Clinical Evaluation of Disposable Probe Nanosecond Laser–Assisted Clear Cornea Cataract Extraction

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Laser Vision Your Vision Our Mission

Athens, Greece

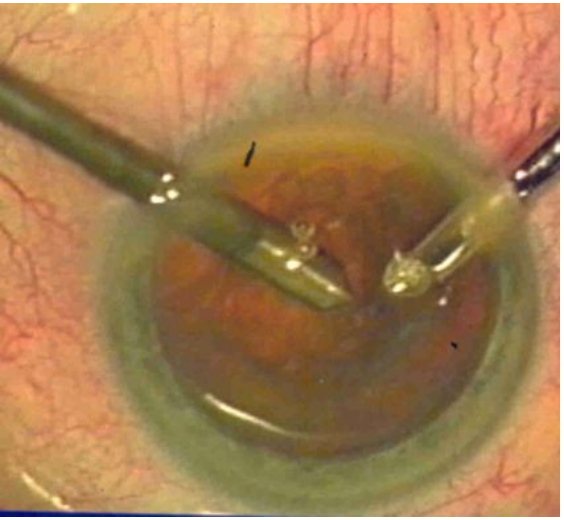
New York University School of Medicine

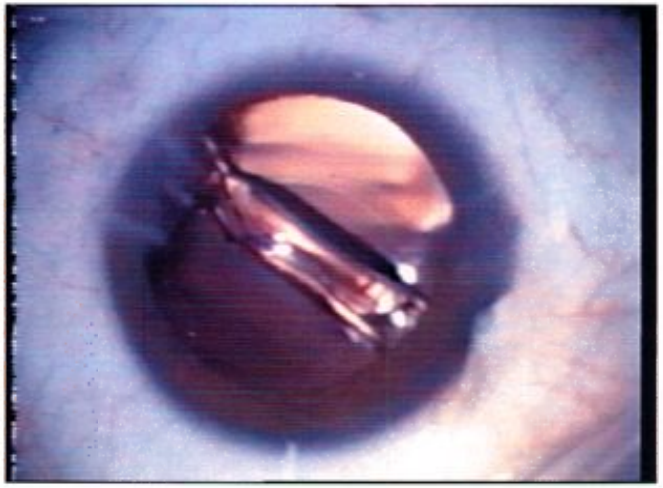
New York City

Laser Cataract Surgery

1999-2 mm barrier
Kanellopoulos, et al.
J Ophthalmol, 1999

- In pursuit of endocapsular CE
- True accommodative IOL





Ophthalmology Times

2-mm incision barrier is broken in Greece

By LYNDA CHARTERS
Reviewed by A. John Kanellopoulos, MD

ATHENS, GREECE—Cataract extraction with a smaller-than-2-mm incision was performed here recently.

A. John Kanellopoulos, MD, broke the 2-mm barrier using the Dodick photolysis Nd:YAG laser, a technique that is proving to be an alternative to ultrasound phacoemulsification. He has worked with it extensively over the past several years (see story at right).

Dr. Kanellopoulos is an attending staff surgeon, the Cornea Service, Manhattan Eye, Ear and Throat Hospital, New York, and director of external diseases, Cornea and Refractive Surgery at the Orasis Hellenic Eye Center, Athens.

Dr. Kanellopoulos

"Over the last several decades, there has been remarkable evolution in the instrumentation, the incision, and the IOL materials and designs involved in cataract extraction," Dr. Kanellopoulos said in an interview with *Ophthalmology Times*.

Laser cataract removal was done through two clear cornea paracenteses of about 1.6 mm in width.

"The cataract surgery incision has been decreasing in size, a process that is limited by the diameter of the cataract fragmentation instruments and the ability to minimize the incision width required for intraocular implantation," he continued.

The primary advancements that enabled the use of the 1.6-mm incision were the development of an appropriate IOL material and a folding technique that even allow IOL implantation with the use of the mini-incision.

