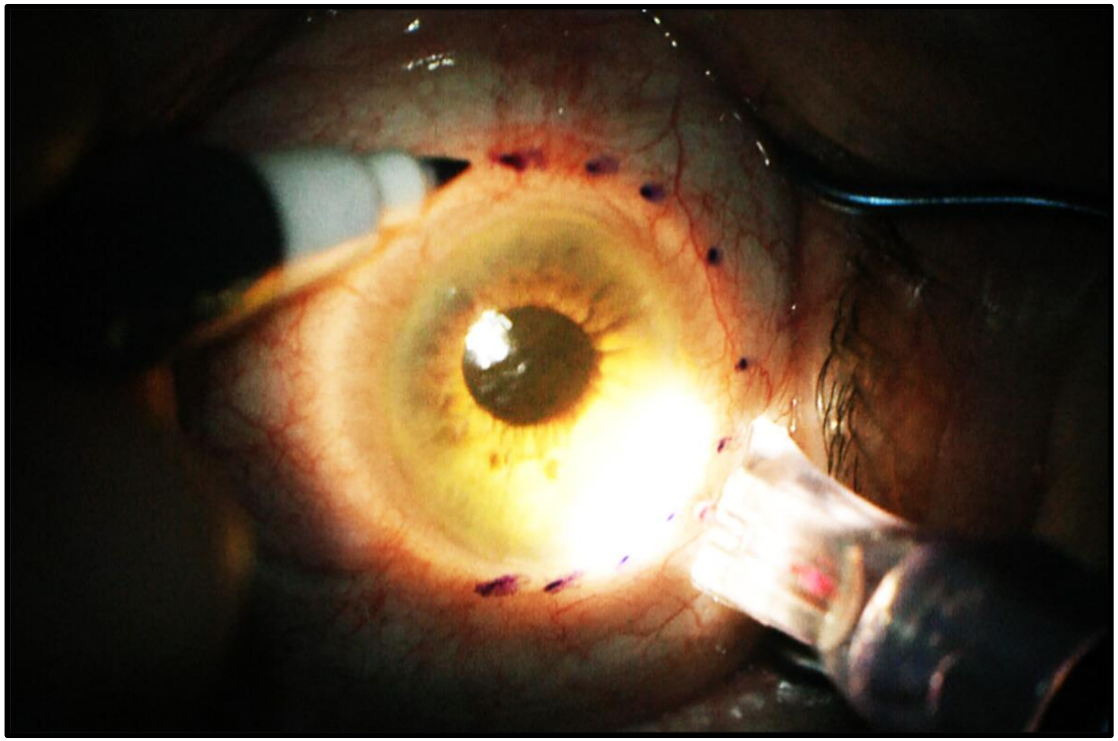
Transillumination-Guided Surgery



Adjustable illumination intensity

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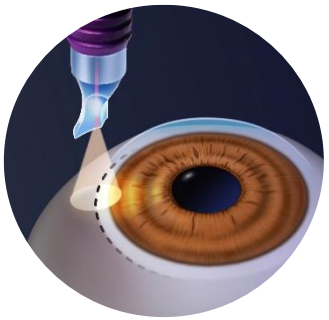
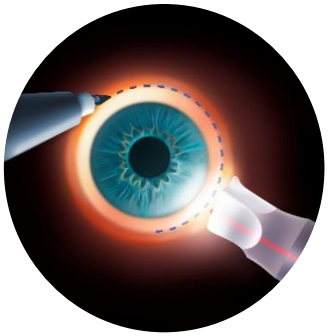
Transillumination-Guided Approaches

G-Probe™ Illuminate

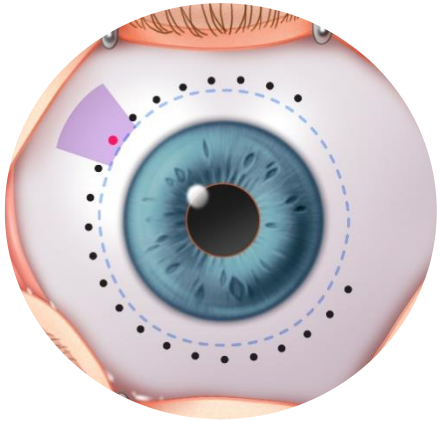


Transillumination Technique #1
G-Probe Illuminate highlights the anterior margin of the ciliary body (dashed line).

