S.V.Malayan's Eye Center, YSMU

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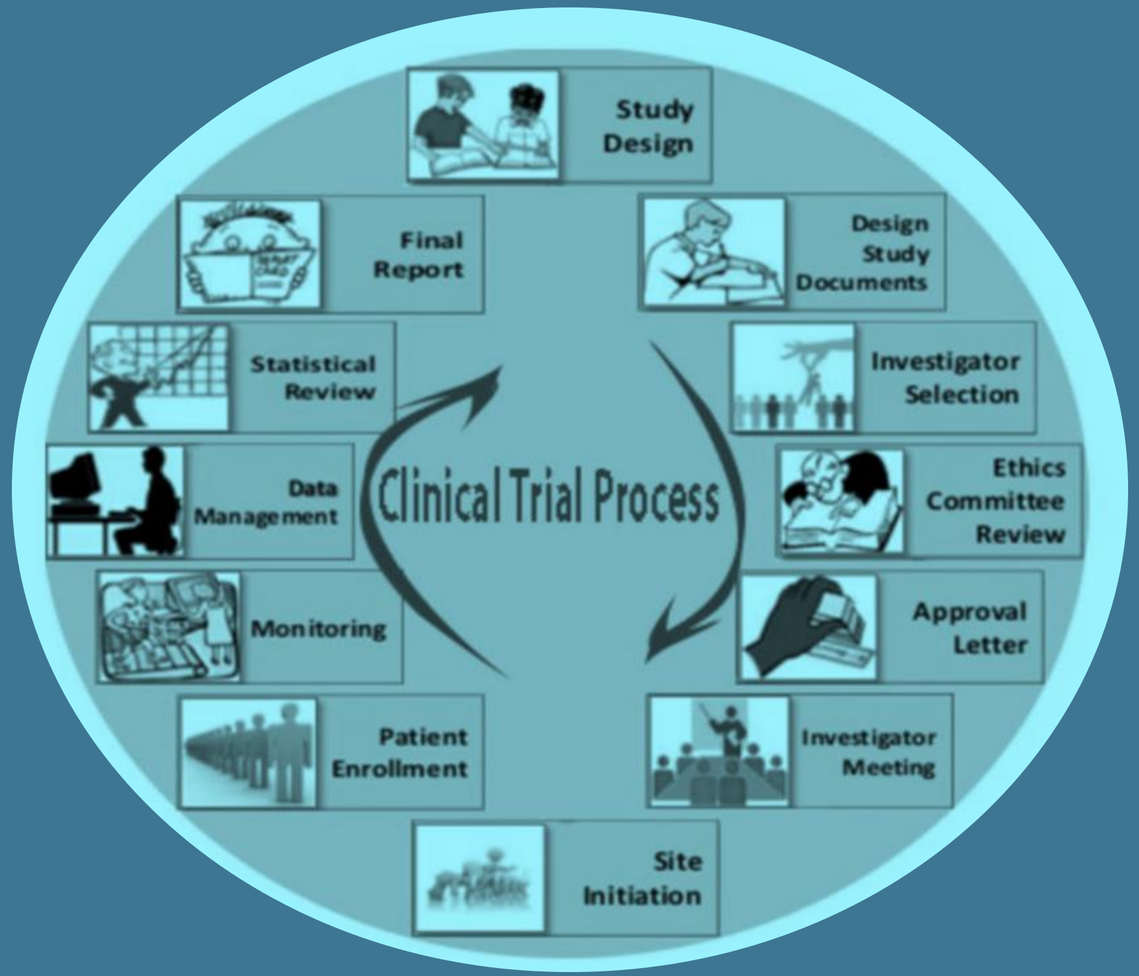
# Clinical Studies in Ophthalmology in Armenia (18 years experience)

Presented by Lilit Voskanyan

# Clinical Trial

- A clinical trial is medical research that involves people who volunteer to take part in different medical studies. Clinical trials are significant because they’re the only way for researchers to find out if a potential new treatment works and is safe.
- There are four types of clinical trials. A trial may focus on new ways to detect, prevent, diagnose or treat diseases.

# Process for clinical trial



# Before that

- **Preclinical tests**: All clinical trials start with a theory about a new therapy like a new drug, a combination of drugs or medical devices. Preclinical tests may involve laboratory tests or studies in animals.
- **Clinical trial protocol**: If preclinical tests show a potential new treatment is effective, researchers develop an action plan or clinical trial protocol. Protocols vary but must include the trial purpose, the kinds of treatments under evaluation and trial endpoints, or what researchers expect they'll be able to measure when they complete the trial.
- **FDA review and approval**: Clinical trials in the U.S. require FDA approval before researchers can start the trial.
- **Institutional review and approval**: This step involves the institutional review board (IRB) or ethics committee for any hospital participating in a clinical trial. The board's focus is on participant safety and rights.

# INFORMED CONSENT

The document is a very detailed description of the trial goals and processes. It also lists any risks and potential benefits. It includes information about any experimental procedures and alternatives to being in a clinical trial. The informed consent document also contains information about how long the trial may last, any follow-up requirements, any costs and compensation.
Finally, the document notes that any participation in a clinical trial is voluntary.

# CRO

A Clinical Research Organization (CRO) is a company contracted by a pharmaceutical, biological or medical device manufacturer to manage clinical research studies and other services to support product development. Learn about the four phases and the key functions of clinical trials.