A new folding technique developed by Christine Kreiner, PhD, president, Acritec, Berlin, allows an approved acrylic IOL manufactured by Acritec (model H44-IC-1) to be implanted through an incision smaller than 2 mm, according to Dr. Kanellopoulos.

"This one-piece acrylic lens that has a 6-mm diameter optic and is 12.5 mm in total length was prefolded by 27% dehydration. This folded lens (19.0 D in power and an A constant of 119.0) has a width of about 1.2 to 1.3 mm. Laser cataract removal was performed through two clear cornea paracenteses of approximately 1.6 mm in width," he said.

The cataract extraction was performed with the patient under topical anesthesia, and a 4.5-mm curvilinear continuous capsulorhexis, hydrodissection, laser nucleus

Figure 1

Manual implantation of a prefolded dehydrated IOL following laser cataract removal. The incision is 1.6 to 1.8 mm. (Photograph courtesy of A. John Kanellopoulos, MD)

removal, and irrigation-aspiration of the residual cortical material were done.

The prefolded, dehydrated lens was then implanted in the capsular bag through the original incision.

The entire procedure was performed in less than 10 minutes of operating room time.

"Over the next 25 to 30 minutes, the implanted lens was fully unfolded within the capsular bag and was well centered. One month postoperatively, the patient's visual acuity was 20/20 uncorrected," he said.

Important development

Dr. Kanellopoulos underscored the importance of this development in cataract extraction.

"The use of this technique or other prefolded techniques and new IOL materials will complement minute cataract removal by laser. Although cataract surgery performed with phacoemulsification is one of the safest and most effective procedures in medicine, there has been increasing interest in utilizing smaller incisions with the potential goal of performing true endocapsular cataract removal," he said.

"Retaining the entire capsular bag would open the field for possible injectable materials that could act as an IOL by filling the capsular bag and possibly retaining accommodation. Some of these entities have been shown to be possible recently in laboratory animal studies. Phacoemulsification probes are limited to a certain diameter because of the necessary cooling sleeve that accompanies the ultrasound needle," Dr. Kanellopoulos continued.

"Of all the 'laser phacos,' the Dodick photolysis unit has achieved a 1.2-mm external diameter laser probe for cataract surgery with relative success. This has widened the horizon for future true endocapsular cataract surgery in the next millennium," he said.

Dr. Kanellopoulos has performed 80 cataract extractions using this procedure and is submitting data on the first 1,000 cases worldwide, which represent the experience from 25 sites in Germany, Austria, France, Spain, Greece, Saudi Arabia, Mexico, and Canada. The primary focus of this investigation was the safety, efficacy, and intraoperative time efficiency of this method of laser cataract removal.

Dr. Kanellopoulos has no proprietary interest in Dodick photolysis technology or the implanted IOL design and company.

Figure 2

The folded IOL is in the capsular bag after implantation and centration.

Figure 3

Thirty minutes after surgery, the IOL is fully unfolded and well centered within the capsular bag.

Figure 4

The same model IOL with the same dehydrating pre-folding technique unfolds in BSS.

