

MIGS i Sverige 2017

Anders Bergström
Ögonkliniken SUS
Malmö-Lund

Nya MIGS

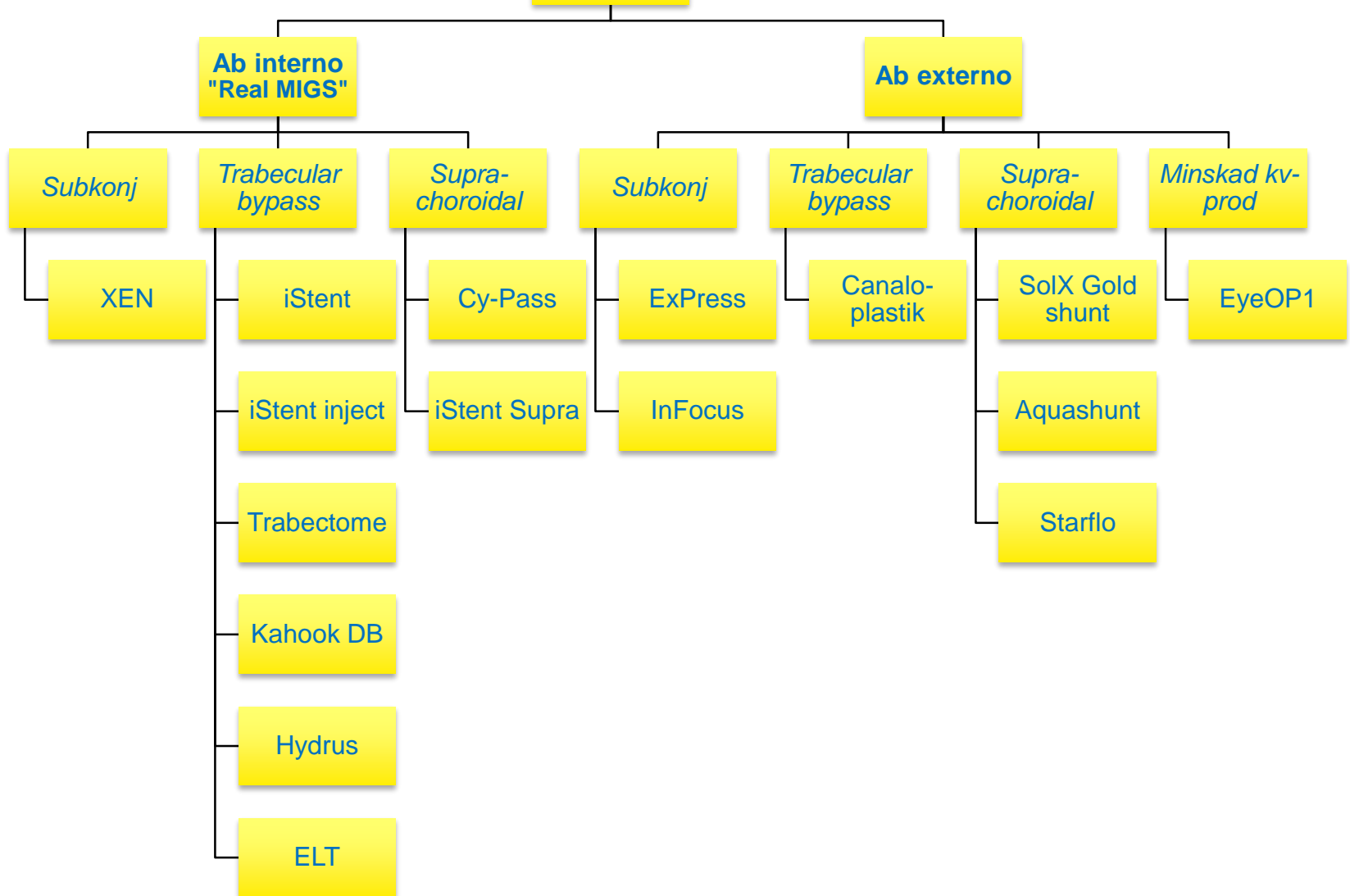
- Minimal Invasive Glaucoma Surgey
- Minimal Incisional Glaucoma Surgery
- Sänker trycket mindre än en trabekulektomi
- MEGS = Minimal Effective Glaucoma Surgery
- Används oftast i kombinerade operationer

1. Ab interno vs Ab externo

2. Subkonj vs Trabecular vs Suprachoroidal

Saheb 2012

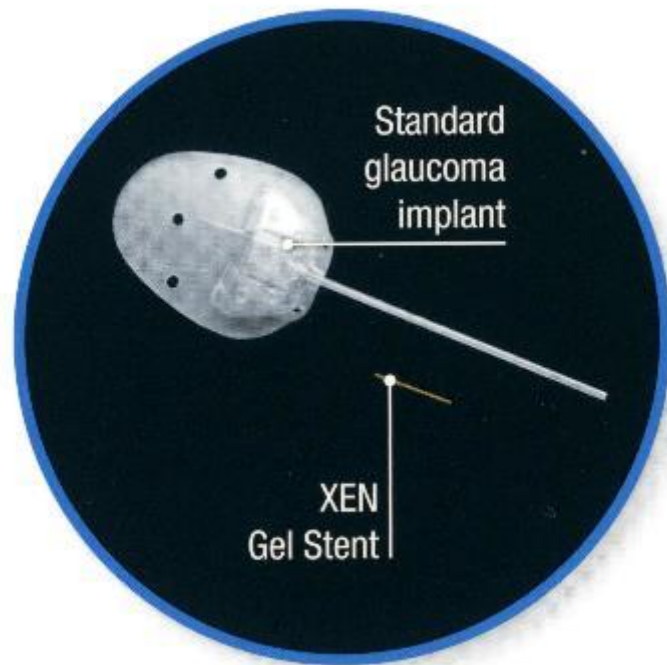
MIGS

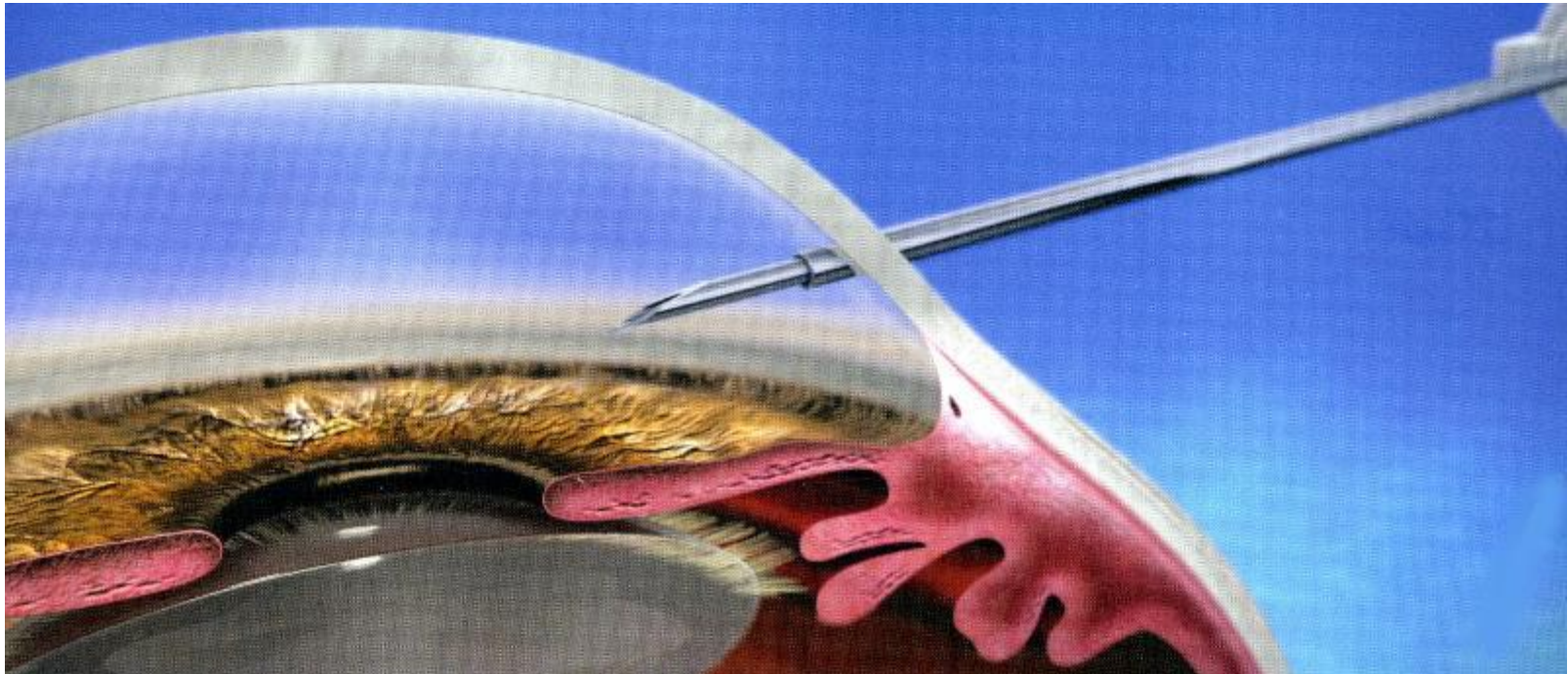


XEN

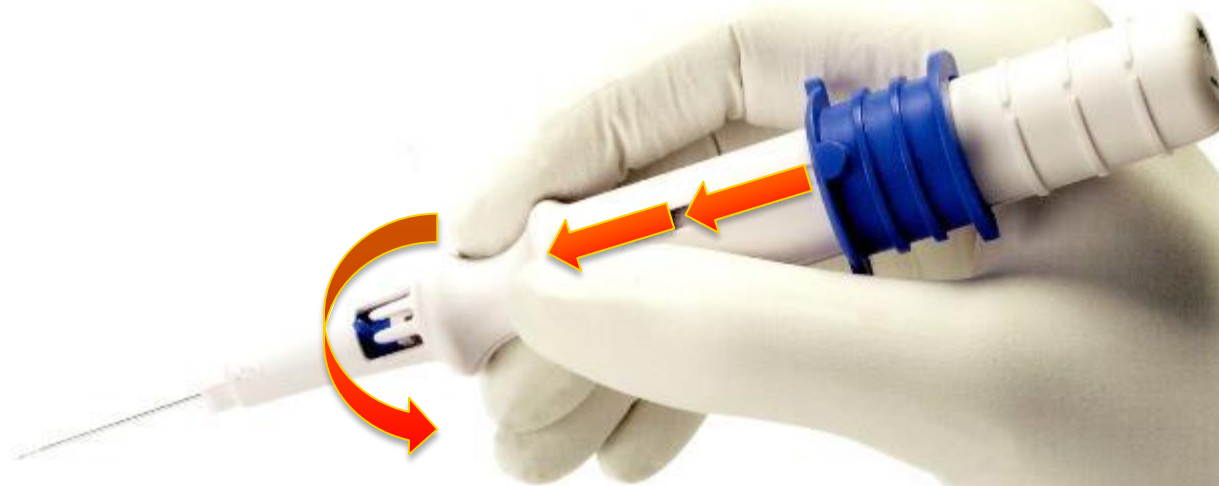
XEN Gel Stent

- *Ab interno* genom snitt i kornea 1,8 mm
- Subkonjunktival filtration
- Gelatin från gris
- <http://xengelstent.com>
- Köptes av Allergan oktober 2015
www.allergan.com