# Clinical Trials

If the preclinical research is promising, they move forward with a clinical trial to see how well it works in humans. Clinical trials happen in several phases during which different questions are asked. Each phase builds on the results of previous phases.

Clinical trials are a way to test new methods of diagnosing, treating, or preventing health conditions. The goal is to determine whether something is both safe and effective.

A variety of things are evaluated through clinical trials, including:

- medications
- medication combinations
- new uses for existing medications
- medical devices

Before doing a clinical trial, investigators conduct preclinical research using human cell cultures or animal models. For example, they might test whether a new medication is toxic to a small sample of human cells in a laboratory.

# Phases

- Phase 0 (Primary goal) of a clinical trial is done with a very small number of people, usually fewer than 15. Investigators use a very small dose of medication to make sure it isn't harmful to humans before they start using it in higher doses for later phases.

- During phase I (Dose-ranging on healthy volunteers for safety) of a clinical trial, investigators spend several months looking at the effects of the medication on about 20 to 80 people who have no underlying health conditions.

- Phase II (testing of drug or device on participants to assess efficacy and side effects) of a clinical trial involves several hundred participants who are living with the condition that the new medication is meant to treat. They're usually given the same dose that was found to be safe in the previous phase.

# Phases

- Phase III (testing on participants to assess efficacy , effectiveness and safety)  of a clinical trial usually involves up to 3,000 participants who have the condition that the new medication is meant to treat. Trials in this phase can last for several years.

- The purpose of phase III is to evaluate how the new medication works in comparison to existing medications for the same condition. To move forward with the trial, investigators need to demonstrate that the medication is at least as safe and effective as existing treatment options.

- To do this, investigators use a process called randomization. This involves randomly choosing some participants to receive the new medication and others to receive an existing medication.

# Phases

- Phase IV(post marketing surveillance of product) clinical trials happen after the FDA has approved medication. This phase involves thousands of participants and can last for many years.

- Investigators use this phase to get more information about the medication's long-term safety, effectiveness, and any other benefits.

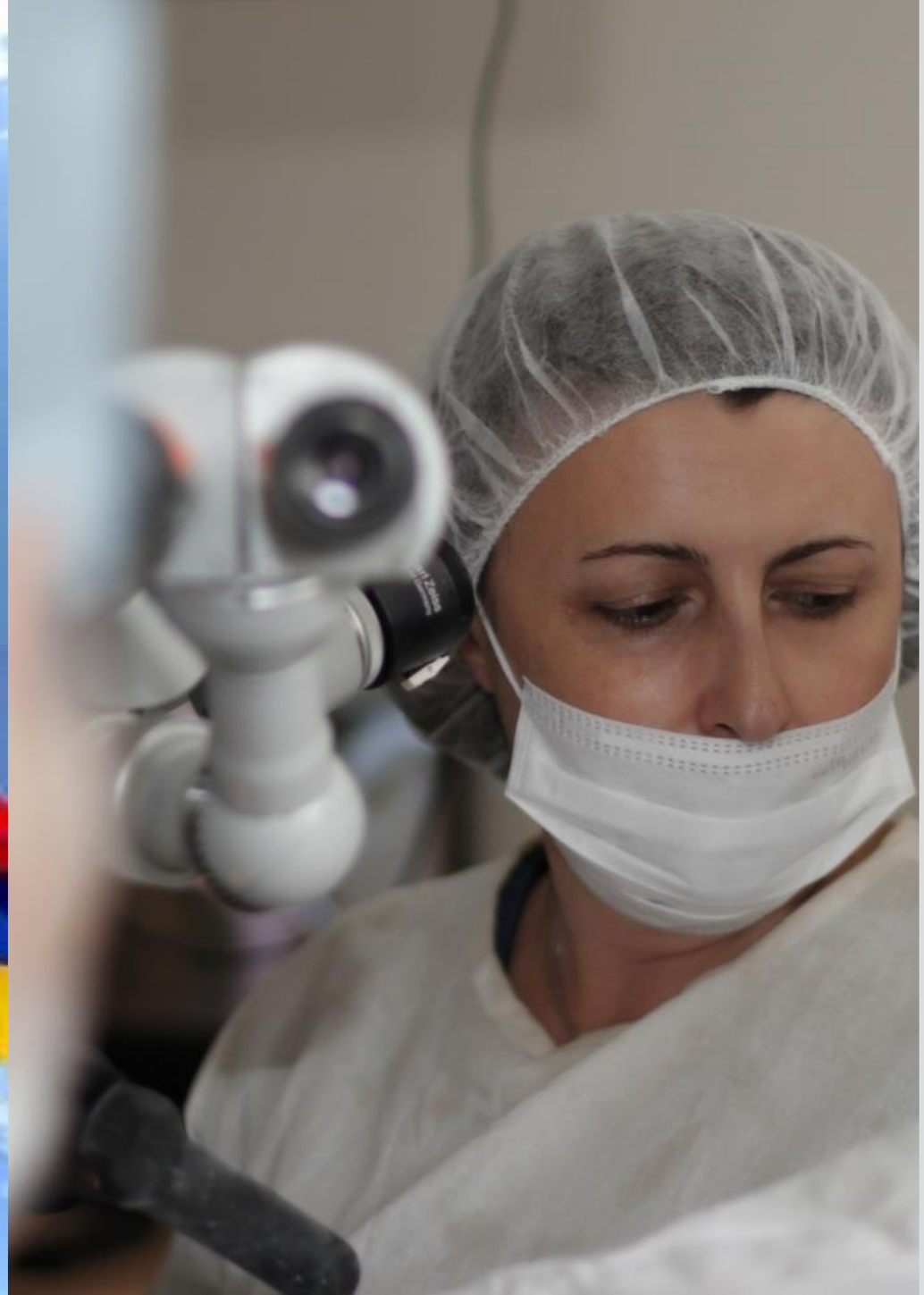
- Clinical trials and their individual phases are a very important part of clinical research. They allow the safety and effectiveness of new drugs or treatments to be properly assessed before being approved for use in the general public.