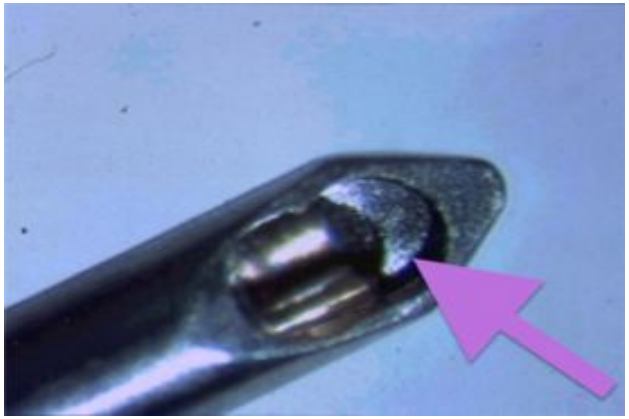
Figure 5

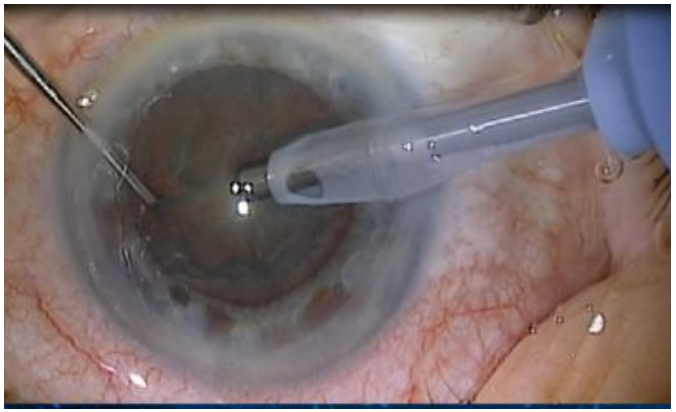
A later stage in the unfolding process seen in Figure 4. (Photographs courtesy of A. John Kanellopoulos, MD)

Clinical evaluation: Nanolaser – Ultrasound Phaco

Performing standard cataract surgery procedure:

- Corneal incision: 2.2mm (Nanolaser), 2.0mm (Phaco)
- 2 Paracentesis (0.5mm each)
- Capsulorhexis
- Nanolaser surgery followed same steps as ultrasound phaco, except no switch to I/A handpiece necessary



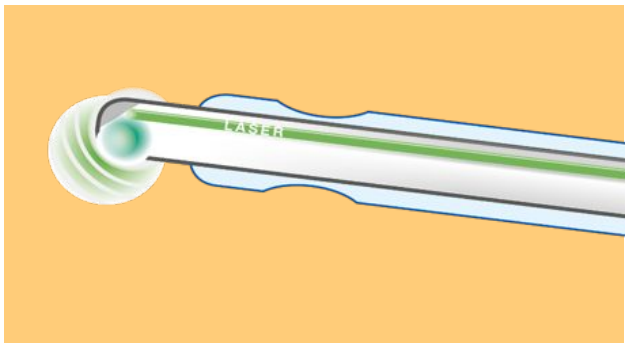


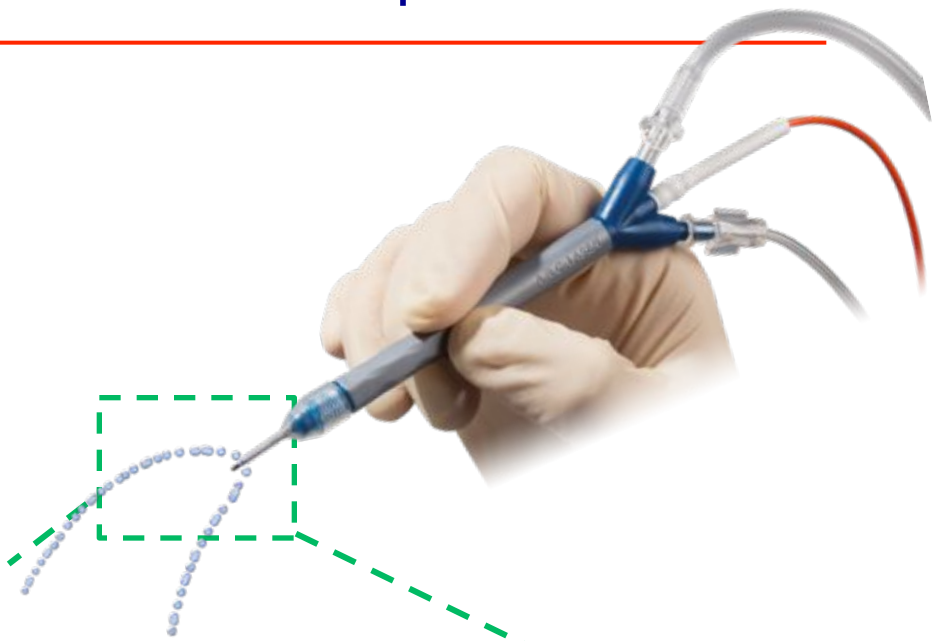
Nano-Laser-System

Technical Specifications	
Laser	Nd:YAG
Wavelength	1064nm
Pulslänge	4ns
Energy	4-8mJ
Frequency	1-20Hz
Diameter of laserfiber	283µm