OR



Transillumination Technique #2
Use marking pen first to illustrate the anterior margin of the ciliary body as highlighted by transillumination.



Application
Wedged tip design supports precise placement around circumference of anterior margin of ciliary body (dashed line).

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Proven Long-Term Efficacy – a Sampling

- 43%, 74 eyes, 1 year follow-up (2007)[1]
- TSCPC vs Glaucoma Valve (2009)[2]
  - Valve group 47%
  - TSCPC group 57%
- 45%, 1½ year follow-up (2014)[3]

G-Probe Illuminate

G-Probe

1. Ansari E, Gandhewar J. Long-term efficacy and visual acuity following transscleral diode laser photocoagulation in cases of refractory and non-refractory glaucoma. *Eye (Long)*. 2007;21:936-940.
2. Yildirim N, Yalvac IS, Sahin A, et al. A comparative study between diode laser cyclophotocoagulation and the Ahmed Glaucoma Valve implant in neovascular glaucoma: A long-term follow-up. *J Glaucoma*. 2009;18:192-196.
3. Aquino MC, Barton K, Tan AM, Sng C, Li X, Loon SC, Chew PT. Micropulse versus continuous wave trans-scleral diode cyclophotocoagulation in refractory glaucoma: a randonmised exploratory study. *Clin Experiment Ophthalmol*. 2014 May 9. doi: 10.1111/ceo.12360.

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G-Probe & G-Probe™ Illuminate

"It has the ability to lower IOP and preserve vision similar to trabeculectomy and tube shunts, while avoiding a complicated filtering surgery."

– Ike Ahmed, MD

G-Probe Illuminate

G-Probe

Ahmed, Ike. Revisiting TSCPC as an option. Ophthalmology Times, pgs. 32-33, published January 15, 2013.

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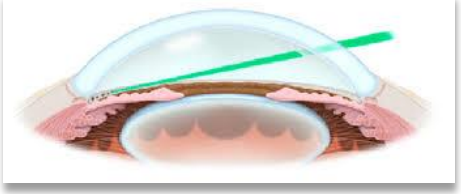
Evolving Treatment Paradigm: Where MP3 and GPI Fit

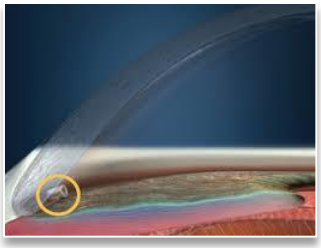
MicroPulse P3

G-Probe Illuminate

Drugs



Trabeculoplasty



MIGS

Traditional Surgery

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CYCLO G6™ Glaucoma Laser System

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Glaucoma Laser System

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MP3
Patient Case Examples

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Patient Case 1

- 65 year-old male, CRVO in right eye
- Treated by retina specialist with PRP and anti-VEGF
- VA 20/80 right eye, 20/20 left
- IOP 40 right eye on maximal meds including Diamox
- Treated with MicroPulse P3 in office (with block)
- IOP 10, no pain, no change in vision
- 2 post-op visits – sent back to referring MD

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Patient Case 2

- 78 year-old woman with PXG right eye
- IOP 38 on 3 meds - recent loss of IOP control
- VA 20/40 right eye with significant visual field loss; VA 20/25 left eye with mild loss
- MicroPulse P3 performed in OR with sedation
- Transient low IOP of 6-10 mm Hg for 1-2 weeks; treated with Durezol
- Final IOP at 12 weeks 15 mm Hg on no meds

