IOPtima
Novel Glaucoma Treatment

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Better & Safer Glaucoma Surgery

Product Introduction

Agenda

- About Glaucoma & the CLASS Solution
- The IOPtiMate System & CLASS Technology
- CLASS Procedure – Step by Step
- CLASS Procedure – Clinical Results
- Summary

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About Glaucoma & the CLASS Solution

Glaucoma
What is it?

- Glaucoma is a group of eye diseases affecting the optic nerve and usually characterized by high intraocular pressure (IOP), which is the major risk factor for glaucoma.

- Without treatment glaucoma can progress to loss of central vision and blindness.

Normal vision

Glaucoma

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Glaucoma
The silent thief of sight

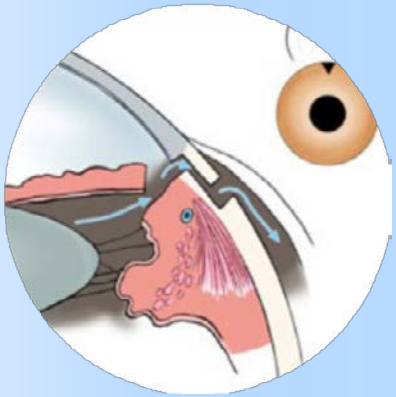
- Glaucoma is the **leading** cause of **irreversible** blindness worldwide.
- The elderly are most affected by glaucoma with incidence of the disease growing as age advances.

Glaucoma
Treatment protocol

IOPtima Target Market

Medications	Office Procedures	Surgeries
Improve aqueous outflow and/or reduce the production of aqueous	**Trabeculoplasty**	**Trabeculectomy, Shunts, Tubes, Values, MIGS**
		
• Limited compliance (only ~50%) • Limited efficacy	• Limited decrease in IOP • Short term effect (months) • Repeated procedures are not effective	• Full penetration invasive (e.g. Trab) - high post-operation complications • Minimally-invasive (e.g. MIGS) – limited effectiveness

Trabeculectomy
But at what cost?



- Long-term reduction of IOP and medication use
- High post-operative complication rate

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There is an alternative

- Similar IOP and medication reduction as trabeculectomy at 5 years
- More than 35% reduction in complications compared to trabeculectomy

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The IOPtiMate System & CLASS Technology

The CLASS Solution
A New Surgical Approach

CLASS™ – CO_2 Laser-Assisted Sclerectomy Surgery, utilizes IOPtiMate, a novel laser technology for performing Deep Sclerectomy glaucoma surgery.

*"The system transforms complex and highly risky glaucoma surgery into a **safe, elegant** and **precise** laser-assisted procedure"*

Prof. Assia Ehud, Meir Medical Center, Kfar Saba. Israel

*"IOPtima's CLASS procedure has true advantages over the Trabeculectomy surgery as it offers an **excellent safety profile** with an **ease of use**"*

Prof. Mermoud Andre, Clinique de Montchoisi, Lausanne, Switzerland

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IOPtiMate™ System

The IOPtiMate system fits any ophthalmic microscope and consists of two main modules:

1. **The Laser & Control Unit** – The surgeon selects the program parameters on the LCD touch-screen and initiates the laser operation.

2. **The Scanner** – By using a sophisticated system of Galvo-motors and optics, the scanner takes the laser beam and accurately ablates the sclera according to the preselected shape & size scan pattern.

IOPtiMate™ System

The CO_2 laser

CO_2 laser: well-known in the medical world for tissue ablation

Unique characteristics:

- **Effectively ablates dry tissue**
- **Highly absorbed by water**

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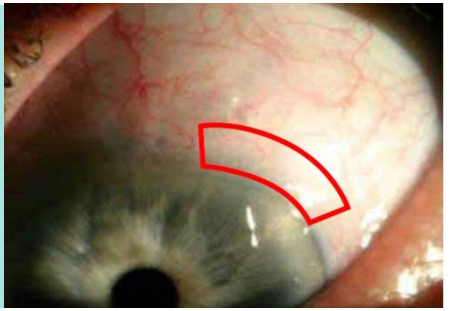
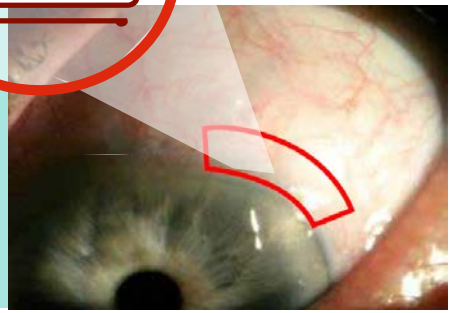
IOPtiMate™ System
CO_2 laser: tissue ablation

- **CO_2 Laser: Principle of Operation**

Effective ablation of dry sclera by the CO_2 laser beam	**Adequate fluid percolation through intact thinned membrane (Schlemm's Canal, TM)**	**Percolated fluid absorbs laser energy and by that generates a self-limited safety mechanism**	

- **Ablation of Scleral Tissue**

The laser beam is focused to a small spot	**The laser spot is scanned very rapidly across the ablation pattern**	**Scanning is Faster than "thermal relaxation time" and by that limits the thermal damage**	

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CLASS Procedure – Step by Step

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Procedure – video

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Procedure – step by step

1

Anesthesia & Eye fixation tilted down; Creation of conjunctiva flap (fornix base method) Creation of the standard flap (5.0 x 5.0 mm into clear cornea – expose the limbus; ⅓ to ½ thickness)

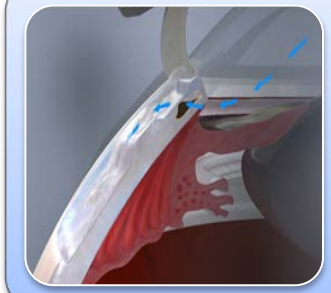
2

Creation of scleral lake and application of Mitomycin C

3

Place top of the scan pattern on the limbus line. Repeatedly perform controlled ablations of thin sclera layers until full exposure of the Schlemm's canal