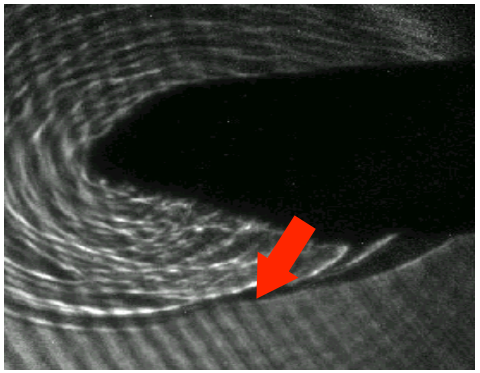
- Emulsification by indirect laser / tissue interaction
- No laserlight outside of lasertip
- No heat generation
- No ultrasound, replaces standard phaco handpiece (single use)
- Used in combination with standard phaco-machine
- Connected to vitrectomy port, triggert by footpedal

The Coaxial Nano-Laser Handpiece

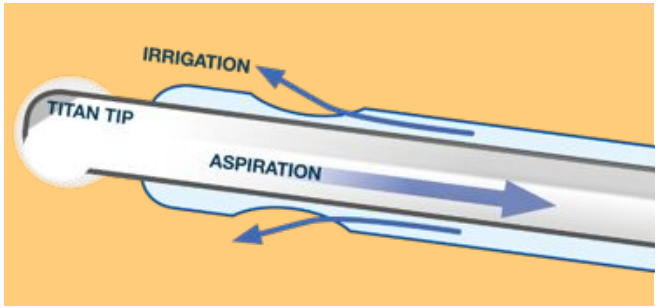




Plasma induction by impact of titanium target and generation of shockwaves



Imaging of laser generated shockwaves in water



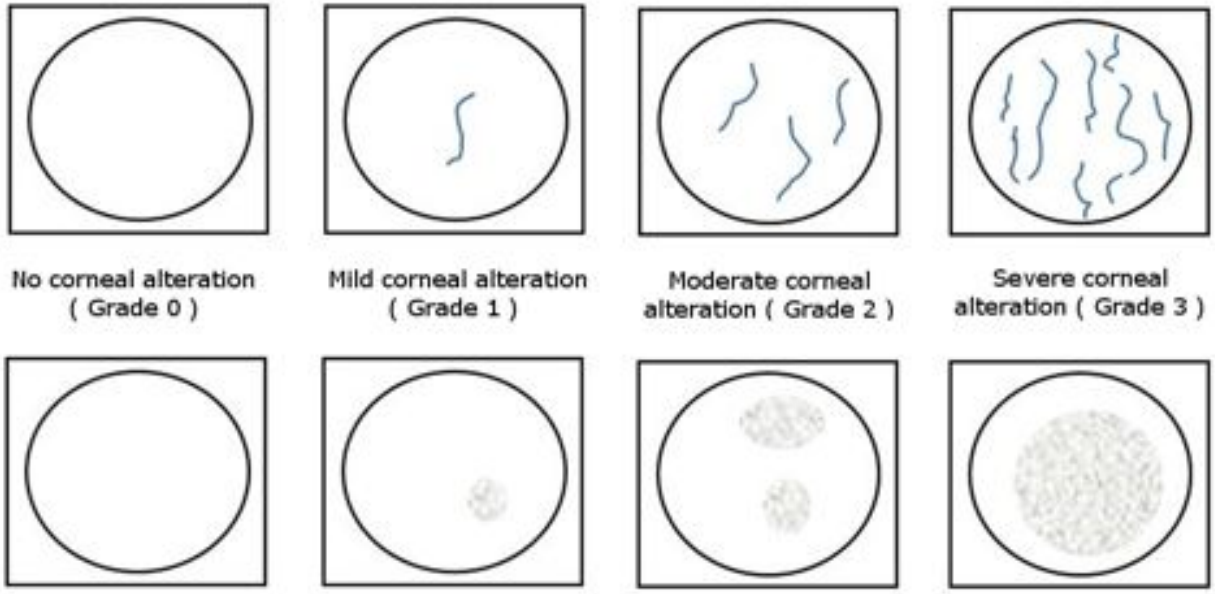
Irrigation and aspiration in koaxial handpiece