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MicroPulse® Technology

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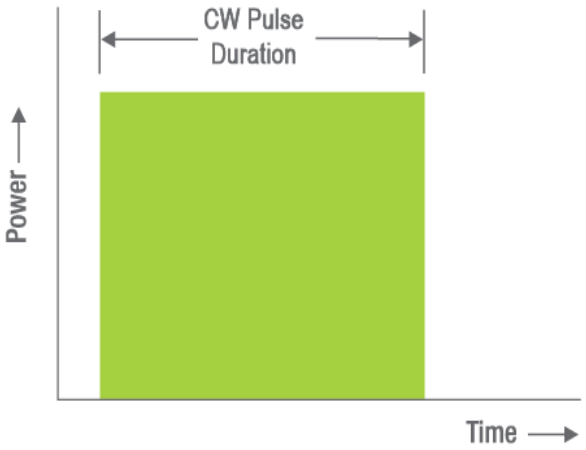
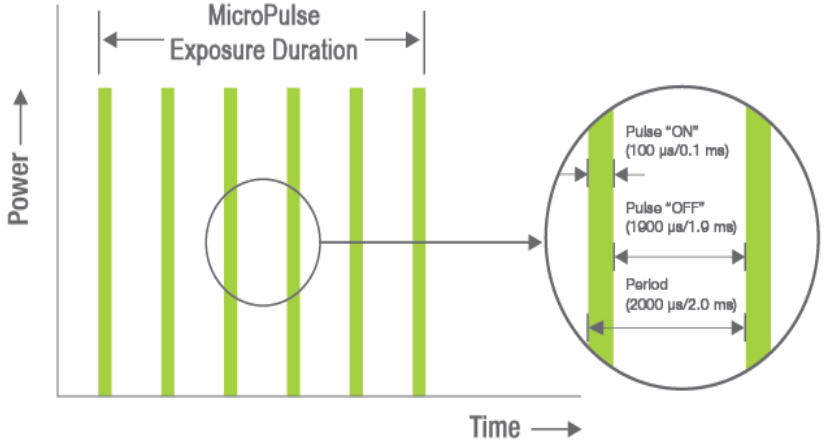
How Does MicoPulse® Work?

MicroPulse technology finely controls thermal elevation by “chopping” a continuous-wave (CW) beam into an envelope of repetitive short pulses.

Continuous-Wave (CW) Mode



MicroPulse Mode



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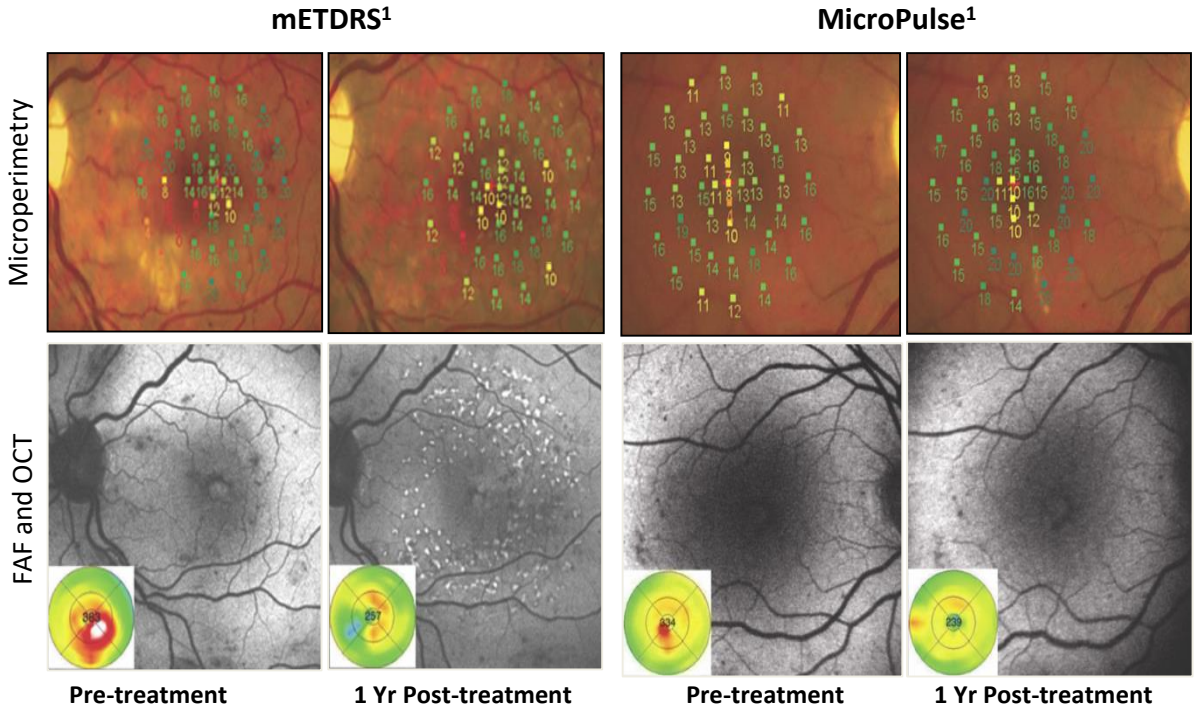
Same Patented MicroPulse Technology Used for Retinal Work and Trabeculoplasties (MLT Equivalent to SLT)