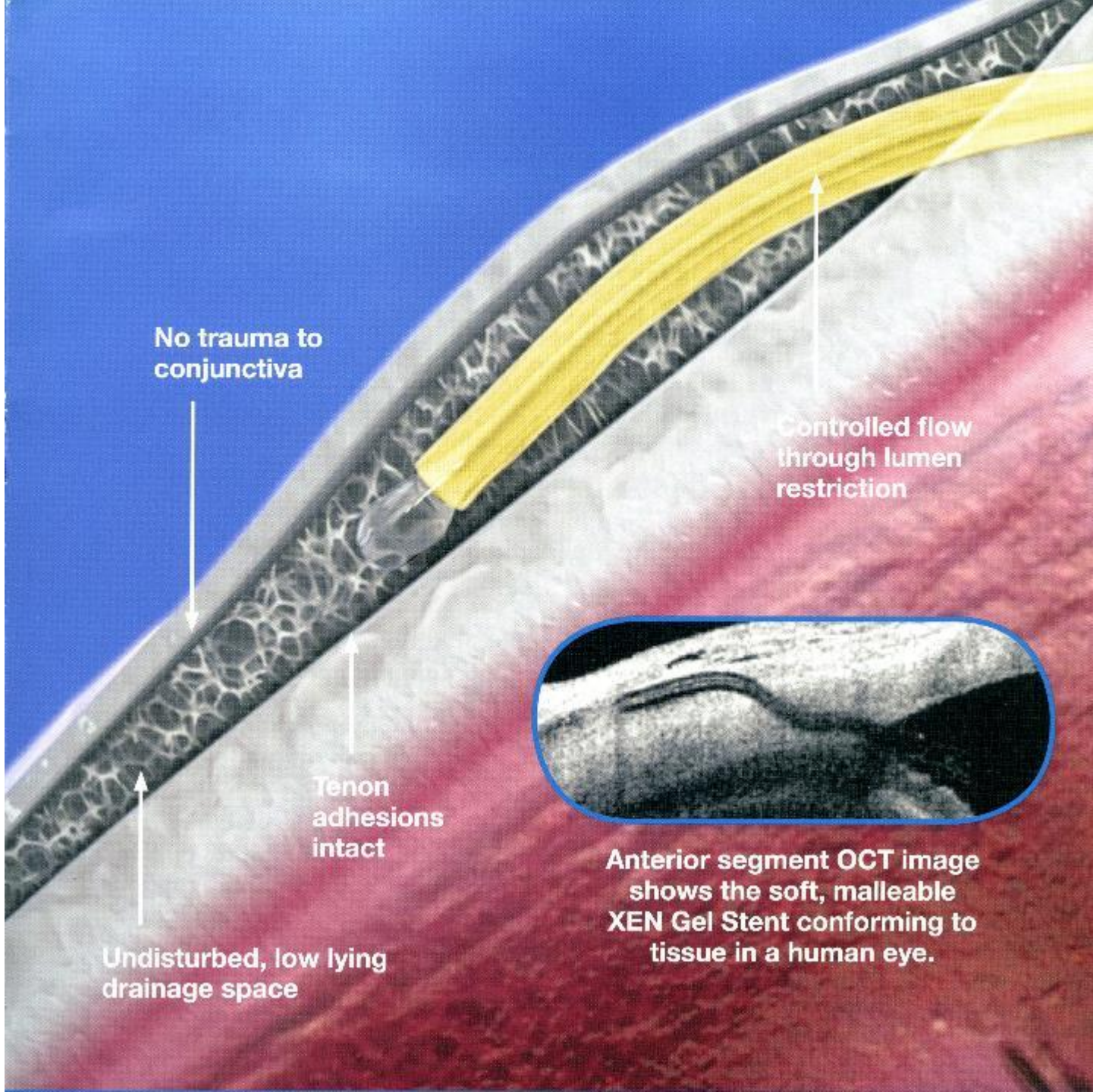








XENTM
G E L S T E N T



No trauma to conjunctiva

Controlled flow through lumen restriction

Tenon adhesions intact

Undisturbed, low lying drainage space



Anterior segment OCT image shows the soft, malleable XEN Gel Stent conforming to tissue in a human eye.

XEN Gel vs Trabekulektomi

- Ingen öppning av konjunktiva
- Ingen öppning av sklera
- Mindre täta kontroller
- Mindre påverkan på synen
- Material: 9000 kr
- Snabb: 10-20 min
- Stor öppning & sutur av konjunktiva
- Öppning & sutur av sklera
- Täta postop. kontroller
- Risk för (stor) synpåverkan
- Billigt material
- Långsam: 30-60 min



XEN Gel Stent

- Flera 10000 inlagda i Europa & Kanada
 - Hösten 2016 godkänd av FDA USA
- Två-årsdata på större material finns publicerade
- Flerårsresultat finns redovisade i abstract
- Sedan juni 2015 i Sverige; Stockholm, Mölndal, Umeå, Malmö m. fl.
- Flera studier pågår

1. Evaluation of the XEN Implant in Moderate POAG Subjects (APEX)

- Prospektiv, icke-randomiserad
- 23 sites, 9 länder
 - Austria, Belgium, England, Germany, Italy, Poland, Spain, Switzerland, Venezuela
- 215 ögon
- Två år, sista pat april 2017, pres AAO nov?
- ClinicalTrials.gov – NCT02006693

Stalmans. ICGS 2016:a1872

Patient demographics at baseline

Table adapted from Stalmans. ICGS 2016:a1872

	N=215
Age, years, mean (SD) Range	72.6 (10.4) 26.4–91.7
Ethnicity, n (%)	
Caucasian	205 (95.3)
Black	4 (1.9)
Asian	5 (2.3)
Other	1 (0.5)
Gender, n (%)	
Male	99 (46.0)
Female	116 (54.0)
Operated eye, n (%)	
OD	106 (49.3)
OS	109 (50.7)
Preoperative IOP, mmHg, mean (SD) Range	21.4 (3.9) 17–35
Preoperative medications, n, mean (SD) Range	2.6 (1.1) 0–5
Surgery type, n (%)	
Implant only procedure	111 (51.6)
Cataract combination procedure	104 (48.4)

Efficacy of XEN™: total population

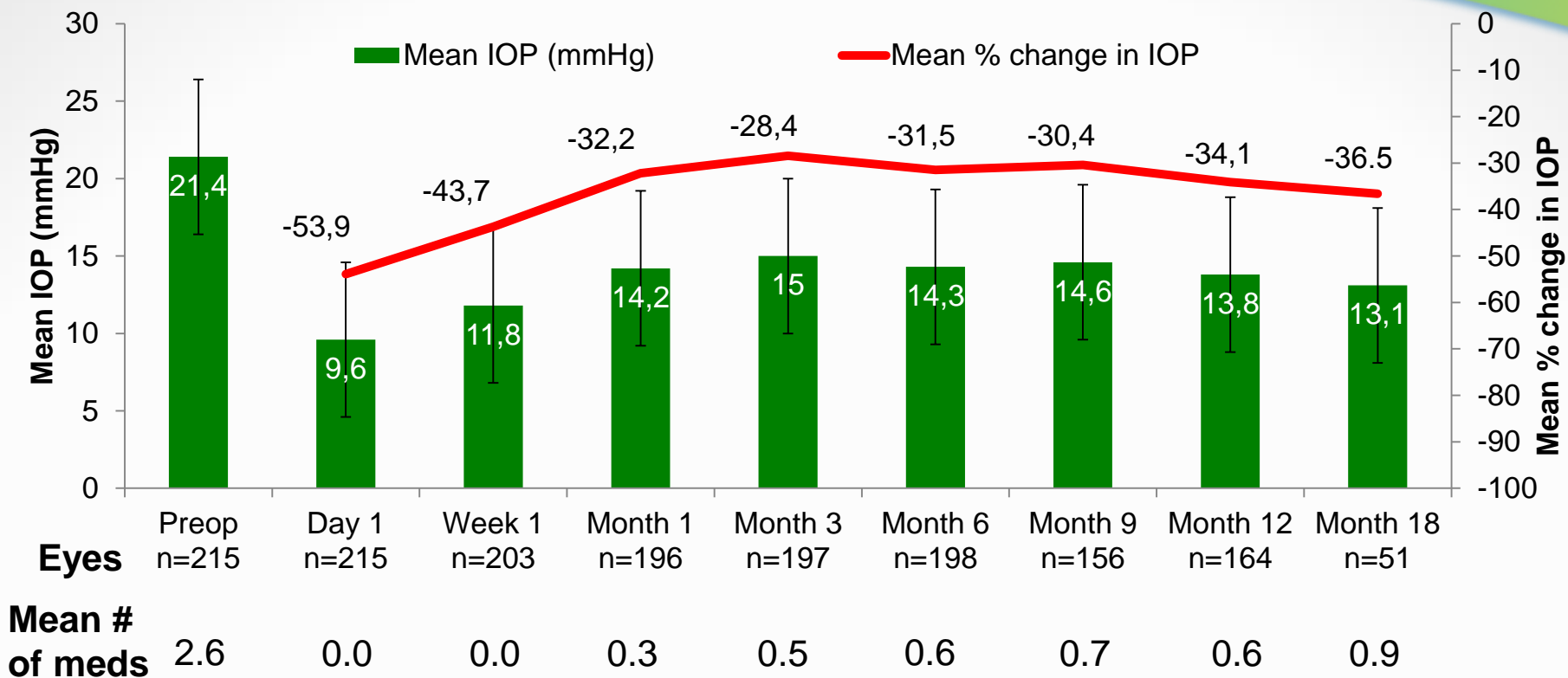


Figure adapted from Stalmans. ICGS 2016:a1872

Efficacy of XEN™ in patients who underwent implant only and those who had combined implant and phacoemulsification