4



Fluid percolation through remaining trabeculum

5

A thin layer remains intact; penetration of the eye is avoided (histology)

6

The scleral flap is closed and sutured
The conjunctiva is closed and sutured

CLASS
Videos

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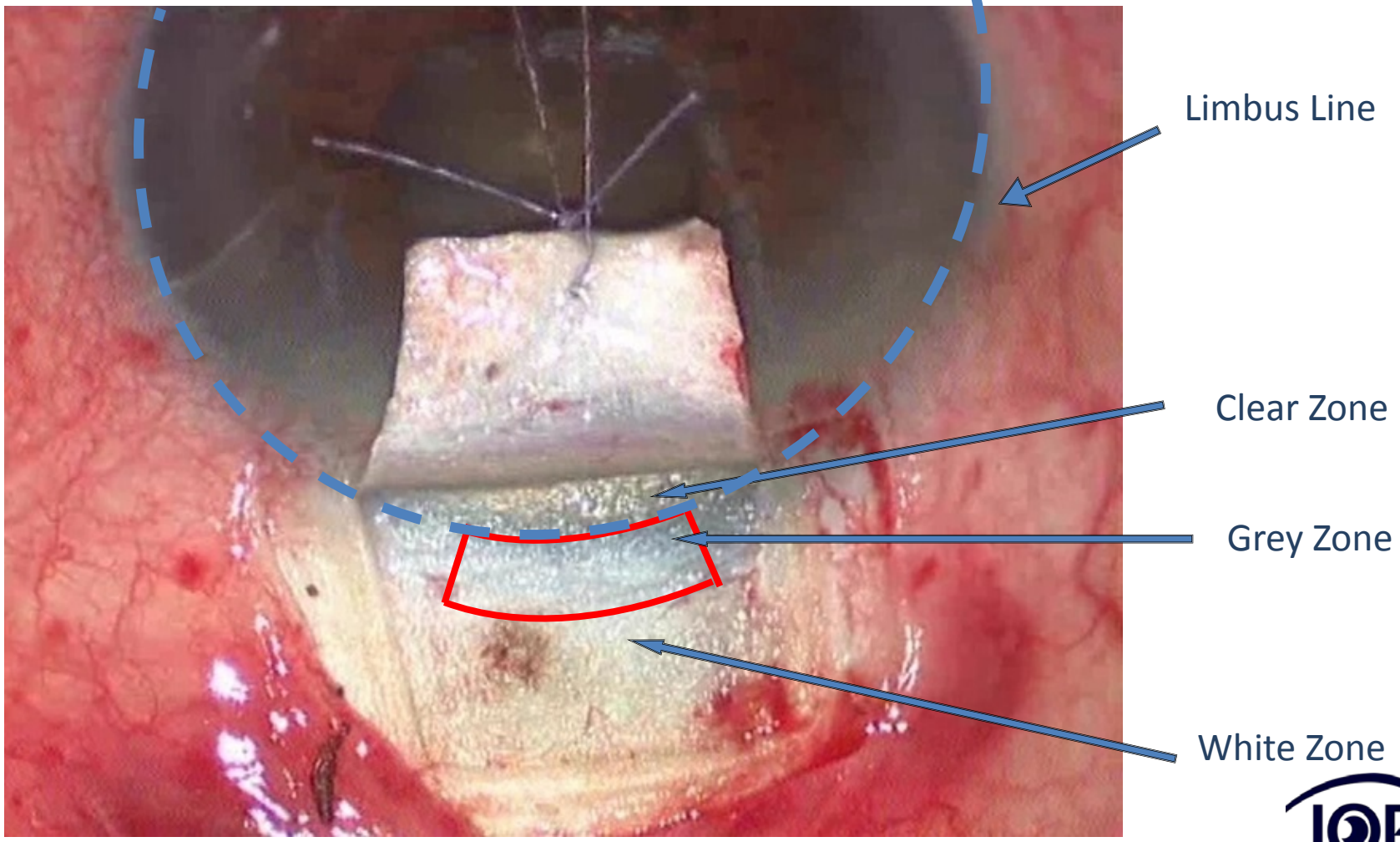
Positioning the Ablation Pattern



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CLASS Procedure – Clinical Results