# Since 2007

- Glaukos corporation with new device for glaucoma, June 2007-5 cases
- 2007 y-Glaukos provides research for 100 glaucoma cases during 6 months
- Annually three types of Glaucoma stents were designed, impoved and implanted in Armenia FIRST  IN THE WORLD.
- 2011 -2012 yy- 600 glaucoma stents implanted with or without cataract.
- 2011- S.V.Malayan's Eye Center recognized as FDA site.
- 2012 American Society of Ophthalmology states the fact , that thanks to  work in Armenia FDA approves i-stent for the treatment in glaucoma
- About 9500 glaucoma intraocular stents implanted since 2007y
- KOL top ophthalmologists from 58 countries visited Armenia to learn new technique.
- 51 clinical trials for the treatment of Glaucoma, 2 for retinal disease with Glaukos
- 3 studies with Ciliatech,France
- 6 studies with Sanoculis, Israel
- 2 studies with Liquor Pharmaceuticals
- 2 studies with Kato Pharmaceuticals

# 2007 year, December, first 100 stents implanted

# Presentations outside of Armenia

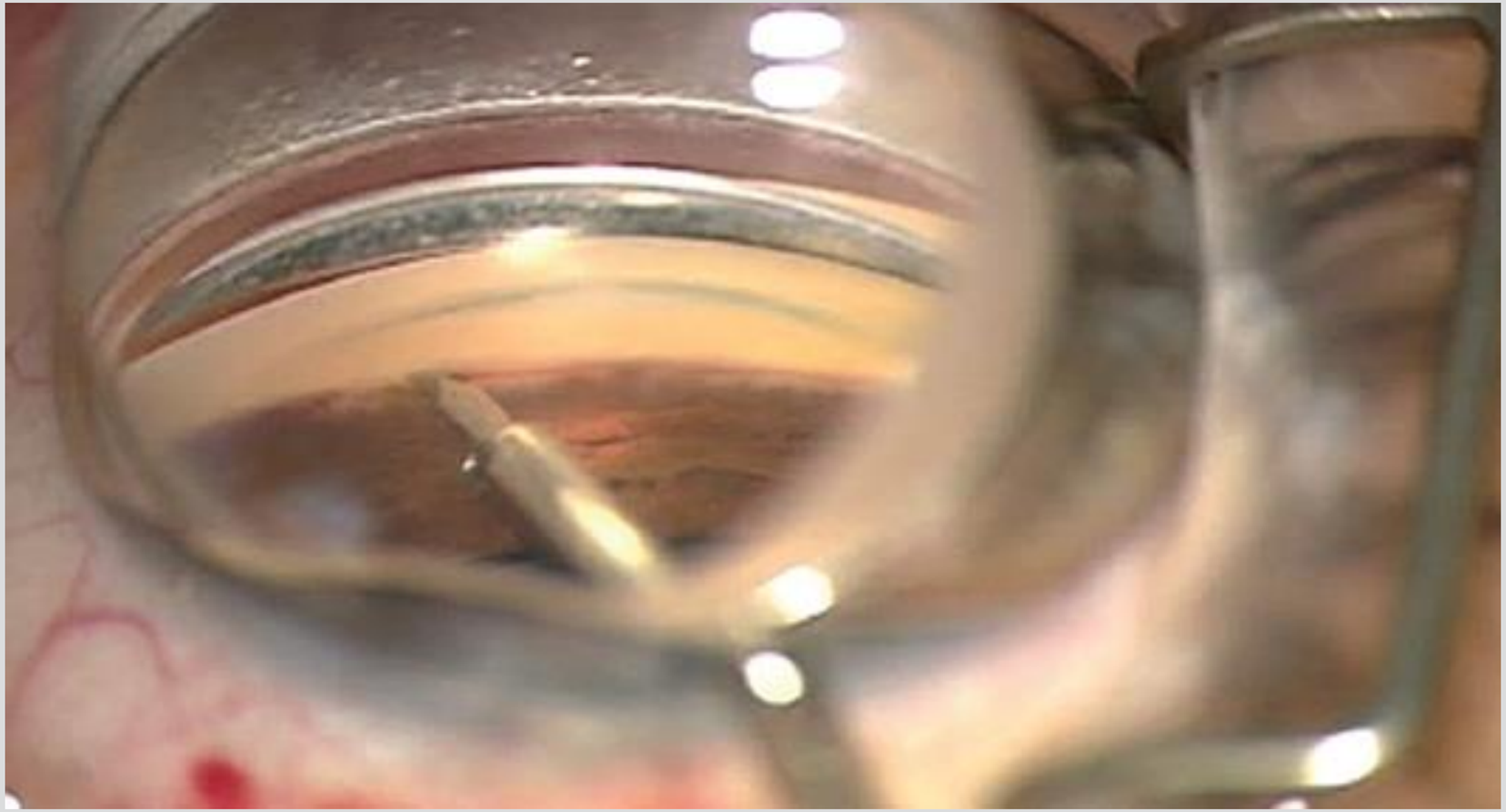


# Combined MIGS and Cataract Surgeries .

Lilit Voskanyan, 2020. Webinar, Brazil

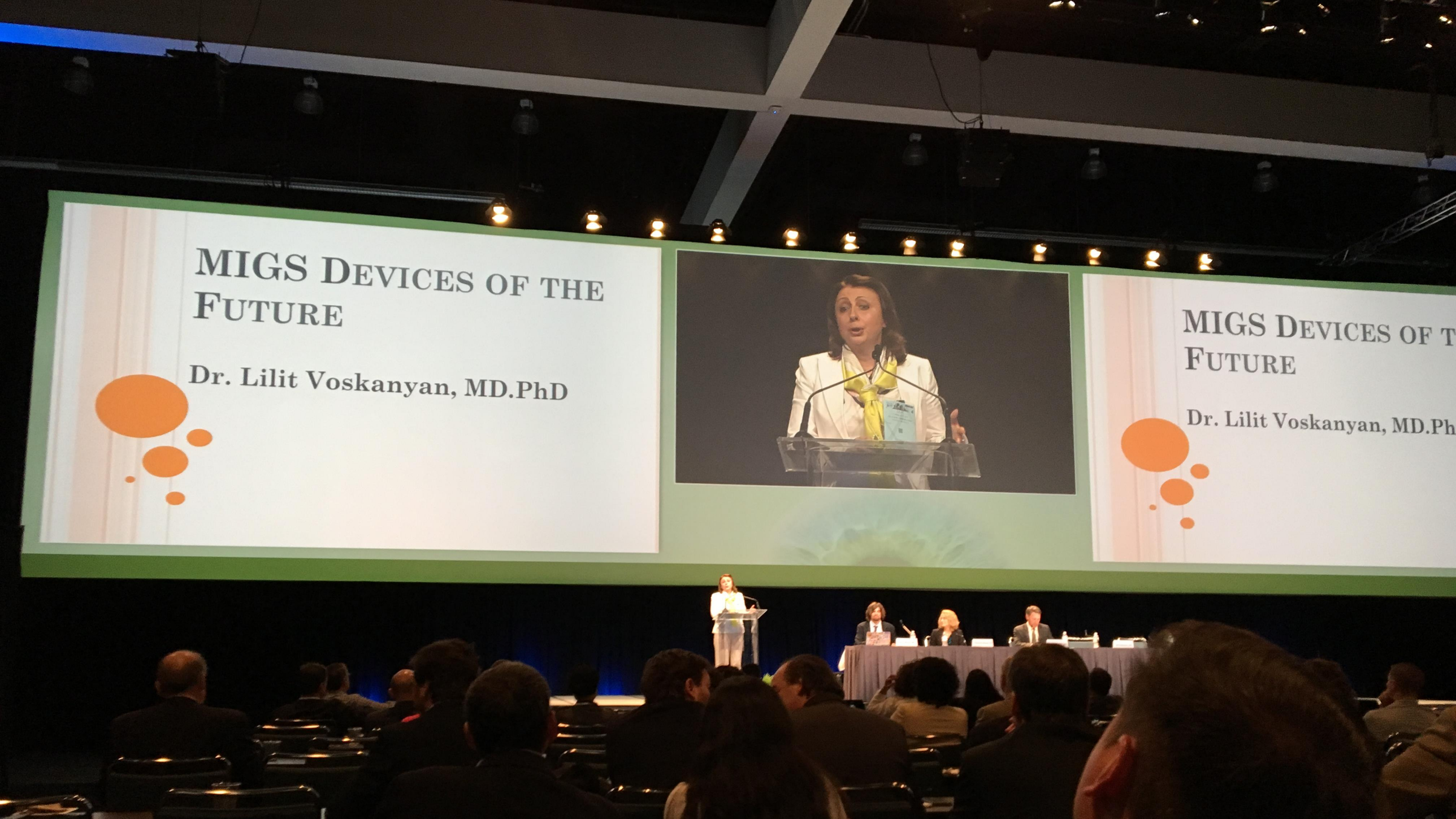
# Clinical Studies, 2010 Armenia

# First time in the world, glaucoma stent



# MIGS Devices of the Future

Dr. Lilit Voskanyan,
MD.PhD,ASCRS,2012,Chicago

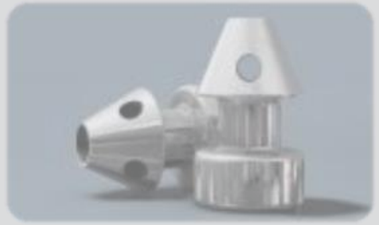

MIGS Devices of the Future
Dr. Lilit Voskanyan, MD.PhD
MIGS Devices of T
Future
Dr. Lilit Voskanyan, MD.Ph