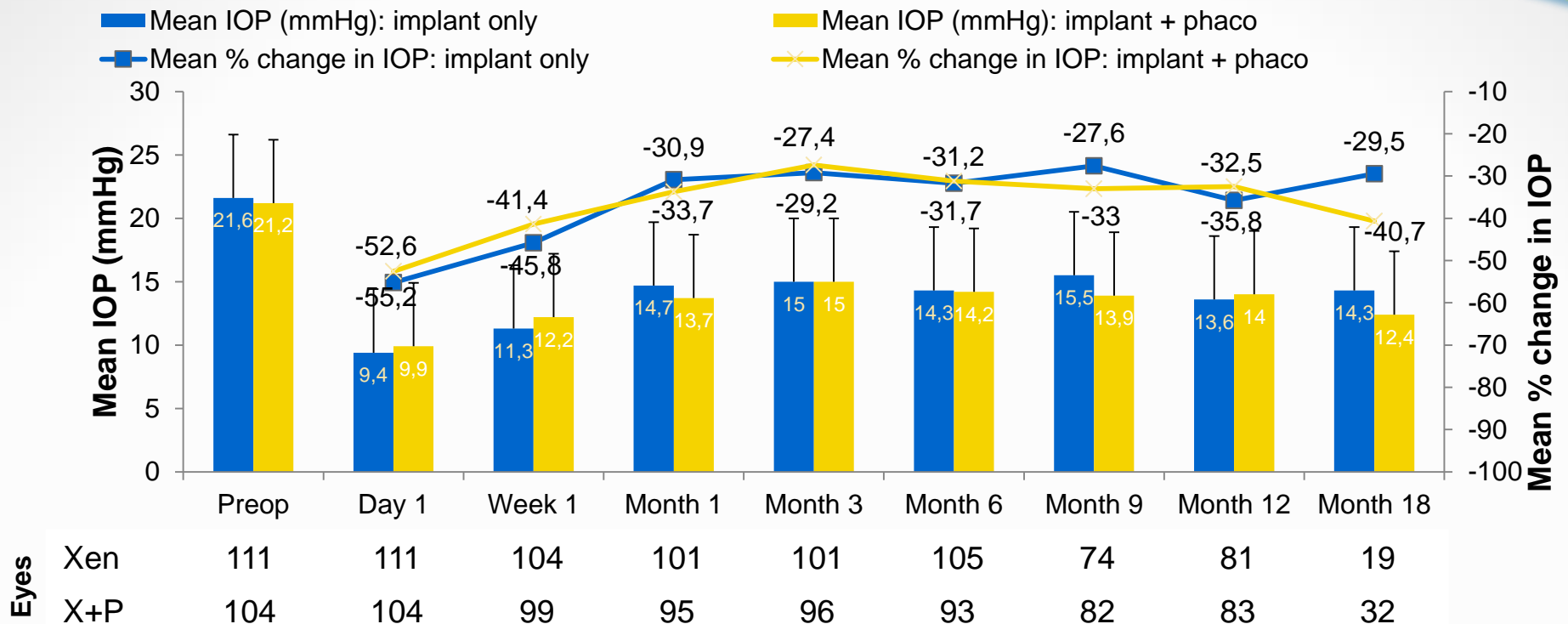


Figure adapted from Stalmans. ICGS 2016:a1872

Blå staplar = enbart XEN: IngångsIOP 21,6, 12 mån 13,6 = -8,0 mmHg. $-8,0 / 21,6 = -37,04\%$

Table 6. Adverse Events Over 1% of Population

N=240		
Operative	All (n)	All (%)
Intraoperative AC bleeding	6	2.5%
OP Total	11	4.6%
n=240		
POST-OPERATIVE	All (n)	All (%)
Choroidal effusion (self-limited, lasting <30 days)	3	1.3%
Hyphema (complaint if >30 days)*	9	3.8%
Conjunctivitis (not involving implant or bleb)	3	1.3%
Implant fracture (secondary to intervention eg: needling or repositioning)	3	1.3%
Implant blockage	4	1.7%
Converted to another procedure	6	2.5%
Secondary surgical procedure (related to XEN)	8	3.3%
Secondary surgical procedure (unrelated; ex: YAG Capsulotomy)	10	4.2%
Systemic condition (non-device related)	3	1.3%
Allergy to post-op medication	3	1.3%
POST-OP Total	76	31.7%

Table from Stalmans. ICGS 2016:a1872

- 11 self-resolved prior to the 2 week visit, 1 persisted to the 1M visit but resolved/not reported beyond that. None were reported as requiring intervention other than observation

Table 8. Needling Rate (n= 215)	
Mean and Range	%
Mean	32.1%
Range: (sites enrolling more than 5 subjects)	
Min	0.0%
Max	68.6%

Table from Stalmans. ICGS 2016:a1872

Conclusions

- Average IOP in the low teens at 12 months
- About 70% has IOP \leq 15mmHg and about 50% \leq 13mmHg at 12 months
- Over 55% medication free at 12 months
- No symptomatic hypotony or major complications

From Stalmans. ICGS 2016:a1872

2. AqueSys XEN 45 Glaucoma Implant in Refractory Glaucoma

- Prospektiv, icke-randomiserad
- Refraktära glaukom, bl.a. tidigare opererade
- 12 sites i USA
- 65 ögon (enbart XEN, ingen linskirurgi)
- 12 månader, avslutad. Accepterad f publ i AJO
- ClinicalTrials.gov – NCT02036541

From Grover. AGS 2017:P0034

Demographic/Characteristic	N=65	
Mean age (SD), y	70.0 (12.3)	
Male / Female, n (%)	30 (46.2) / 35 (53.8)	
Type of glaucoma, n (%)		
POAG	57 (87.7)	
Pseudoexfoliative	6 (9.2)	
Pigmentary	1 (1.5)	
Mixed etiology	1 (1.5)	
Had prior cataract surgery, n (%)	45 (69.2)	Apex
Had prior glaucoma procedure, n (%) ^a	55 (84.6)	0
Mean medicated IOP (SD) mmHg	25.1 (3.7)	21,4 (3,9)
Mean IOP-lowering medications, n (SD)	3.5 (1.0)	2,6 (1,1)
Total number, n (%)		
1	2 (3.1)	
2	8 (12.3)	
3	18 (27.7)	
4	28 (43.1)	
5	9 (13.8)	
Surgical eye – right/left, n (%)	31 (47.7) / 34 (52.3)	

IOP, intraocular pressure; POAG, primary open-angle glaucoma

^a 32 with incisional or cilioablative procedure and 23 without

From Grover. AGS 2017:P0034



Skånes universitetssjukhus

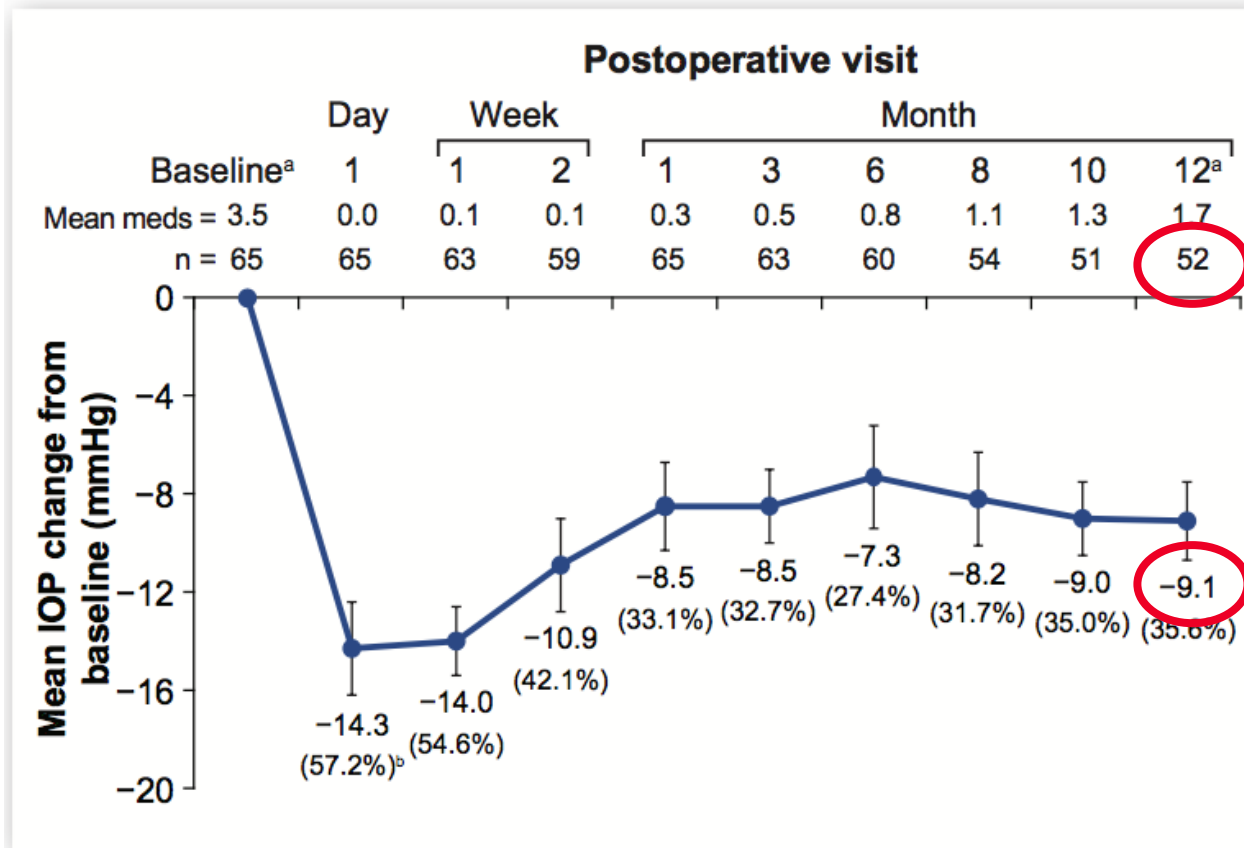
En del av Region Skåne

Resultat

- At month 12, 76.3% of patients achieved $\geq 20\%$ IOP reduction from baseline on the same or fewer medications (imputed data)
- Mean diurnal IOP reduction was 6.4 mmHg (95% CI: 4.2, 8.7)
 - $6,4/25,1=25,5\%$ (APEX 37%)