CLASS Clinical Trial

111 patients

9 sites

5 years follow-up

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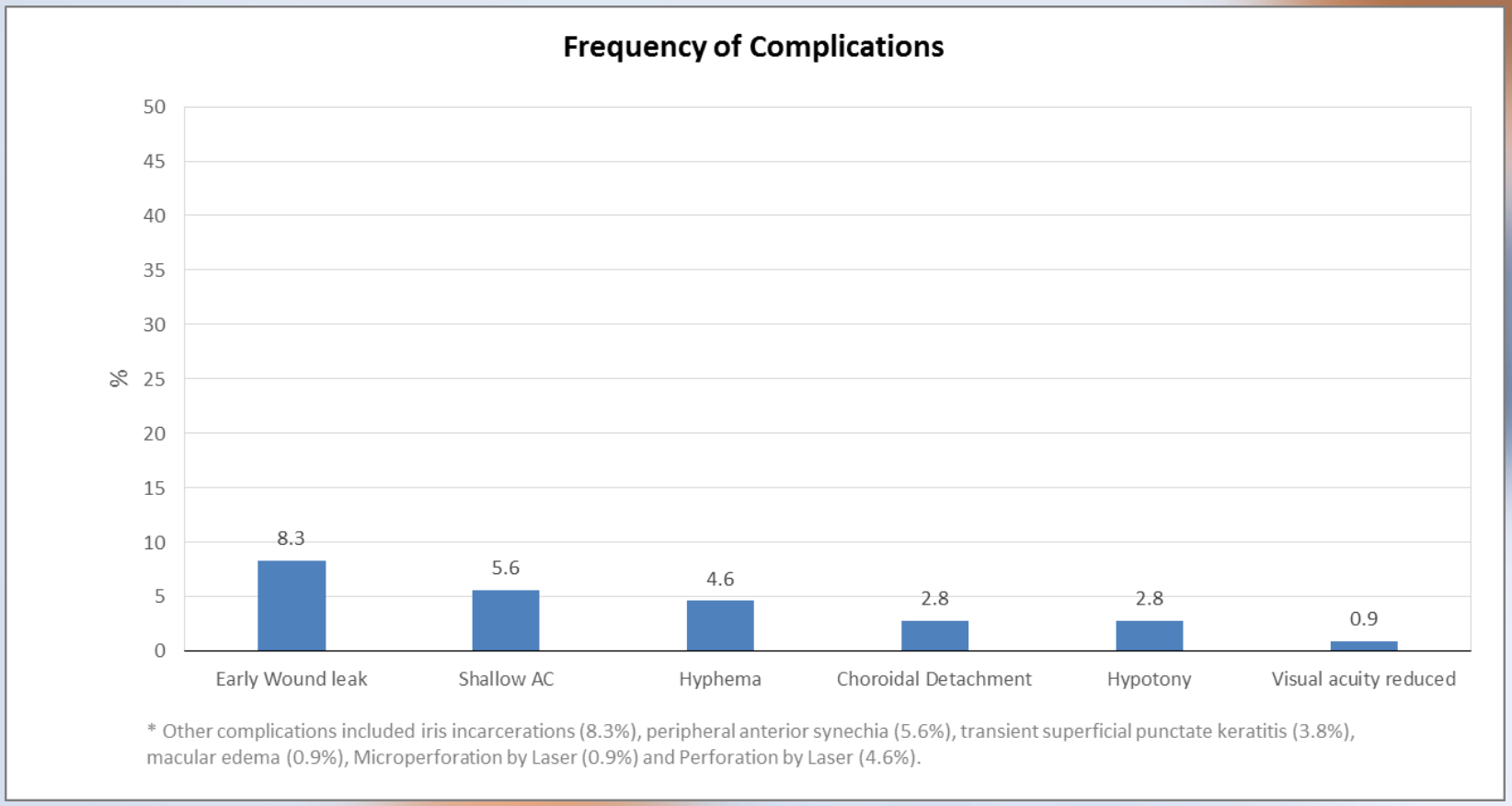
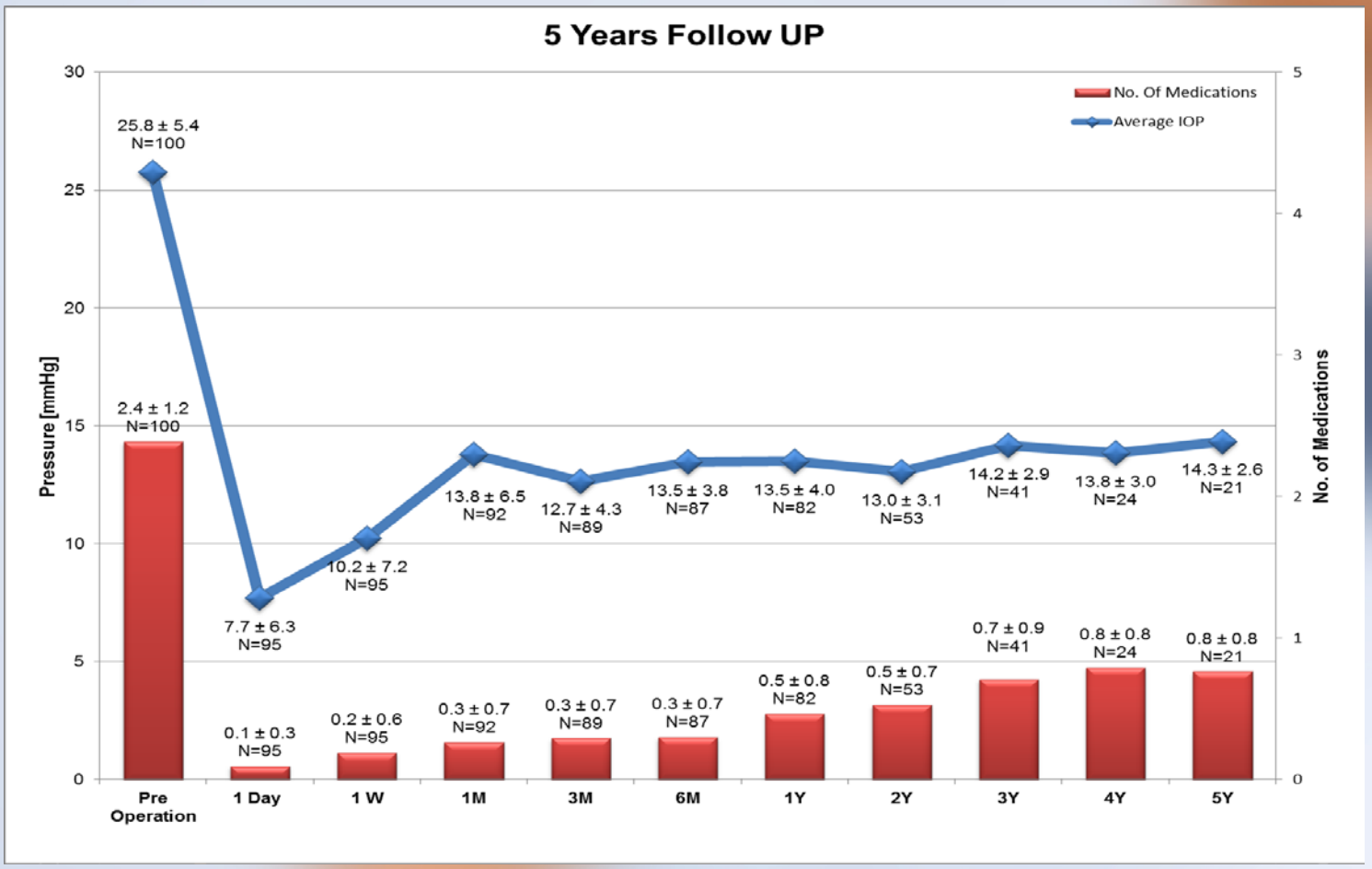
Clinical Results

Safety (total n=108)



Clinical Results

Efficacy –IOP & Med.