# TRANSFORMATIONAL SHIFT TO MICRO-SCALE INJECTABLE THERAPY

*Restore Flow* → *Further Enhance Flow* → *Combination Drug & Flow*

## Injectable Flow Platform

Used in combination with cataract surgery



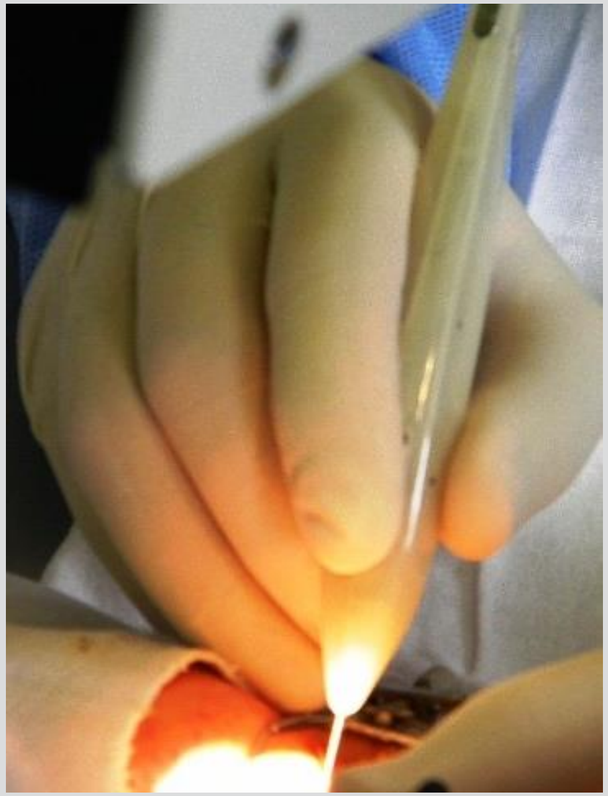
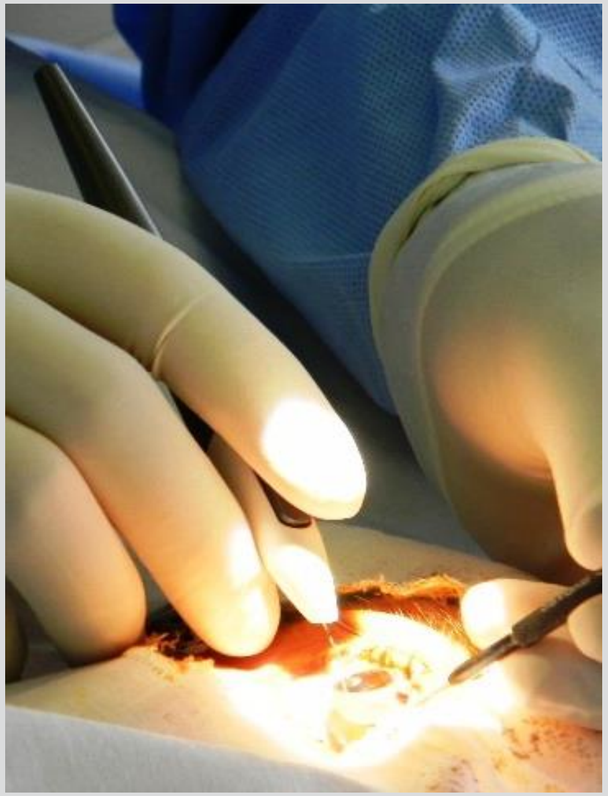
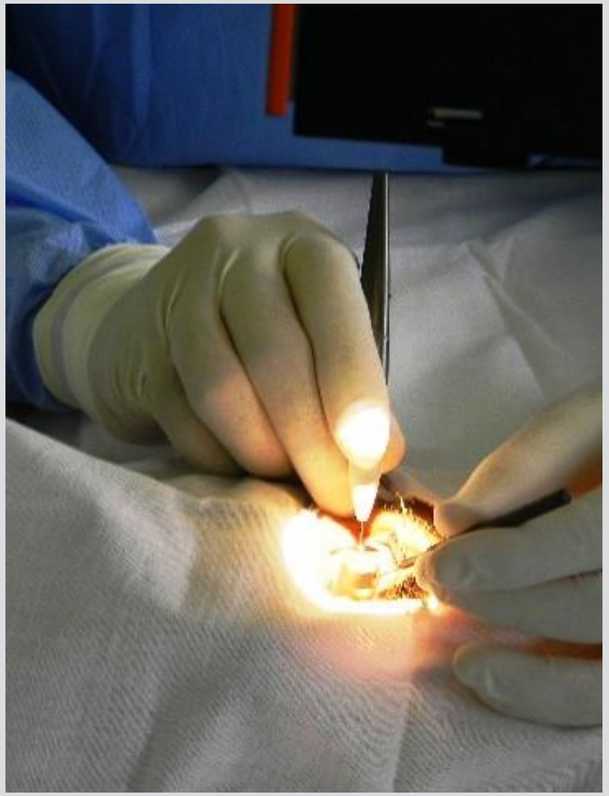
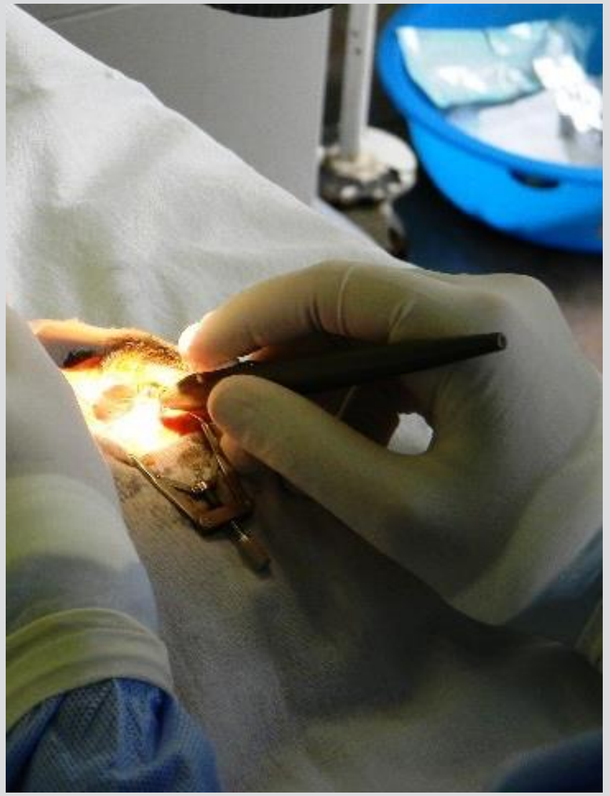
Injectable 2-stent therapy for combo-cataract and standalone procedures

