CLASS by IOPtima

A new CLASS™ of Glaucoma Surgery

IOPtima
Novel Glaucoma Treatment

The CLASS solution

CLASS™ (CO_2 Laser Assisted Sclerectomy Surgery) is a novel, minimally invasive, laser-assisted surgical solution for the long term treatment of Glaucoma. **CLASS™** is performed with the use of the **IOPtiMate™** system consisting of a CO_2 laser and scanner, which enables eye surgeons to perform an accurate none-penetrating laser-assisted Glaucoma surgery.

CLASS™ reduces the elevated intraocular pressure (IOP) by unroofing the Schlemm's canal, thus enabling an effective drainage without penetrating into the anterior chamber. The none-penetrative nature of **CLASS™** significantly reduces the risk of intra-operative and post-operative complications and the follow-up manipulations commonly associated with penetrating surgical alternatives.

Owing to the CO_2 laser's unique properties of tissue ablation and absorption in fluid, the surgeon is able to delicately ablate layers of scleral tissue while the laser's energy is being safely absorbed in the percolating intraocular fluid.

Advantages of the CLASS procedure

MD Driven

- Simplified, reproducible procedure
- High efficacy
- Less follow-up care required
- Minor / transient adverse events
- Suitable for combined procedures
- Non-penetrating laser surgery
- Increased patient satisfaction
- Easy to adopt, short learning curve

Hospital Driven

- Potential increase of treatments & revenue
- Increased safety: less liability
- Less follow-up; less resources
- Attractive business models

Patient Driven

- Increased quality of life
- Long-term efficacy
- Reduction of anti-glaucoma medications
- Non-penetrating laser surgery
- Minor/ transient adverse events
- Less follow-up care required
- Cost effective

Payer Driven

- Lower costs due to fewer complications
- Fewer post-op manipulations
- Reduced lifetime anti-glaucoma medications
- Cost effective procedure

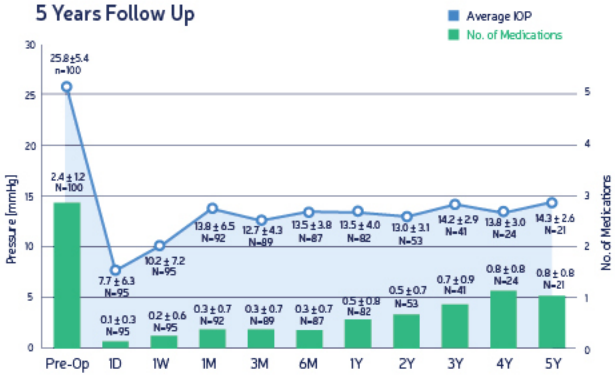
Clinical Results

Data from a global multi-center clinical study performed on 111 patients in 9 sites with 5-year follow up demonstrate:

- Significant long term IOP reduction, stable over time
- Extremely low post operative complication rates
- Long term reduction in medication
- Better safety profile than Trabeculectomy
  (based on indirect comparison with published data on Trabeculectomy)