P<0.008 using Bonferroni correction for multiple comparisons

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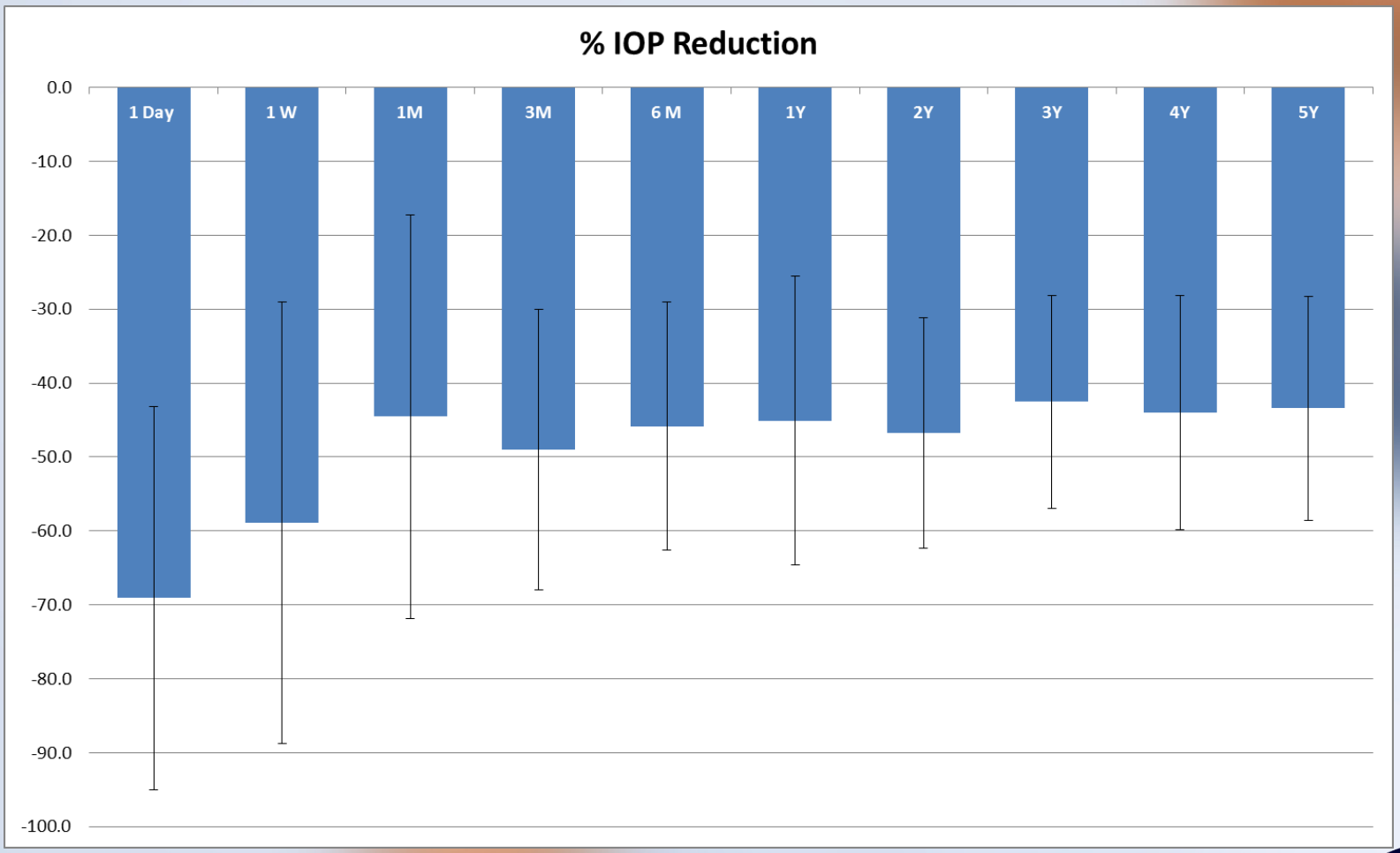
Clinical Results