Clinical parameters

Measuring irrigation fluid use during procedure

- Rhexis
- Emulsification
- IA
- Aspiration of viscoelastics

Evaluation of corneal edema postop day 1



Patient demographics

178 successive patients (83 male, 95 female) were included into a clinical study to compare nanosecond-laser –assisted (group A) versus manual phacoemulsification cataract surgery (group B). 89 eyes were treated with nanosecond-laser and 89 eyes received ultrasound phacoemulsification.

The consumption of irrigation fluid, duration and energy of phacoemulsification and laser pulse rate and total energy were evaluated.

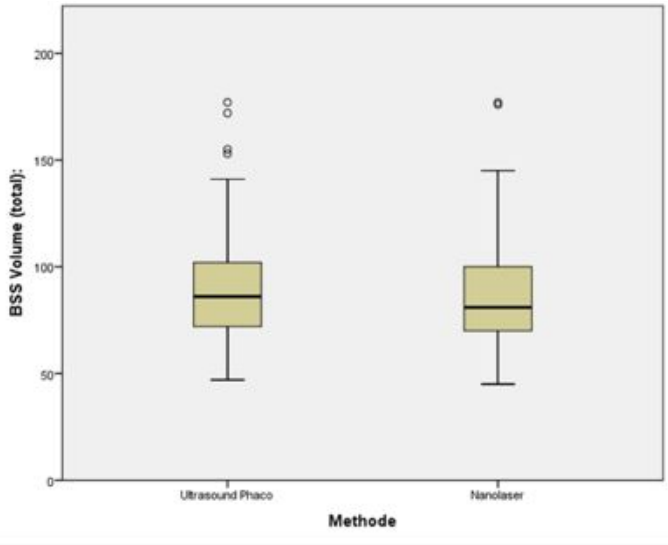
Corneal edema and Descemet's membrane folds and cornea edema were measured at postoperative day one using an arbitrary scale ranging from 0 to 4 (0= no folds and no edema, 4=dense folds and significant edema obscuring iris detail).

Patient demographics

	Group-A Phaco	Group-B Nano-Laser	
Age	71.8 ± 7.9	68.4 ± 7.4	p = 0.11
Eyes (n)	89	89	
Right (OD): Left (OS) eyes	43: 43	49: 40	
Male: Female	46: 43	37: 52	
LOCS	3.66 ± 0.54	3.47 ± 0.68	p = 0.038
IOL power (D)	20.56 ± 3.46	20.65 ± 2.80	p = 0.41

Results : Irrigation Fluids

- Consumption of irrigation fluids after each surgical step:
  - Rhexis
  - Phacoemulsification
  - I/A
  - Aspiration of viscoelsatics



	Rhexis	Nucleus removal	Epinucleous aspiration	Aspiration of viscoelastic	Total
nano (group-A)	2.02 ± 1.05	33.9 ± 14.4	21.7 ± 13.9	32.7 ± 10.7	90.6 ± 25.6
phaco (group-B)	1.65 ± 1.02	41.5 ± 15.2	22.6 ± 13.8	21.4 ± 9.4	87.3 ± 25.7
p-value	0.014	0.001	0.67	<0.001	0.389

Results

Mean energy: Group A Nano; 4.8 Joules (+/- 2.5), average 148 laser pulses (+/- 117). Group B phaco: 13.4 Joules ± 3.4.