Prospective, Masked, Randomized Clinical Trial[1]

- 62 eyes (50 patients)
- Untreated, center-involving CSME
- Randomized to mETDRS or 810 nm MicroPulse

1 Year Results

- MicroPulse was as effective as mETDRS in
  - stabilizing VA
  - reducing macular edema
- With added benefits of
  - no tissue damage detectable at any time point postoperatively
  - significant improvement in retinal sensitivity

1. Vujosevic S, Bottega E, Casciano M, Pilotto E, Convento E, Midena E. *Retina* 2010

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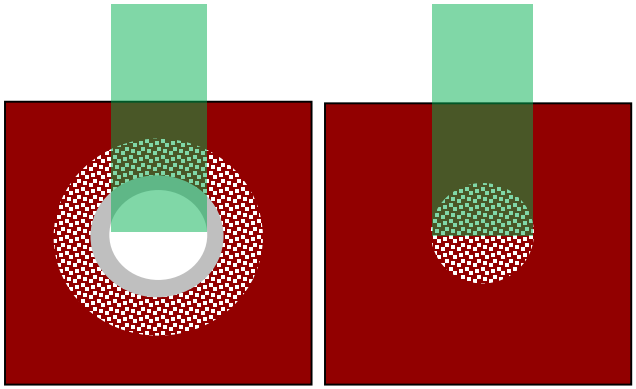
What we've learned in the last 10 years - MicroPulse® Stimulates Biological Factors

PEDF[1] | TSP1[2] | SDF1[3] | ß-Actin[3]

Modulation of the expression of intracellular biological factors



Visible Conventional CW (DRS/ETDRS)

Tissue-sparing MicroPulse

MicroPulse laser treatment, produces a stress response and induces beneficial intracellular biological factors that are primarily anti-angiogenic and restorative without tissue damage as seen in CW.

PEDF - plays a role in inhibiting neovascularization by its anti-angiogenic activity

TSP1 - one of the most potent anti-angiogenic factors

SDF1 - plays a key role in recruitment of bone marrow-derived reparative cells

ß-actin - protein that is involved in cell motility, structure and integrity

1. Ogata N, Tombran-Tink J, Jo N, Mrazek D, Matsumura M: Upregulation of Pigment Epithelium-Derived Factor after Laser Photocoagulation. *Am J Ophthalmol* 2001;132(3):427-9.
2. Binz N, Graham CE, Simpson K, Lai YK, Shen WY, Lai CM, Speed TP, Rakoczy PE: Long-Term Effect of Therapeutic Laser Photocoagulation on Gene Expression in the Eye. *FASEB J* 2006;20(2):383-5.
3. Yu AK, Merrill KD, Truong SN, Forward KM, Morse LS, Telander DG: The Comparative Histologic Effects of Subthreshold 532- and 810-Nm Diode Micropulse Laser on the Retina. *Investigative Ophthalmology & Visual Science* 2013;54(3):2216-2224.