From Grover. AGS 2017:P0034

Figure 4. Mean IOP change from baseline over time, with 95% CI
Subgruppsanalys



IOP, intraocular pressure

^a Mean diurnal IOP

^b Shown in parentheses are the mean IOP percentage changes from baseline

From Grover. AGS 2017:P0034

Adverse events	n (%)
Needling	21 (32,3)
Hypotoni <6 mmHg	16 (24,6)
IOP-ökning ≥ 10 mmHg Varav 7 löstes med medicin, needling o/e FK-tap. 7 krävde reop/explantation	14 (21,5)
Bestående synnedläggning ≥ 2 rader >12 mån	4 (6,2)

Table adapted from Grover. AGS 2017:P0034

XEN Gel Implant – personliga åsikter

- Passar tidiga glaukom (men även mer avancerade glaukom)
- Har relativt få komplikationer
- Kräver postoperativa kontroller och ibland needling, oftare på tidigare opererade ögon
- Låter oss operera tidigare
 - om vi och patienten vill

XEN Kortversion

FILM

iStent

- *Ab interno*
- Trabecular bypass
- Heparincoated titan
- Begränsad erfarenhet
- Relativt kort uppföljningstid
- Två generationer i designen
- www.glaukos.com



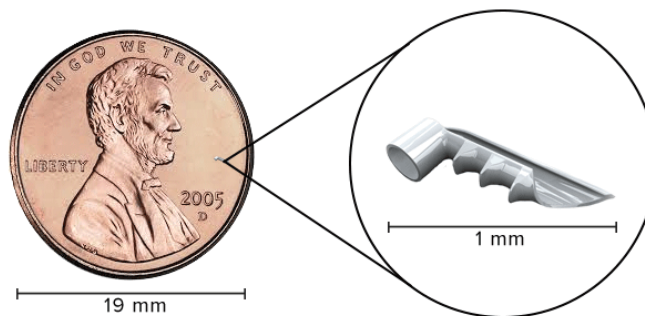
Br J Ophthalmol. 2012;96(5):645-9

iStent

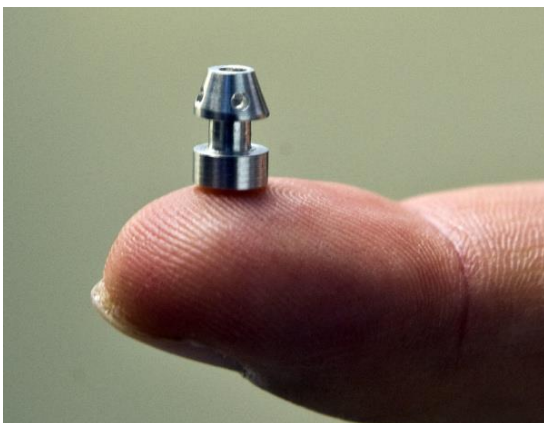
1



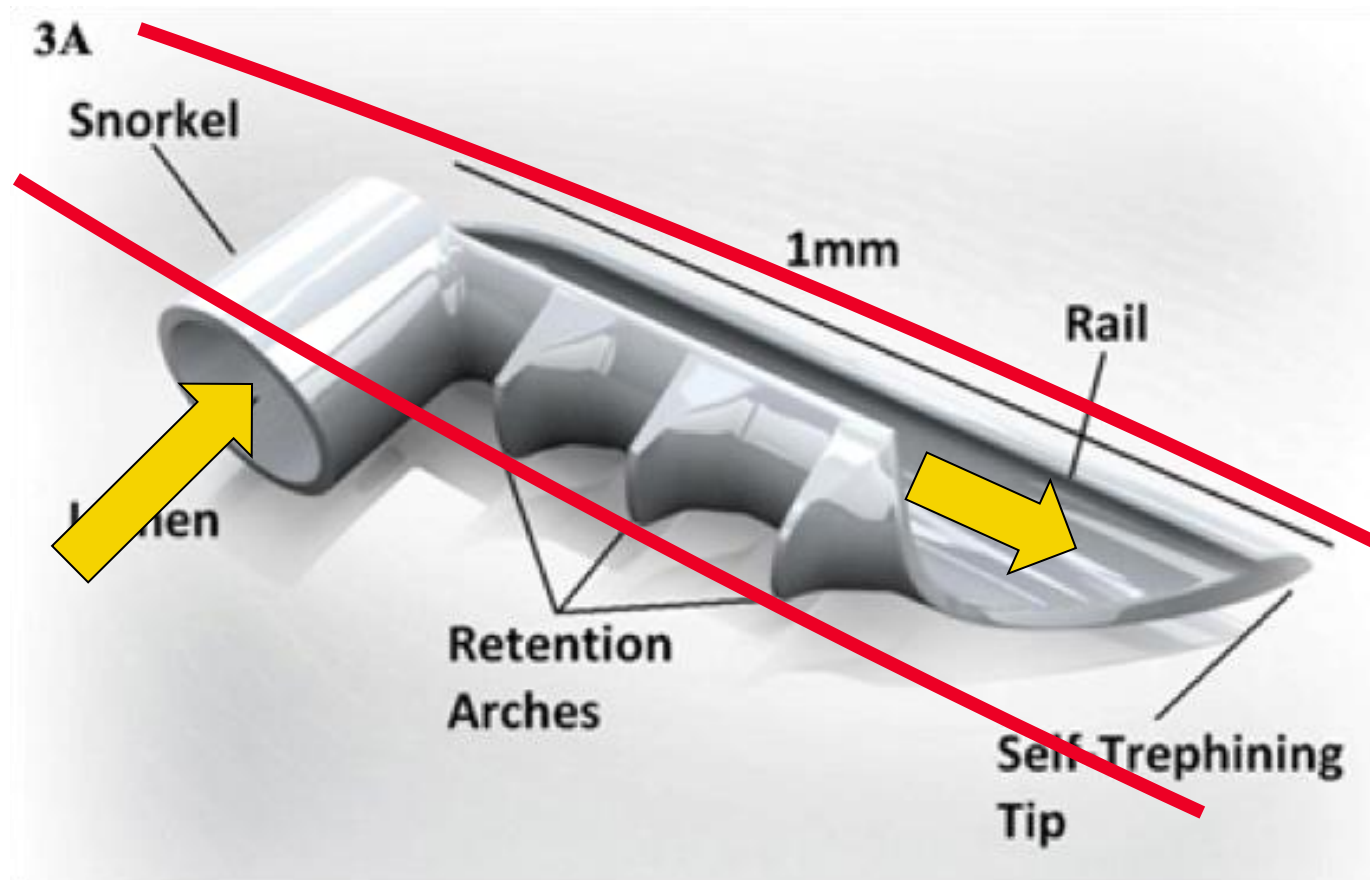
1 mm lång
60 μ g



2



iStent







Shaped Graspers

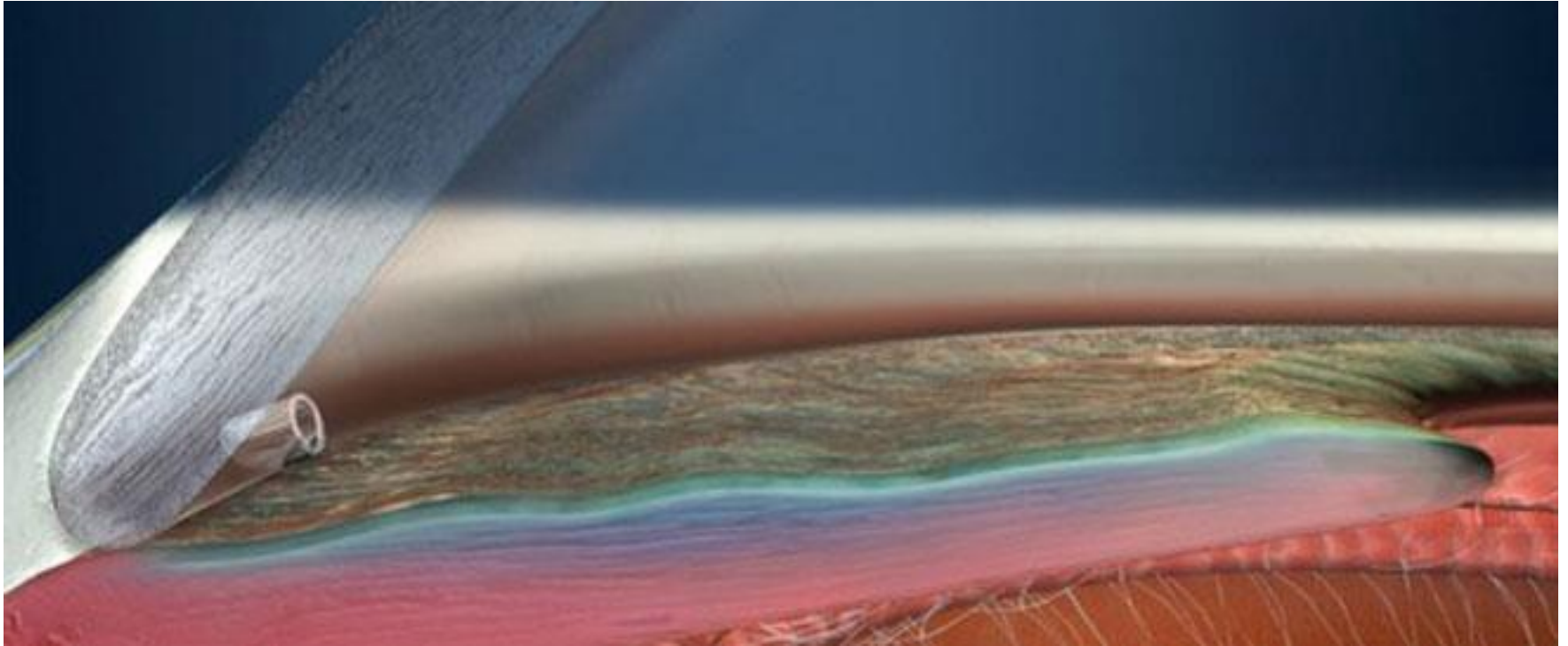
GLAUKOS

Pre-loaded Inserter

Modified Button Mechanics

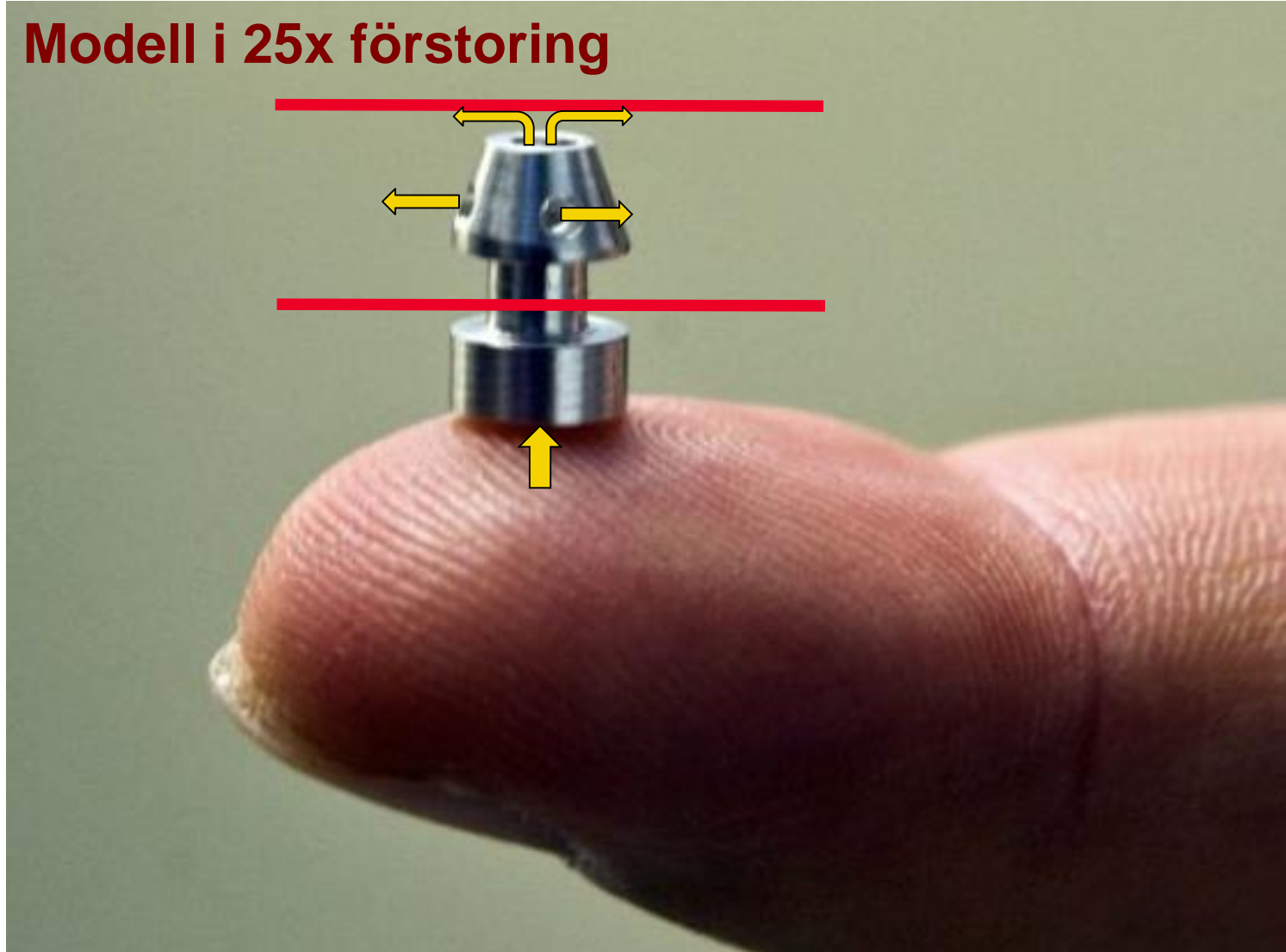


Stiffened Tapered Insertion Sleeve



iStent Inject

Modell i 25x förstoring





iStent



- Tillgänglig i Europa, Kanada och USA
 - Har exploderat i USA – kataraktkirurger!
- Hösten 2016 i Sverige
 - Kalmar, Sankt Erik, Malmö, flera?
- Vanligen i kombination med kataraktkirurgi
 - Men i Sverige tillåten singel på faka/ps-faka ögon