Accesses secondary outflow pathway

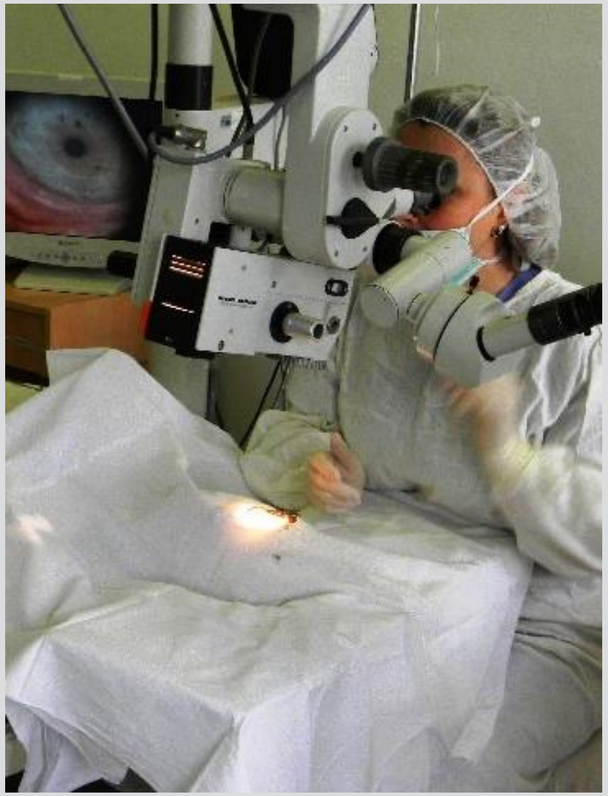
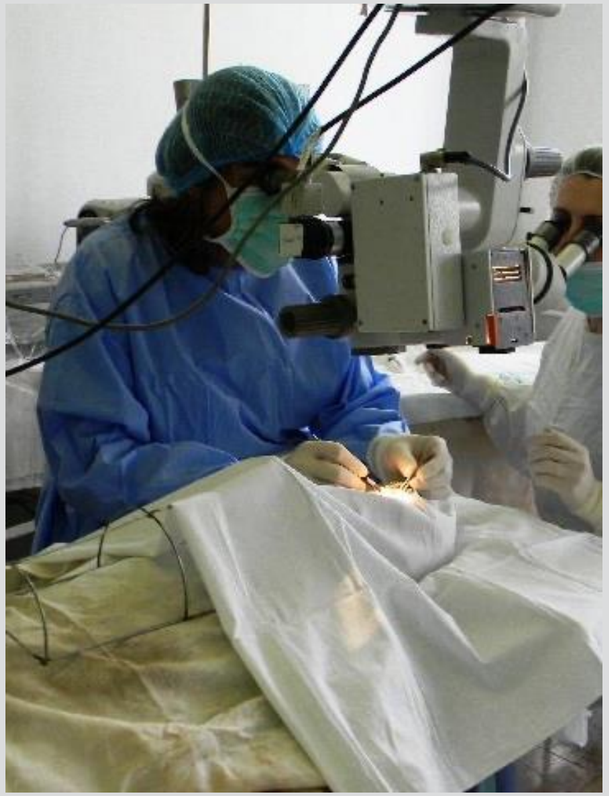
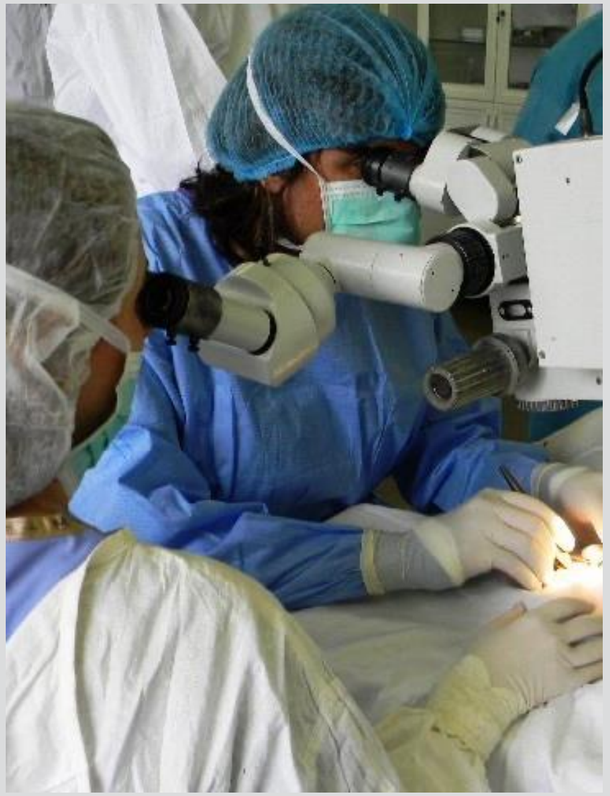
## Injectable Drug Delivery