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Mechanism

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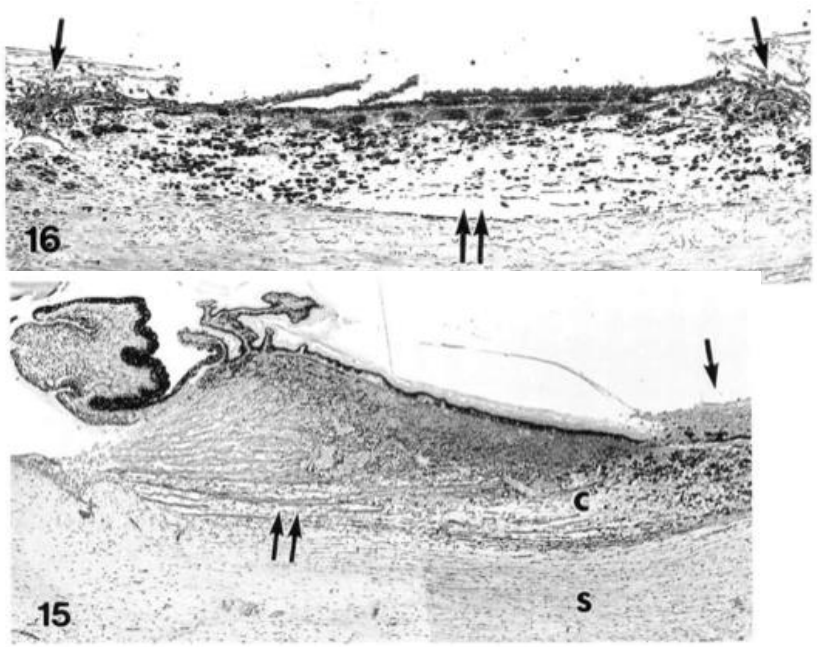
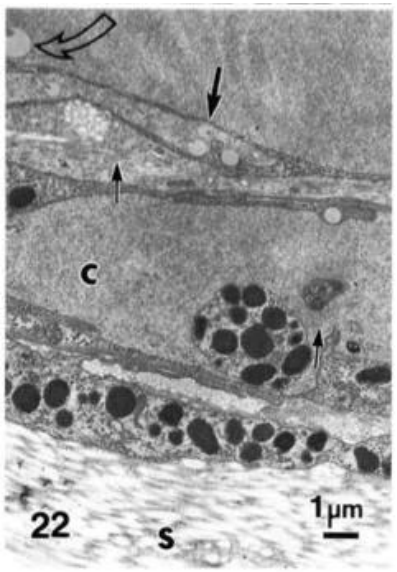
What is MicroPulse doing in the case of TSCPC?

(Early Clinical Work Theorizes it May Be Increasing Uveoscleral Outflow Through Enlarged Extracellular Space)

Double arrows indicate enlarged extracellular space leading to suprachoroidal area



Latex spheres identified in ora serrata region in the opened suprachoroidal space



Liu, Guo-Jing, et al "Mechanism of Intraocular Pressure Decrease after Contact Transcleral Continuous-Wave Nd: YAG Laser Cyclophotocoagulation", *Ophthalmic Res* 1994;26:65-79

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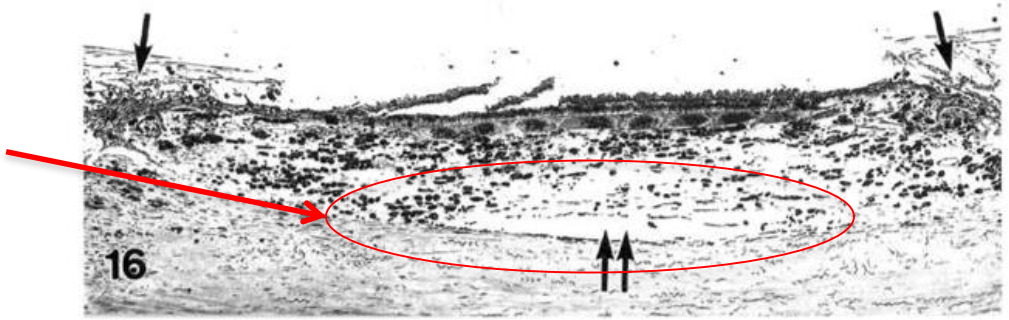
Proposed Mode of Action
Clinical evidence of uveoscleral outflow in primate models