Fluid consumption, was respectively for Group A compared to Group B:

Capsulorrhexis (1.65ml ± 1.0ml Vs. 2.02ml ± 1.65 ml), **emulsification** 41.5ml ± 15.2 Vs. 34 ml ± 14.3 ml) , **cortical aspiration:** 22.6 ml ± 13.8 ml Vs. 21.7 ± 13.9ml **aspiration of viscoelastic**: to 21.4 ml ± 9.4 ml Vs. 32.7 ml ± 10.7 ml.

Descemet's folds mean value: 0.42 ± 0.74 Vs. 0.26 ± 0.58.

Corneal edema 0.20 ± 0.46 Vs. 0.22 ± 0.47.

ECC 1 month: 5% Vs 7%

Comparison Nano Laser – Conventional Phaco

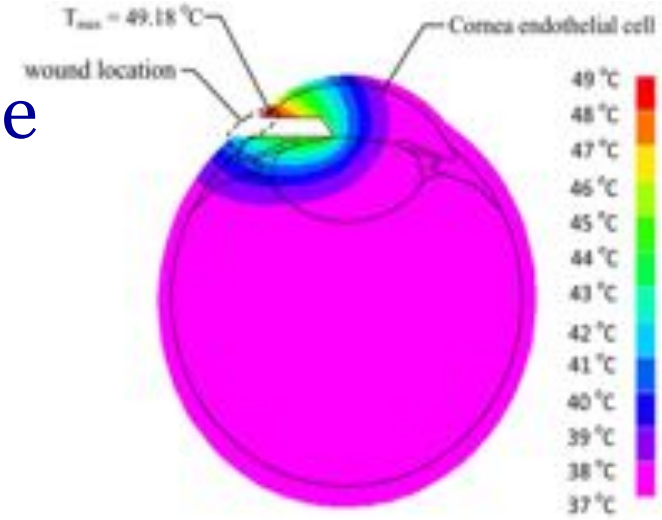
Nano Laser	Ultrasound Phaco
Single Use	Multiple use, sterilisation required
LOCS 1 - 4	No limitation
Longer precedure time	Shorter procedure time
No change of handpiece during procedure	Change to I/A handpiece
Plastic (light)	Metall (heavy)
No thermal damage	Heat development

Surgeon has to adapt to new system
→ Quick learning curve

Conclusions

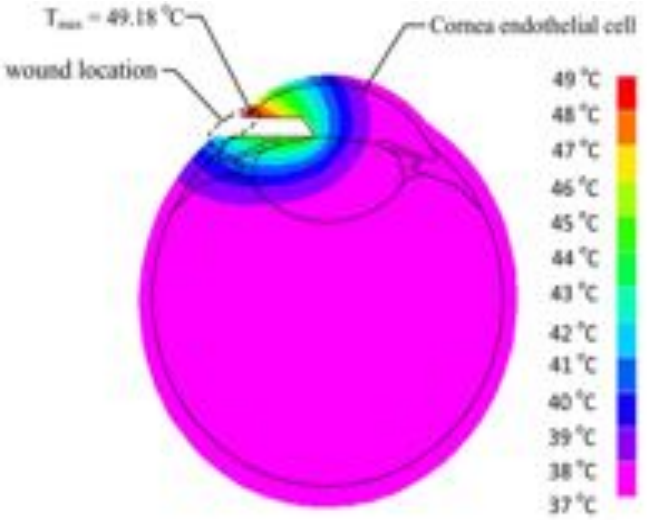
Operating with low pulse energy provided by infrared nanosecond-laser may offers a safe and effective alternative to phacoemulsification for the majority of candidate cataract patients.