Efficacy - %IOP reduction



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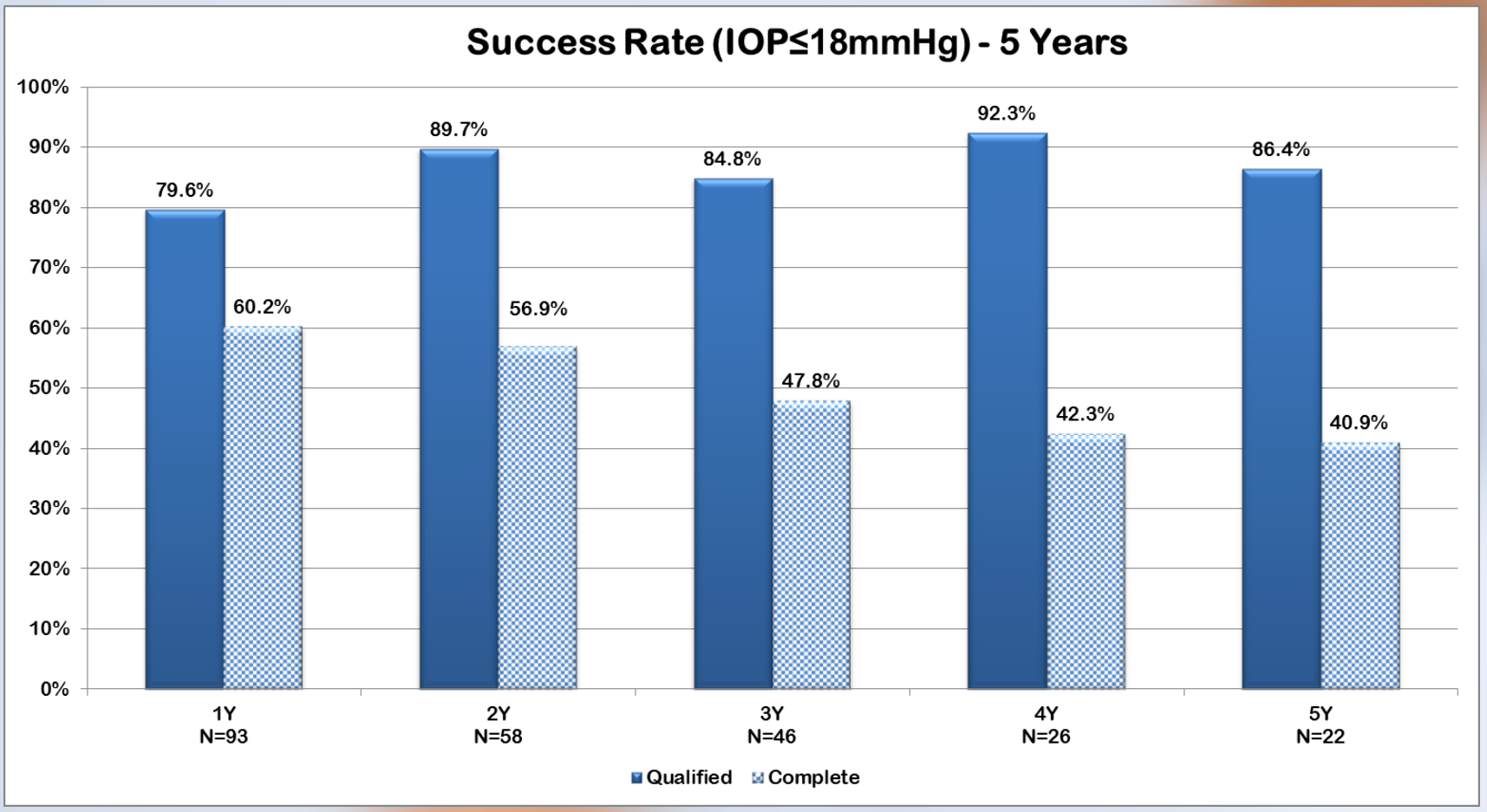
Clinical Results

Success Rate IOP≤18mmHg*



** Penetration by laser, additional glaucoma surgery and loss of 2 snellen lines in VA were considered as failure*

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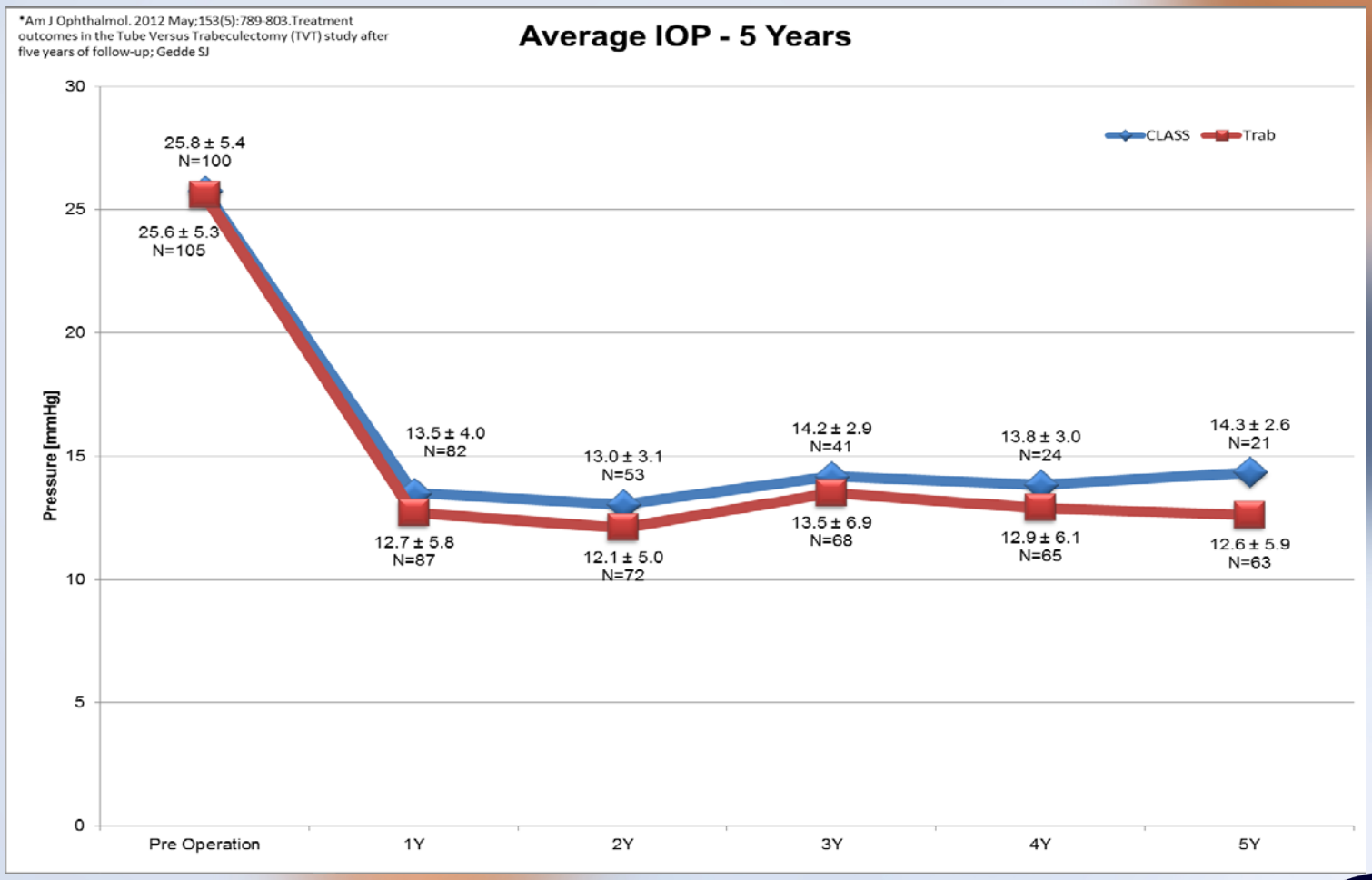
Clinical Results