- **Laser energy delivered pars plana on 11 primates (figure below)**
  - – Lower IOP at 6 months with tracer particle accumulation at the enlarged extracellular space of the stroma and the opened suprachoroidal space.
    - Liu MD et al, *Ophthalmic Res 1994; 26:65-79*

- **Post-mortem studies of aqueous outflow due to pars plana transscleral photocoagulation**
  - 51% increase in outflow as compared to controls. Results suggested both transneuroepithelial and transscleral outflow.
    - Schubert MD et al*, Ophthalmic Surgery 1990; 21:835-839*

Extracellular space was widened.
Same mechanism as prostaglandin.



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Treatment Techniques

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What are the Treatment Techniques?

MicroPulse® P3 Probe (MP3)

Placement
Side view of the MP3 positioned perpendicularly to the surface of the globe.

Application
The tip design of the MP3 supports a sweeping motion from the 9:30-2:30 and 3:30-8:30 clock positions.

G-Probe™

Placement
Side view of the G-Probe positioned on the limbus and held parallel to the visual axis.

Application
Wedged tip design of G-Probe supports precise placement around the circumference of the limbus.

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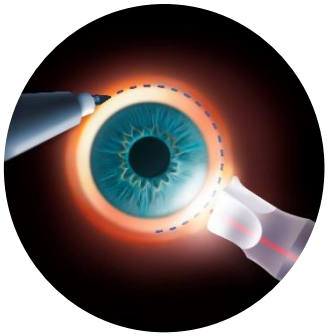
What are the Treatment Techniques?

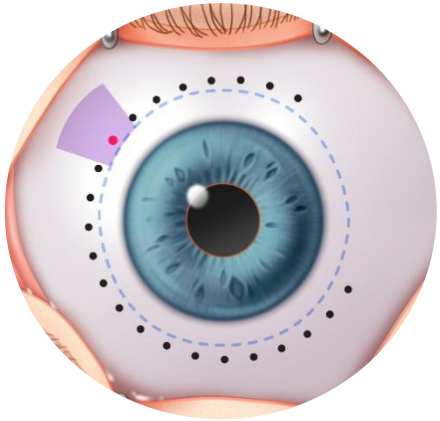
G-Probe™ Illuminate

Transillumination Technique #1
G-Probe Illuminate highlights the anterior margin of the ciliary body (dashed line).

OR



Transillumination Technique #2
Use marking pen first to illustrate the anterior margin of the ciliary body as highlighted by transillumination.



Application
Wedged tip design supports precise placement around circumference of anterior margin of ciliary body (dashed line).

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Reimbursement

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CPT 66710 in the Office

	OFFICE REIMBURSEMENT 2017*
Cyclophotocoagulation (CPT 66710)	$446

Q: How many follow-ups do you schedule for a Trab patient?

*Reimbursement figures are based on US national averages. Please consult your local Medicare and non-Medicare carriers for coverage and payment policies.

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CPT 66710 in the ASC

	PHYSICIAN FEE 2017*
Cyclophotocoagulation (CPT 66710)	$400

	FACILITY FEE 2017*
Cyclophotocoagulation (CPT 66710)	$791

*Reimbursement figures are based on US national averages. Please consult your local Medicare and non-Medicare carriers for coverage and payment policies.

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CPT 66710 in the HOPD

	PHYSICIAN FEE 2017*
Cyclophotocoagulation (CPT 66710)	$400

	FACILITY FEE 2017*
Cyclophotocoagulation (CPT 66710)	$1,701

*Reimbursement figures are based on US national averages. Please consult your local Medicare and non-Medicare carriers for coverage and payment policies.

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CYCLO G6™ Glaucoma Laser System

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