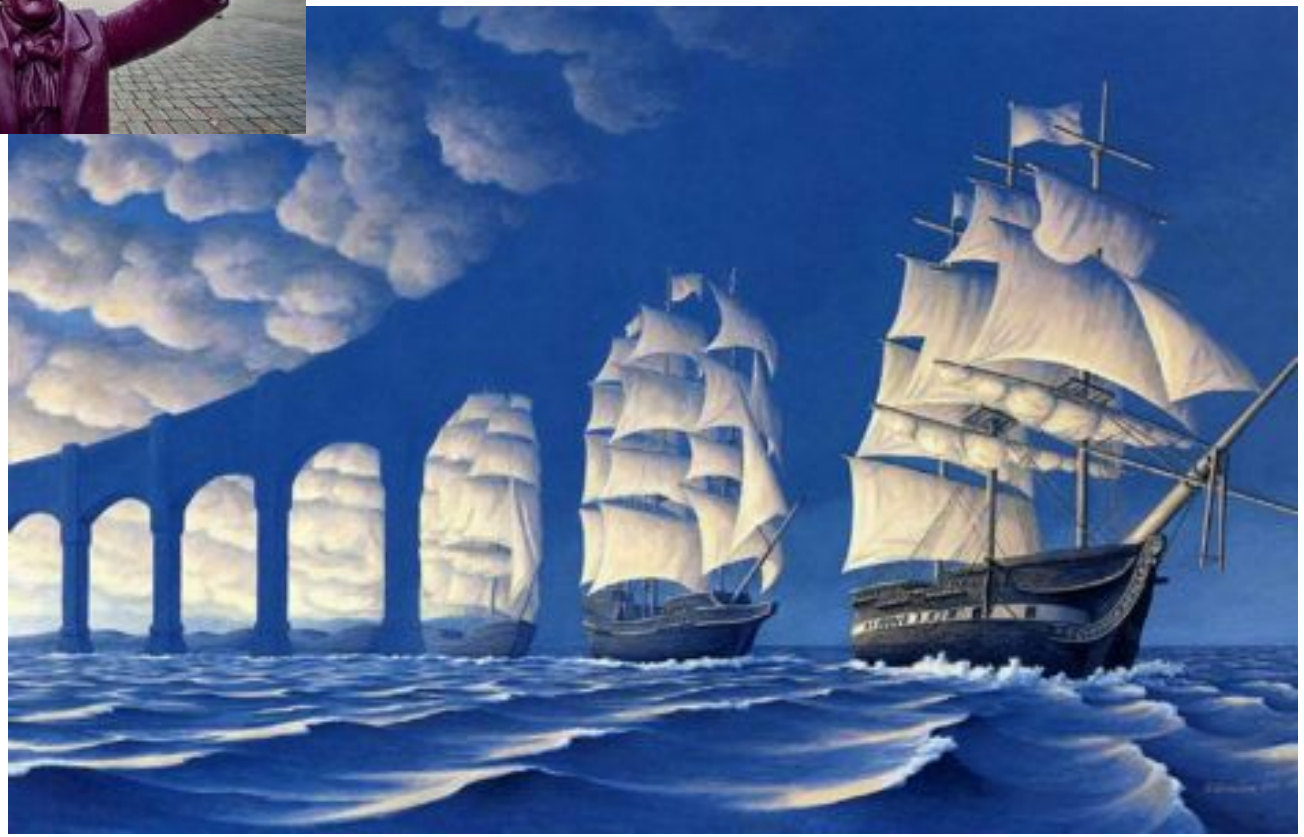
This laser probe, which is adaptable to most existing phacoemulsification systems, offers low energy levels and essentially no thermal corneal damage at the incision site



Conclusions

- Significantly less intraocular energy needed
- No re-sterilisation!
- No handpieces switch (Phaco – I/A)
- No phaco-test necessary
- Single-use laserprobe and fiber
- 100% Laser cataract extraction





Thank You!