CLASS vs. Trab – Avg. IOP



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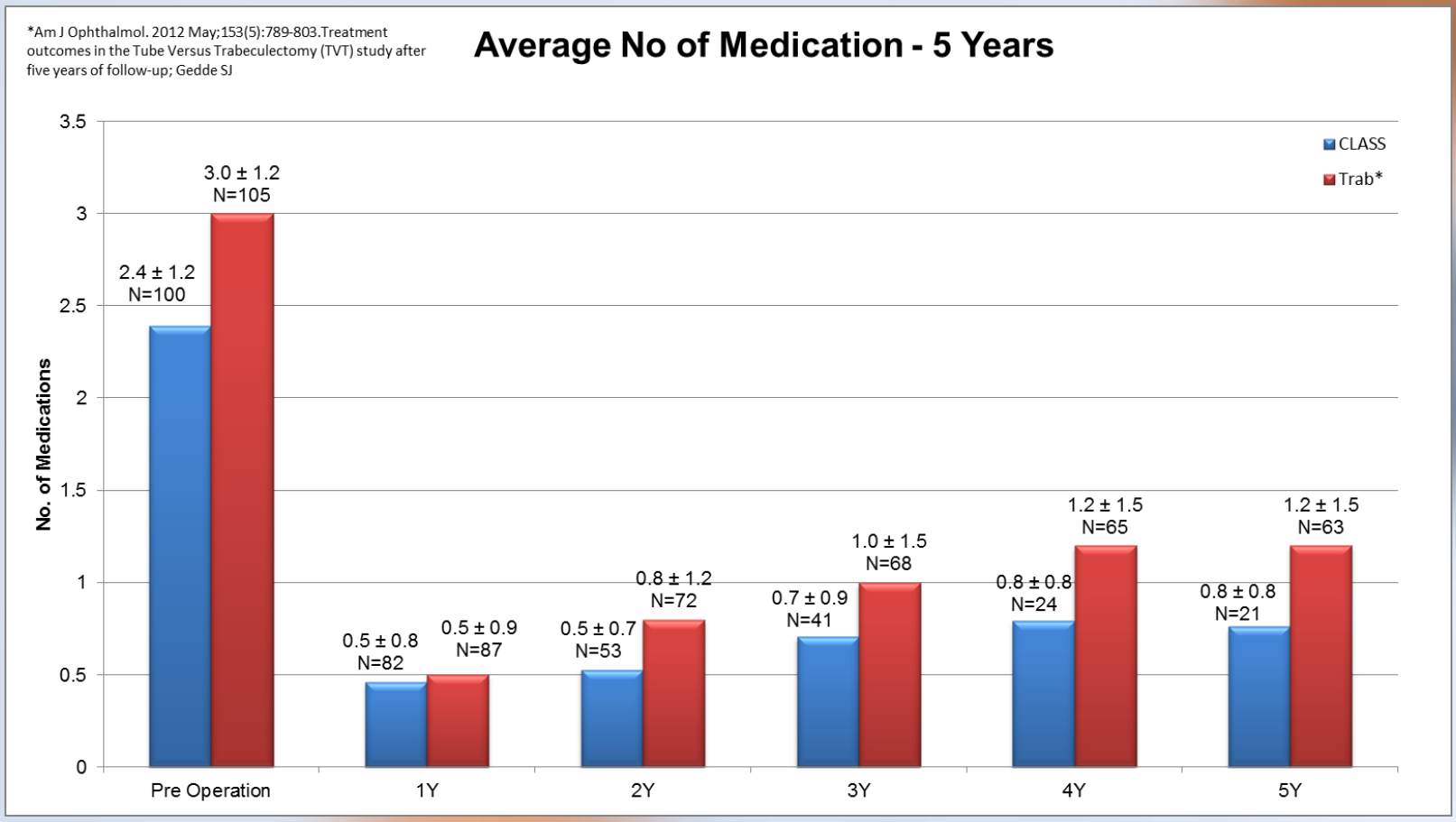
CLASS vs. Trab – no. of Med.

*Am J Ophthalmol. 2012 May;153(5):789-803.Treatment outcomes in the Tube Versus Trabeculectomy (TVT) study after five years of follow-up; Gedde SJ