Targeted injectable drug-delivery implant, 24/7 sustained drug therapy

# Portfolio of implants from Glaukos
# G1 iStent, G2-M-IS iStent inject, G3 iStent Supra

# Surgery,2009

16 Aug 2021 Plan

TV

TV

WhatsApp
Camera Set-Up

Ani A:
Recording

CRA
Nune

CRA
Astghik

Dani:
Oversight

Scrub Nurse
Lucine

Dr. Lilit
Voskanyan

Circulating Nurse
Anna

Dr. Yana
Oganova

Coordinator Ani B


# MIMS® CE

## New Arrival: a Fresh Approach to Treating Glaucoma

«Ս.Վ.ՄԱԼԱՅԱՆԻ ԱՆՎԱՆ
ԱԿՆԱԲՈՒԺԱԿԱՆ ԿԵՆՏՐՈՆ»

Dr. Lilit Voskanyan*

Chairman of Ophthalmology Dept., Yerevan State Medical University
Chief of Glaucoma Dept.,
S.V. Malayan Eye Center, Yerevan, Armenia

Results Highlights
**Interim report**

Dr. Lilit Voskanyan, PI

Dr. Ike Ahmed

## *120 cases, 12 months follow-up*

100 standalone, 20 combined with cataract
109 procedures by Dr. Voskanyan, 11 by Dr. Ahmed

IOP reduction:

***45% at 12 months***

Medications reduction:

***97% at 12 months***

Duration:

***2:03 ± 0:43 minutes***

***No major intra- and post-operative complications***


Masterclass, ESCRS, Vienna 2023

# MINT™

## Stent-less, Simple & Fast Glaucoma Surgery

Dr. Lilit Voskanyan*

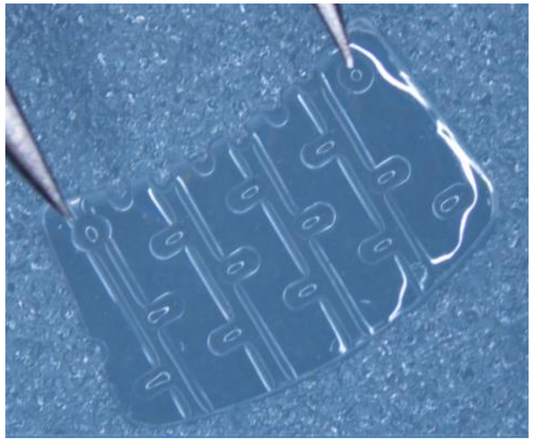
Chairman of Ophthalmology Dept.,
Yerevan State Medical University