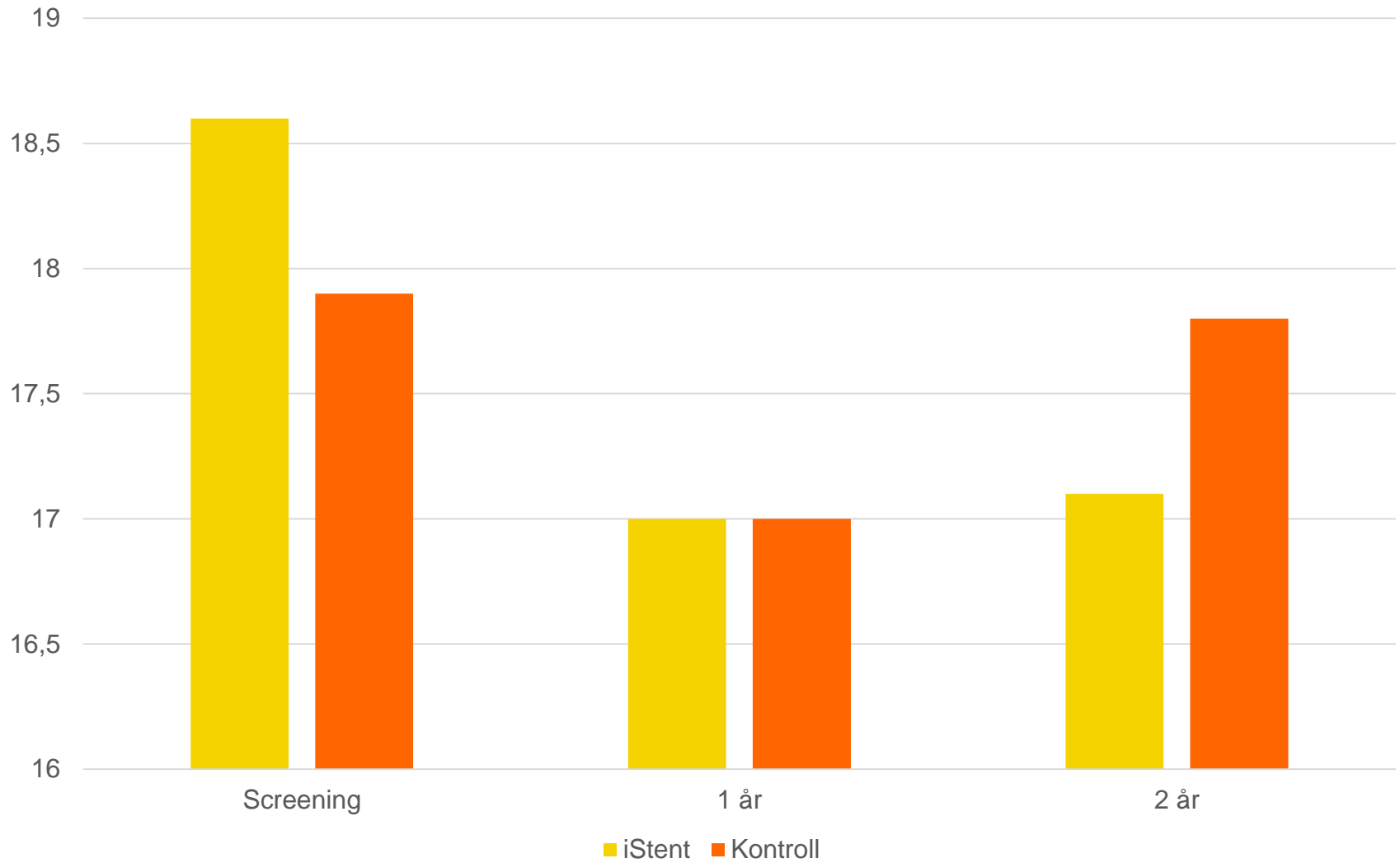


US FDA-study iStent

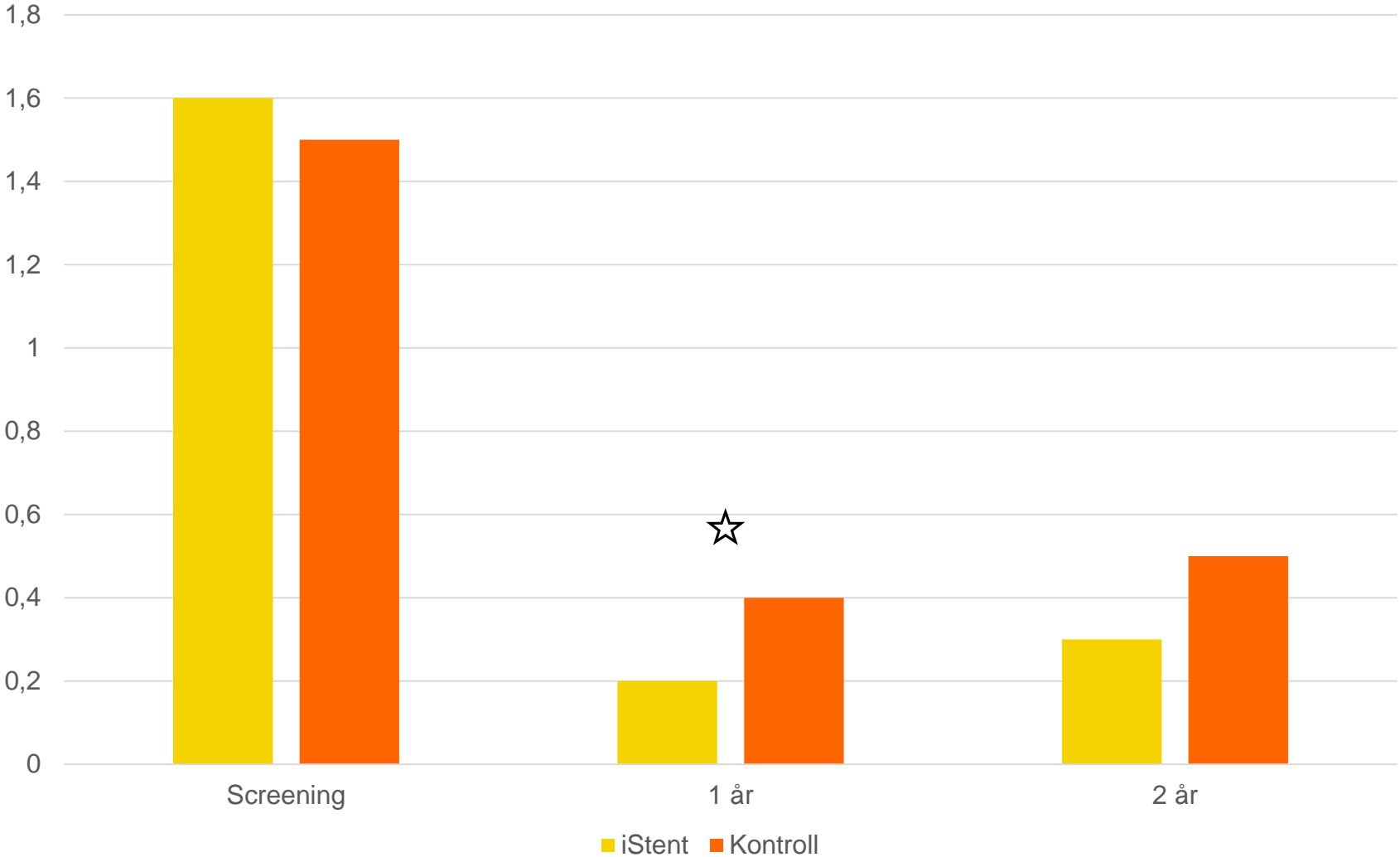
- Mild to moderate POAG inkl PEX
- Behandlat IOP ≤ 21 mmHg på 1-3 mediciner
 - Wash-out, obeh IOP 22-36 mmHg
- 240 ögon (239 pat)
 - 117 katop + iStent
 - 123 katop enbart
- FU 2 år

J Cataract Refract Surg 2012; 38:1339–1345

IOP