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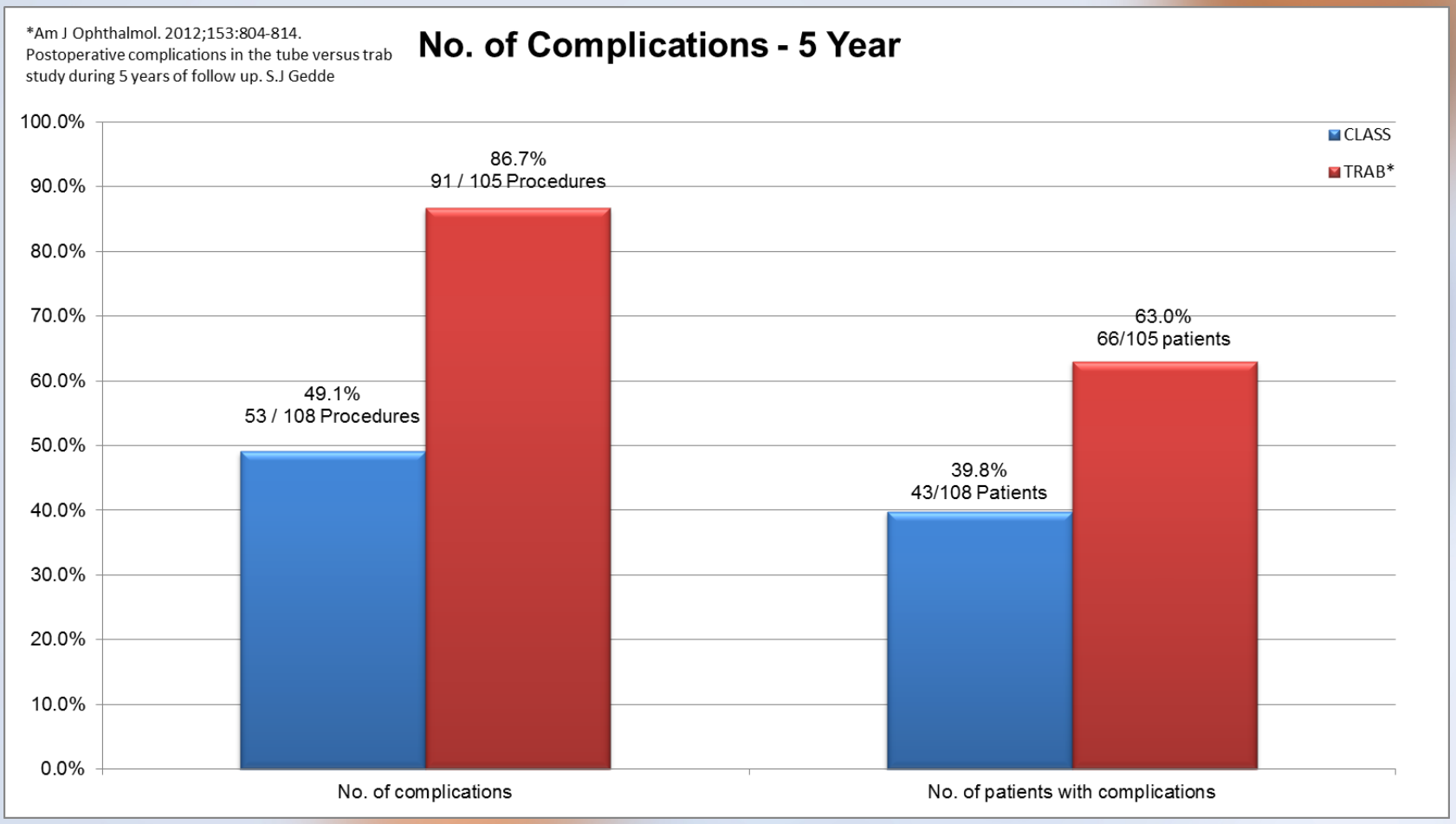
CLASS vs. Trab – Safety

*Am J Ophthalmol. 2012;153:804-814. Postoperative complications in the tube versus trab study during 5 years of follow up. S.J Gedde



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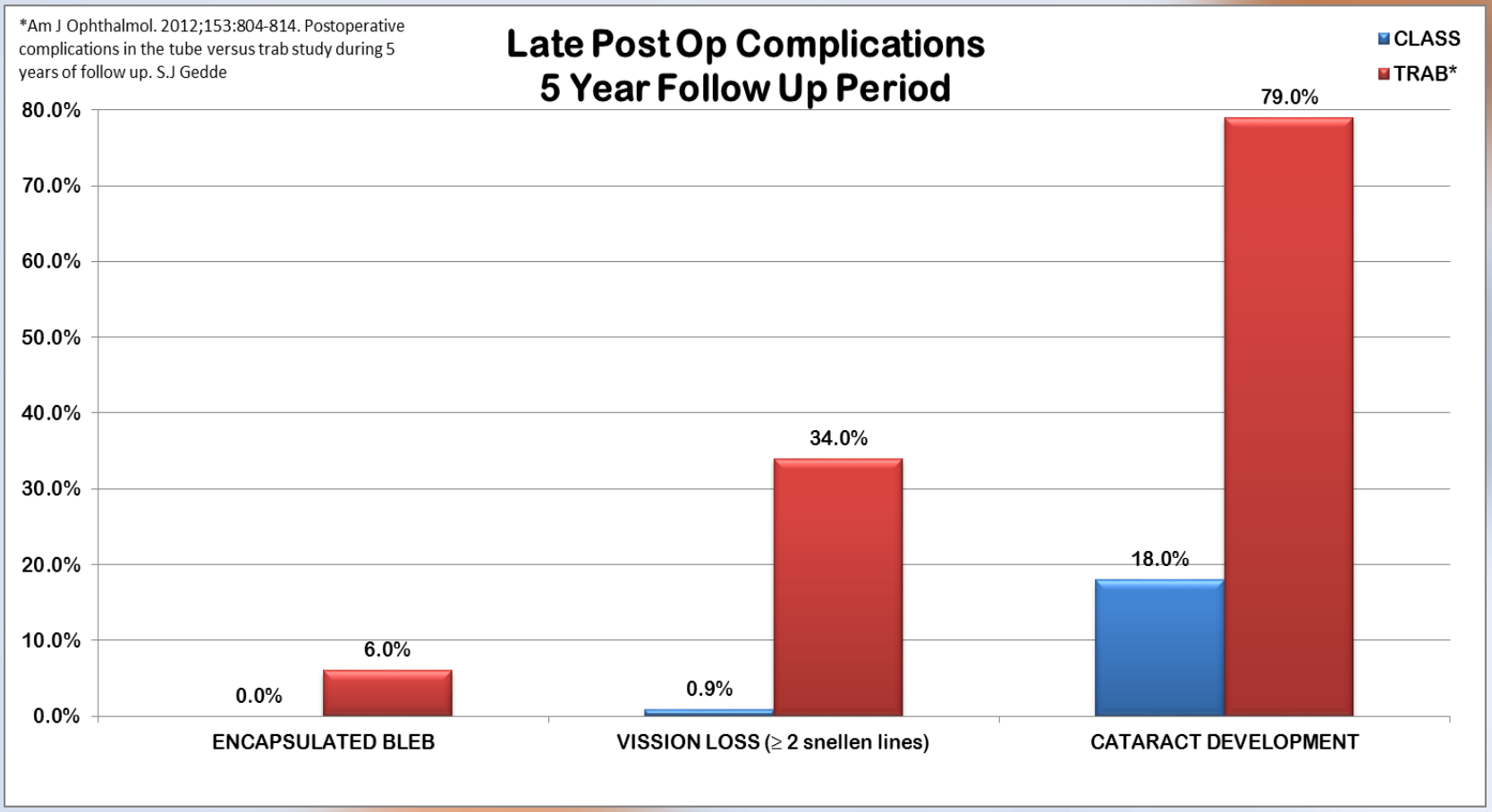
Clinical Results

CLASS vs. Trab – Safety (cont.)