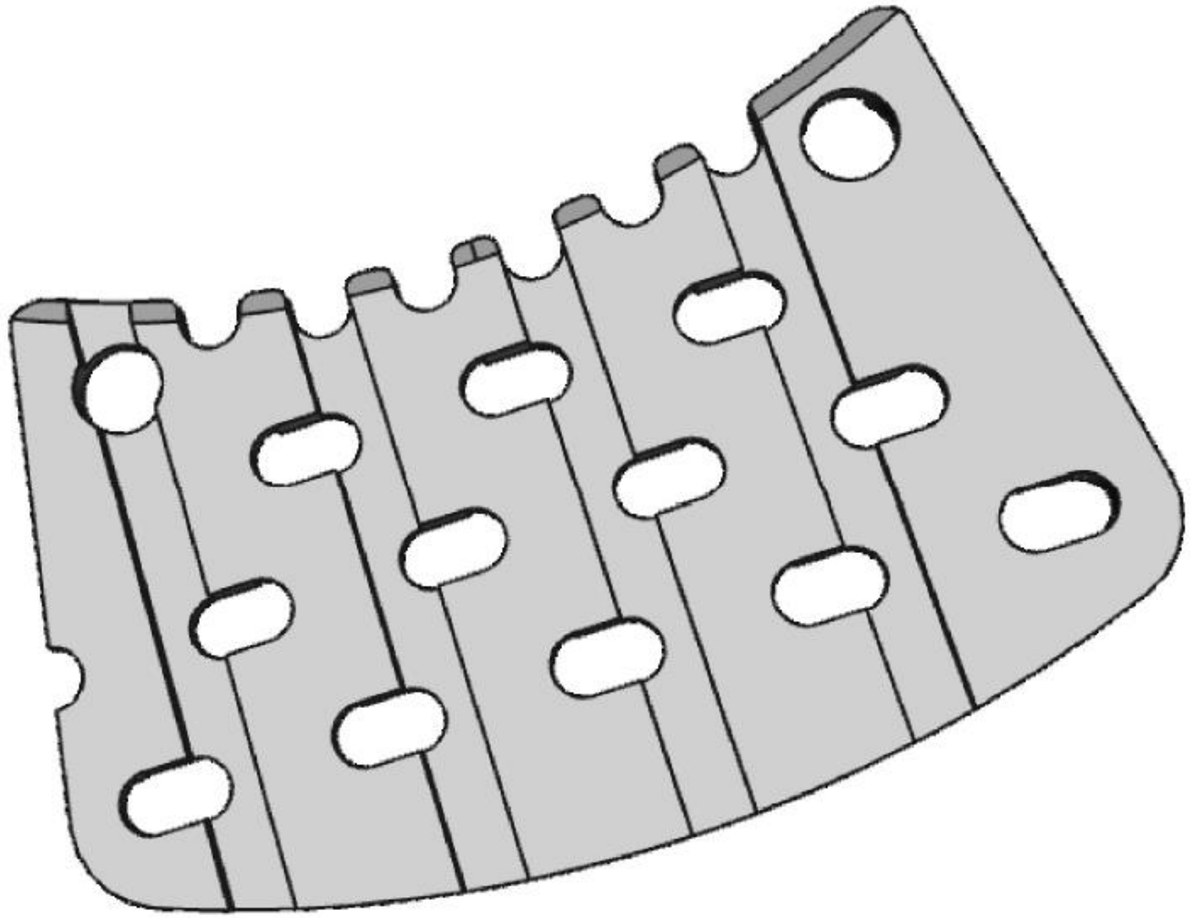
Chief of Glaucoma Dept.,
S.V. Malayan Eye Center, Yerevan, Armenia

# SUPRAFLOW

## Site Initiation Visit
## Site: Ophtalmological Center After S.V.Malayan
## 23-Nov-2020

SUPRAFLOW





# SUPRAFLOW

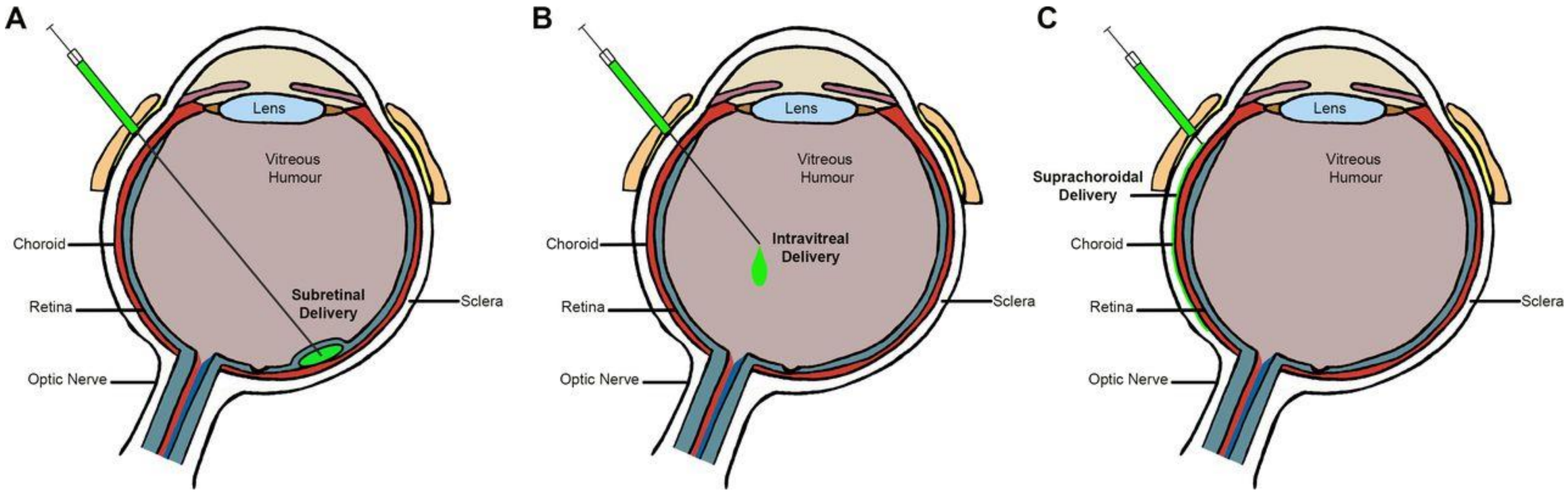
## Multicentre, non-randomised clinical study evaluating the efficacy and safety of the Supraflow® v1.3 medical device in glaucoma surgery

# Eye Care Clinical Case

Here is where your presentation begins

Each case is a lesson

# Learning delivery systems



# MIMS® - MINT™ E-Posters


E-poster number is: **PO0873**


E-poster number is: **PO0874**

# First stent in Brazil

# THANK YOU