Mediciner



iStent

FILM

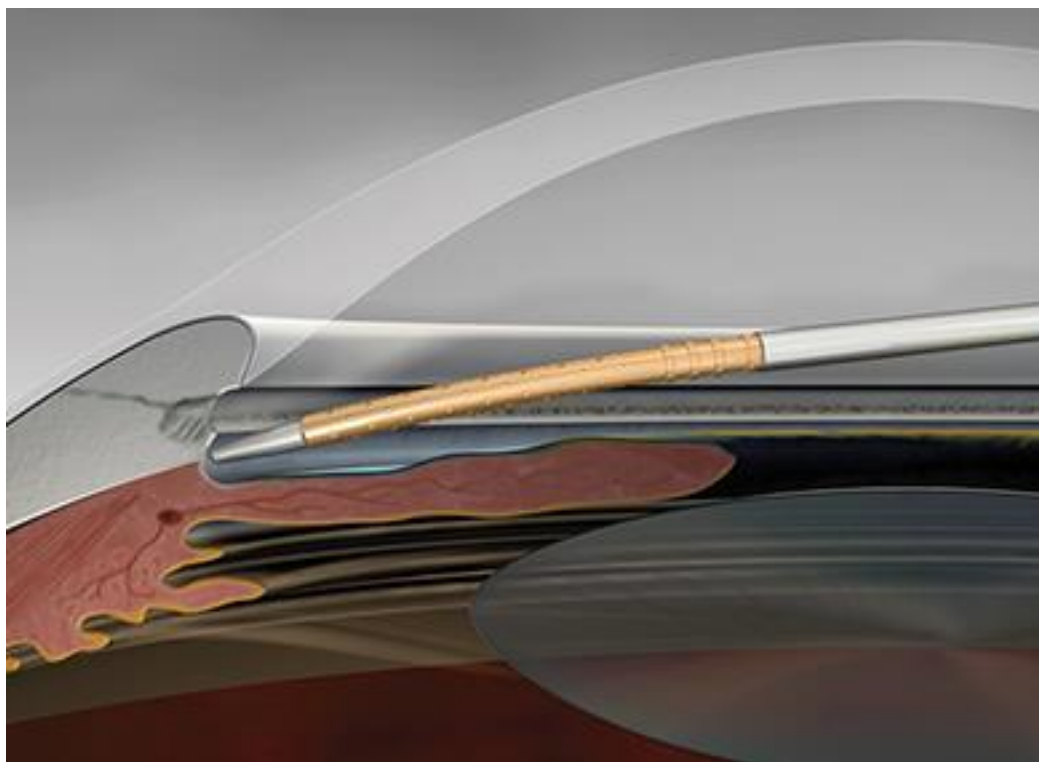
iStent inject

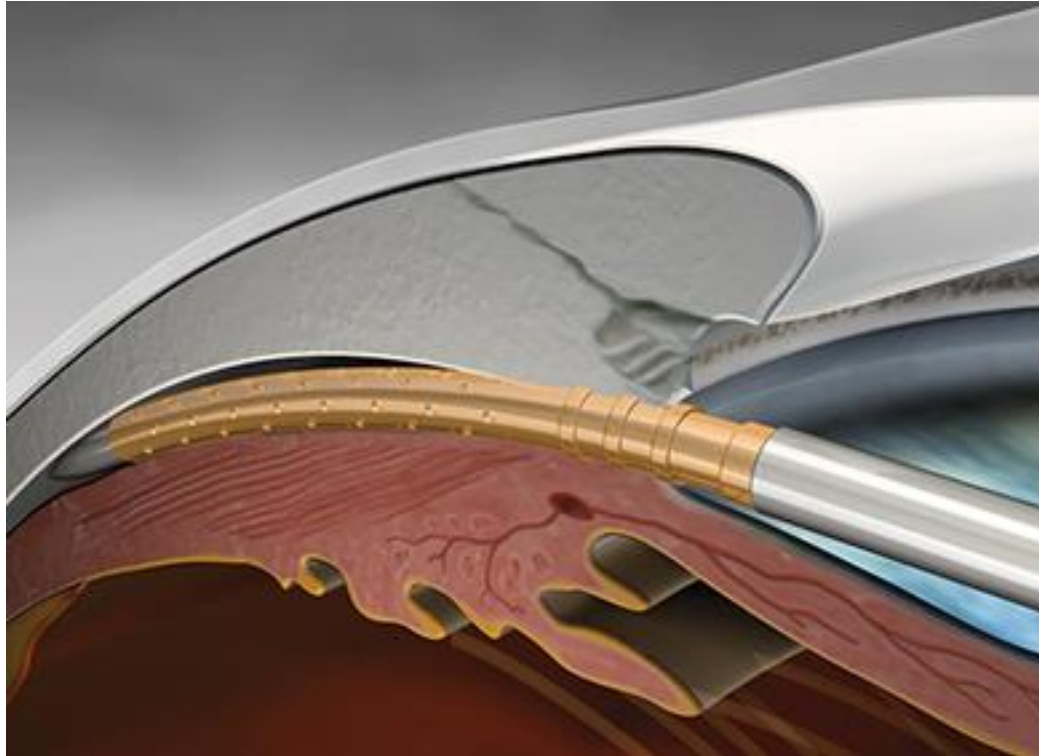
FILM

CyPass Micro-Stent

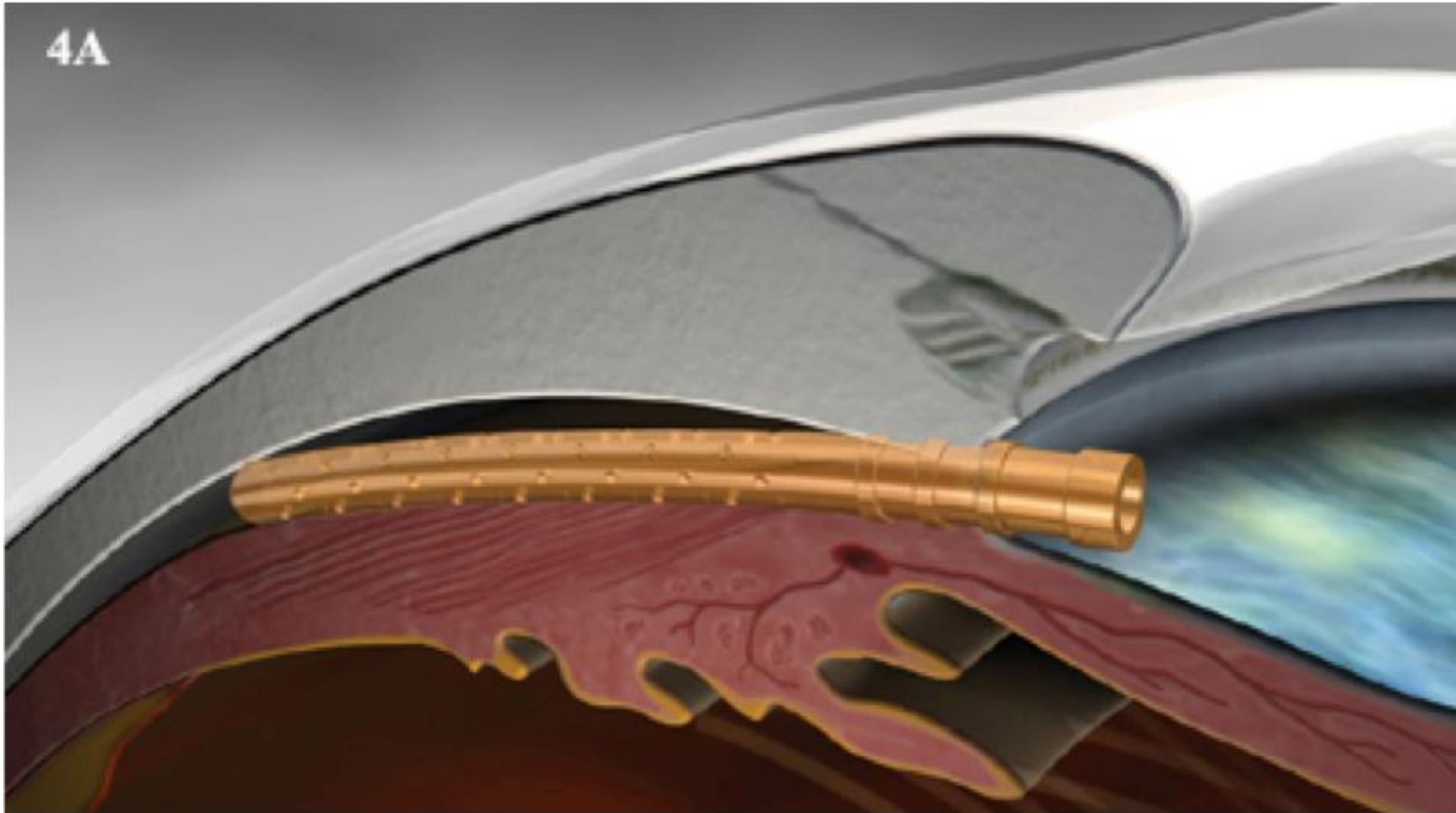
- *Ab interno*
- Ut i suprachoroidala rummet
- Uppköpt av Alcon www.alcon.com
- www.myalconstore.com/glaucoma-surgery/cypass-micro-stent/