*Am J Ophthalmol. 2012;153:804-814. Postoperative complications in the tube versus trab study during 5 years of follow up. S.J Gedde



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Clinical Results
Summary

Safety:

- Low Complication Rate

Efficacy:

- High and Consistent Success Rates
- Significant IOP reduction
- Controlled IOP over time
- Significant Medications reduction

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Summary

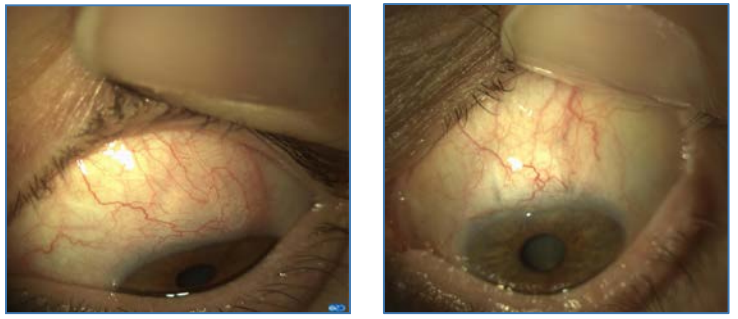
Summary
Advantages of CLASS

Safe

- ✓ Non-penetrating procedure
- ✓ Self-regulated laser procedure
- ✓ Doesn't leave a foreign body in the eye
- ✓ Less complications
- ✓ Less post-op micro-manipulations
- ✓ High comfort-level to the surgeon
- ✓ Simple to perform
- ✓ Short learning curve

Effective

- ✓ long-term reduction of IOP – similar to Trab
- ✓ Reduces the need for medications
- ✓ More than **1500** patients have already been operated worldwide
- ✓ Simple to perform with short learning curve
- ✓ Cost effective - Flexible business models



Typical Diffused Bleb at ~1 month follow-up

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KOLs endorse CLASS

Prof. Assia Ehud

Meir Medical Center,
Kfar-Saba,
Israel

Prof. Shaarawy Tarek

HUG Hospital, Genève,
Switzerland

Prof. Traverso E Carlo

University of Genova,
Italy

Prof. Melamed Shlomo

Head of the Goldschleger
Eye Institute,
Sheba medical center,
Israel

Prof. Mermoud Andre

Clinique de Montchoisi,
Lausanne,
Switzerland

Prof. Tham Clement

The Chinese University of
Hong Kong,
China

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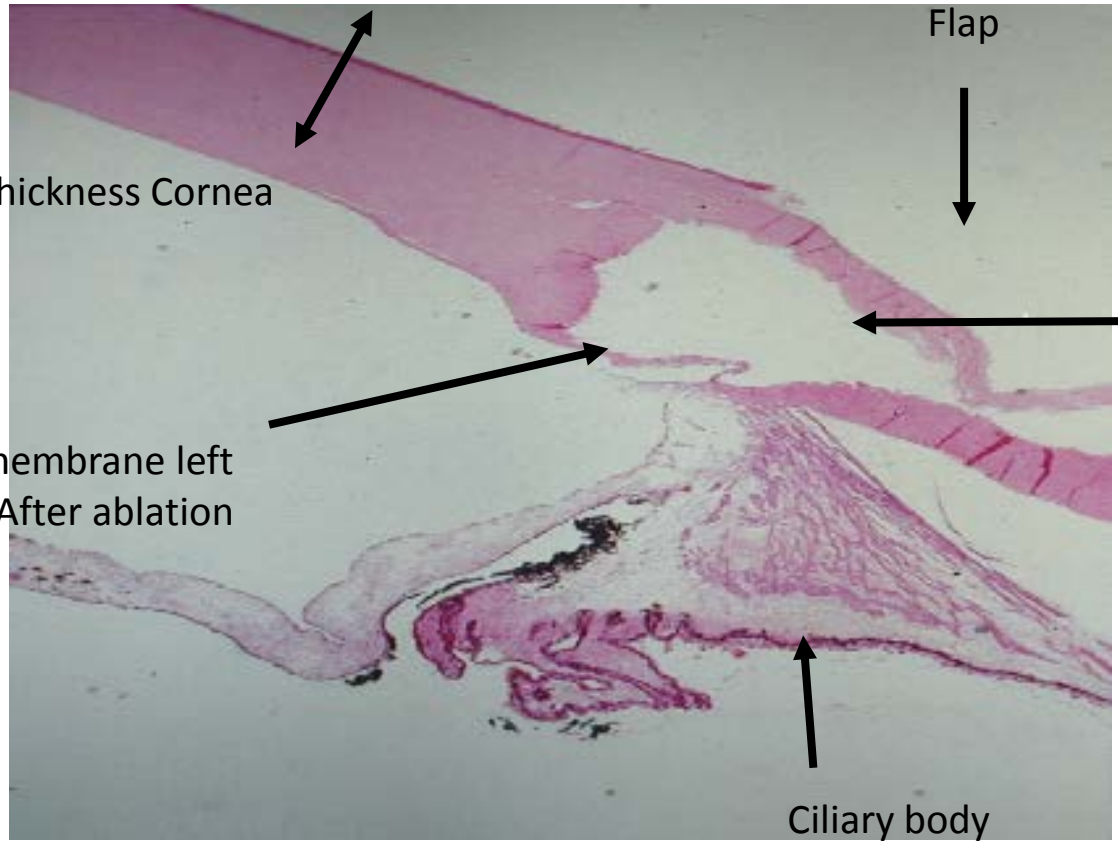
Thank you!

Histology - Human Cadaver Eyes



Human Cadaver Eye

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