Clinical Results
Efficacy

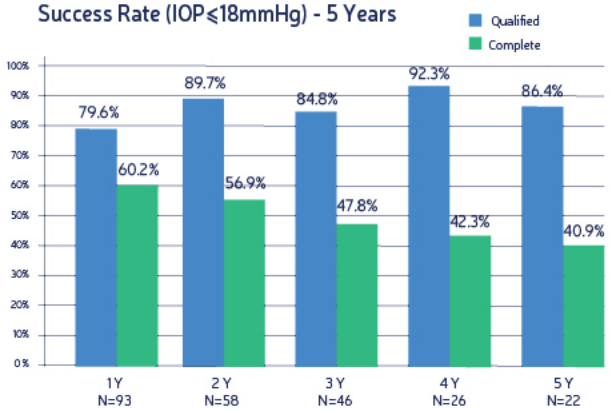
5 Years Follow Up



P < 0.008 using Bonferroni correction for multiple comparisons

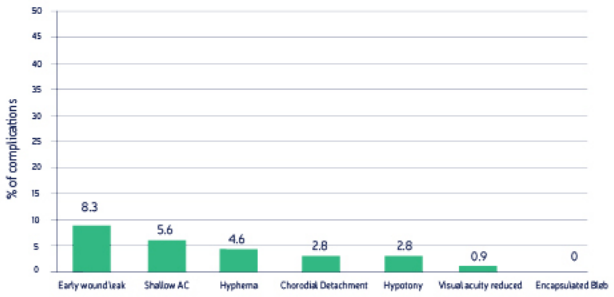
Clinical Results
Success Rate

Success Rate (IOP≤18mmHg) - 5 Years



Clinical Results
Safety

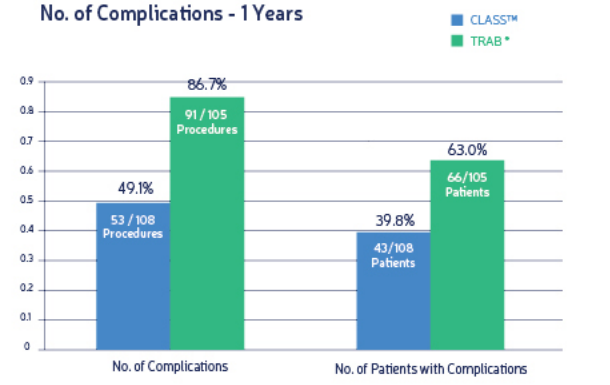
Frequency of complications



*Other complications included iris incarcerations (8.3%), peripheral anterior synechia (5.6%), transient superficial clerato keratitis (3.8%), macular edema (0.9%), and Perforation by Laser (4.6%).

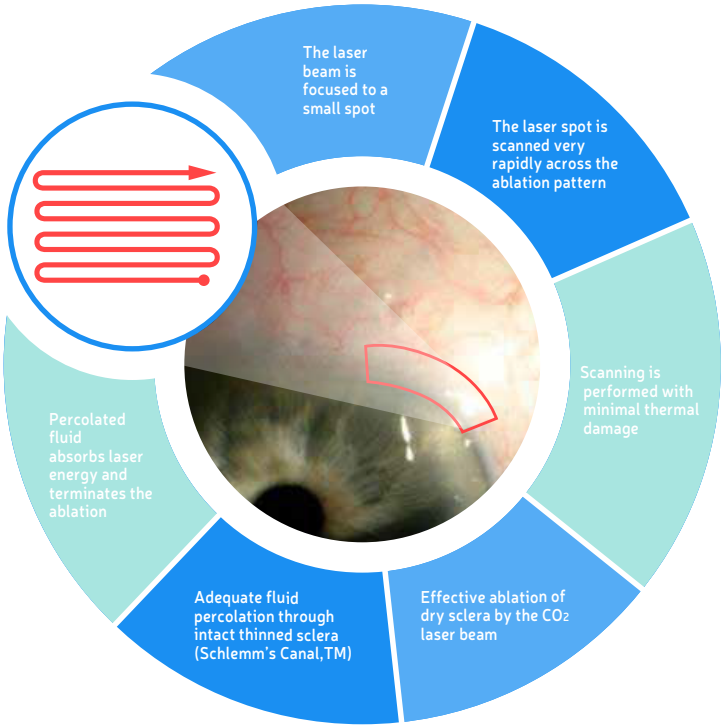
Clinical Results
CLASS vs. Trab – Safety

No. of Complications - 1 Years



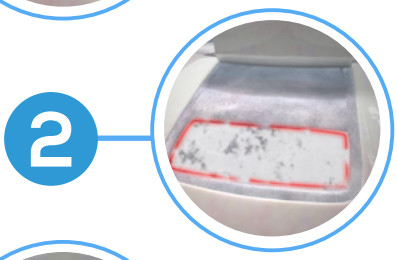
*American Journal of Ophthalmology (2007) Volume: 143, Issue: 1, Pages: 23-31; Surgical complications in the Tube Versus Trabeculectomy Study during the first year of follow-up; Steven J Gedde.

CO_2 Laser Principle of Operation



The CLASS Procedure

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)

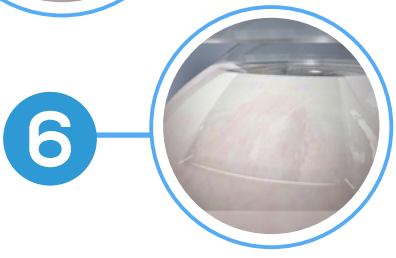


2. Creation of scleral reservoir with the use of the laser and application of Mitomycin C

3. Position a pre-selected ablation pattern on the limbus line.
The laser beam is scanned rapidly, ablating thin layers of sclera until unroofing the Schlemm's canal

4. Fluid percolation through intact trabecular meshwork

5. A thin layer remains intact, penetration of the eye is avoided



6. The scleral flap and the conjunctiva are closed and sutured

Publications

Ton, Geffen, Kidron, Degani & Assia. (2012). CO_2 laser-assisted cleratomy surgery part I: concept and experimental models. *Journal of Glaucoma*, 21(2), 135-140.

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Skaat, Goldenfeld, Cotlear & Melamed. (2014). CO_2 laser-assisted deep cleratomy in glaucoma patients. *Journal of Glaucoma*, 23(3), 179-184.

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Shaarawy. (2015). Glaucoma surgery: Taking the sub-conjunctival route. *Middle East African Journal of Ophthalmology*, 22(1), 53.

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The IOPtiMate™ is currently unavailable in the United States and has not been evaluated or approved for use by the U.S. FDA

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