4A



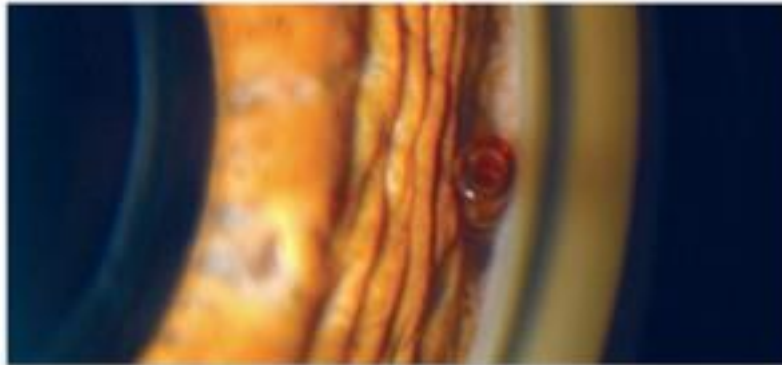
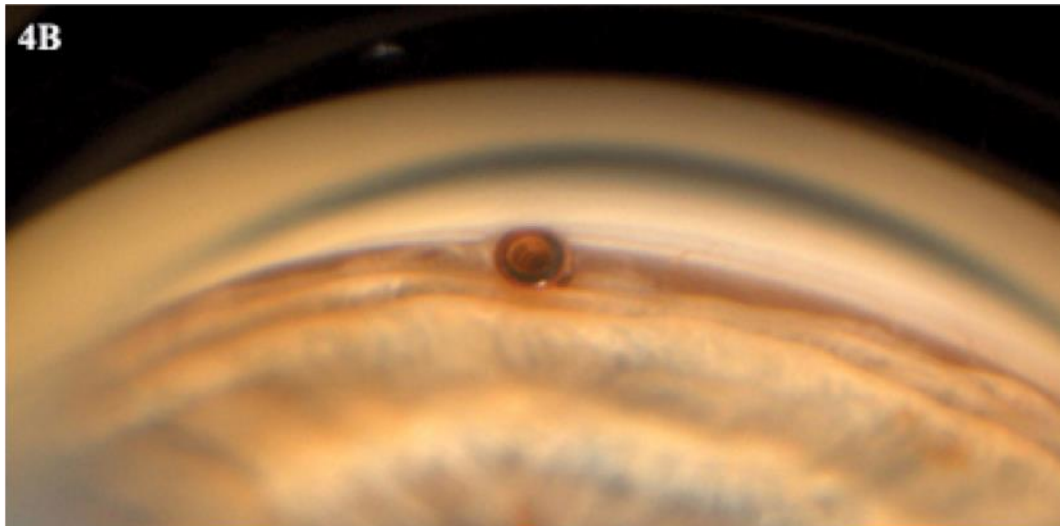


FIGURE 3 CyPass® Micro-Stent. The stent is inserted just below the scleral spur so that the distal end is resting in the supraciliary space, and the proximal end is visible in the anterior chamber. (Image courtesy of Matt Poe, COA.)



CyPass Micro-Stent

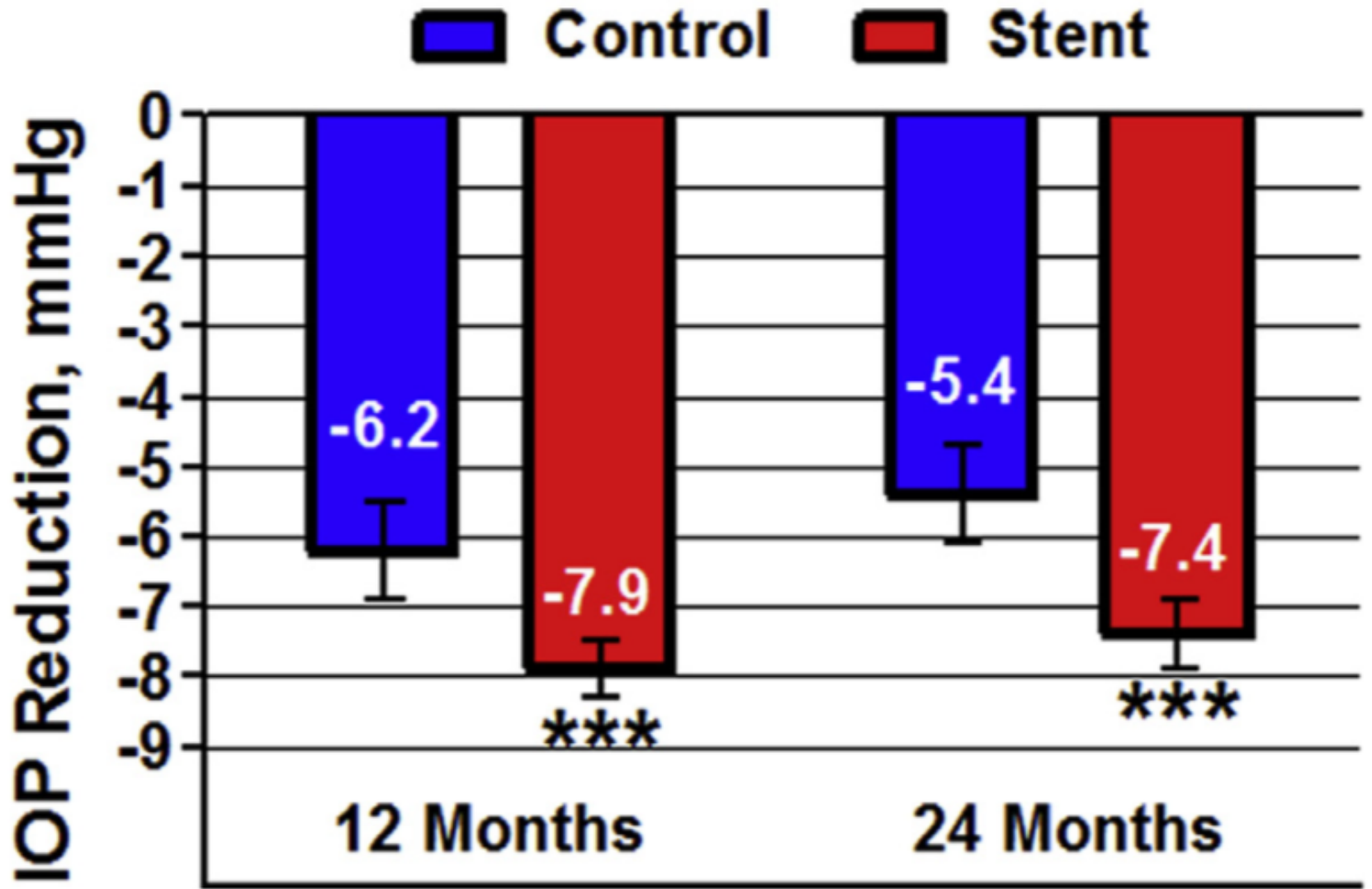
- >1000 ögon
- Godkänd i USA augusti 2016
- USA RCT COMPASS, klar 2015
- Europa/Sverige 2017-18

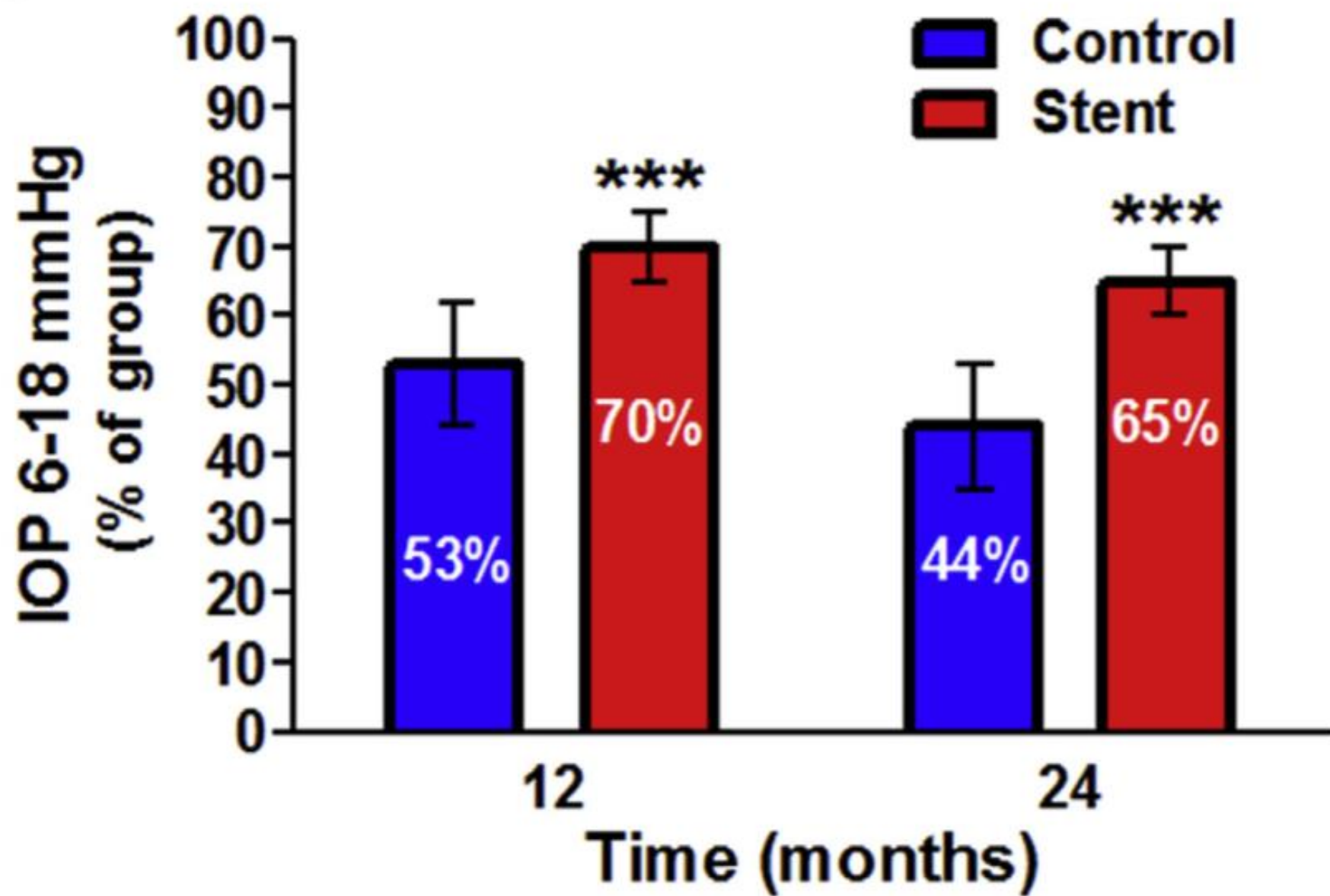
Ophthalmology 2016;123:2103- 2112

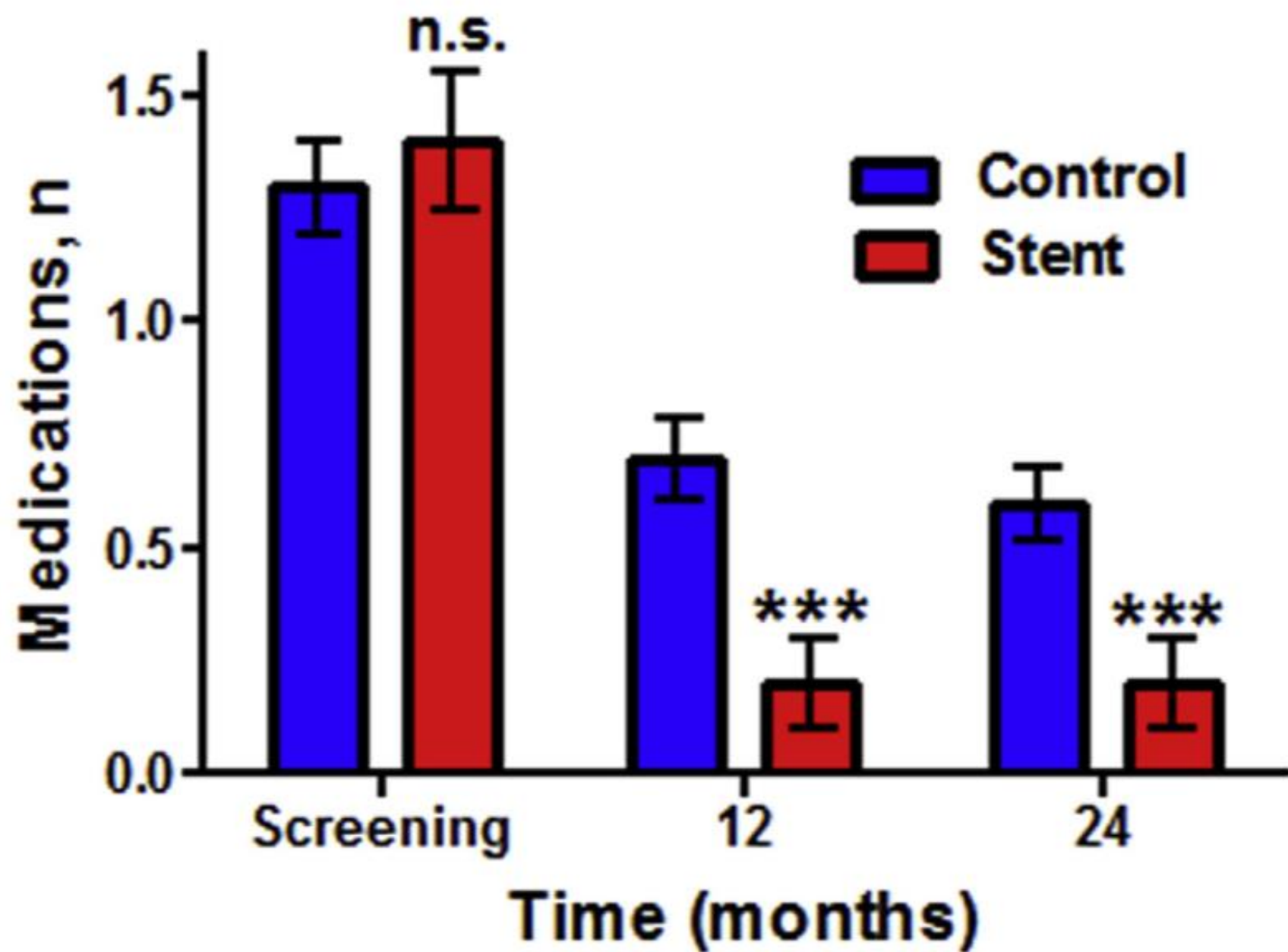
COMPASS

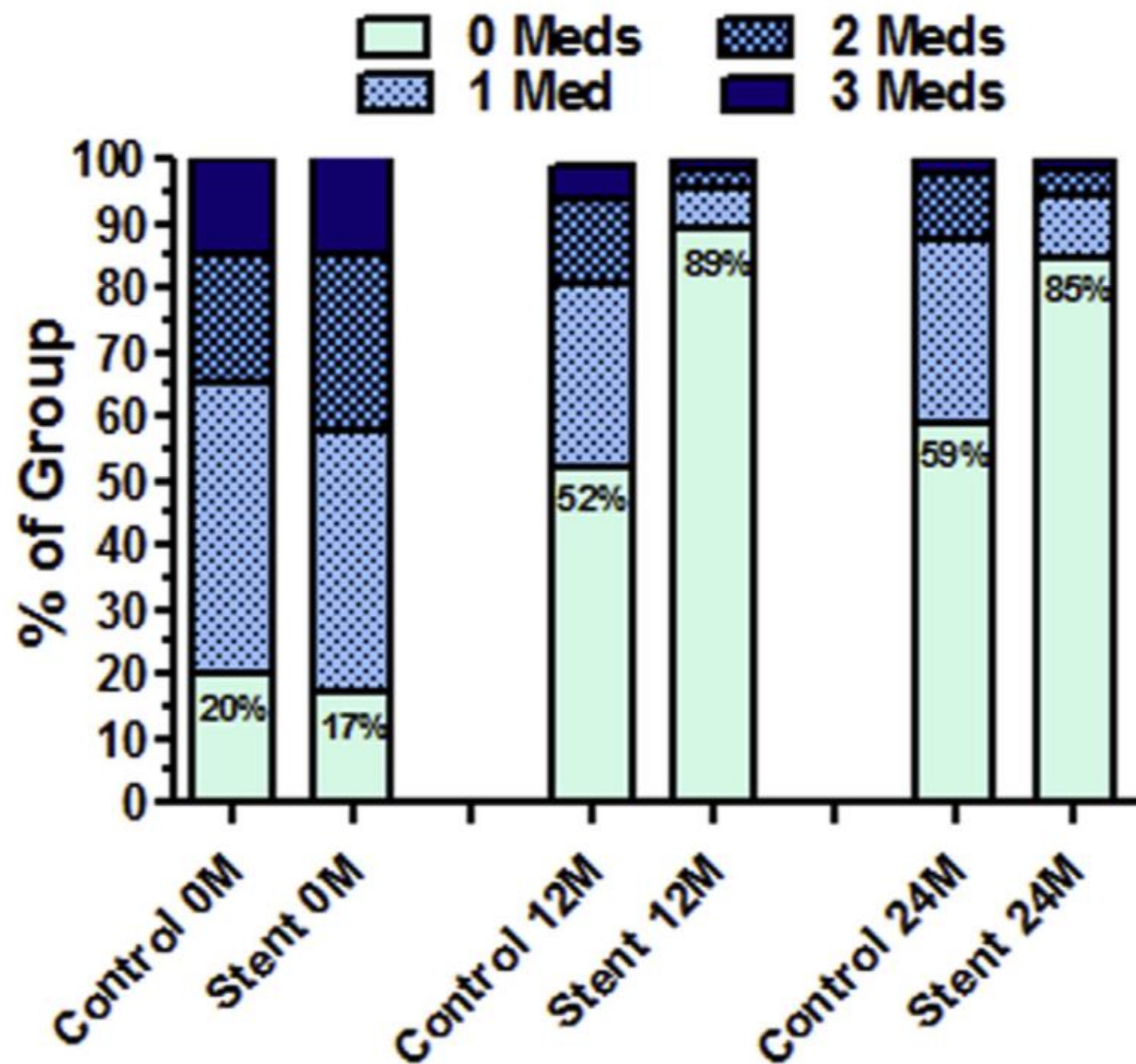
- Interventional randomized clinical trial
- POAG med katarakt (inga PEX)
- Obeh IOP 21-33 mmHg
 - 505 random
 - 374 katop + CyPass
 - 131 enbart katop
- FU 2 år

B



C

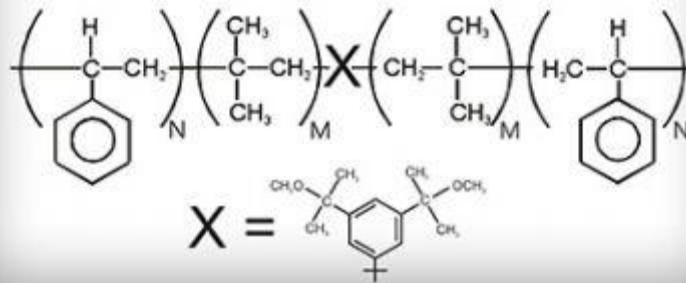
A

B

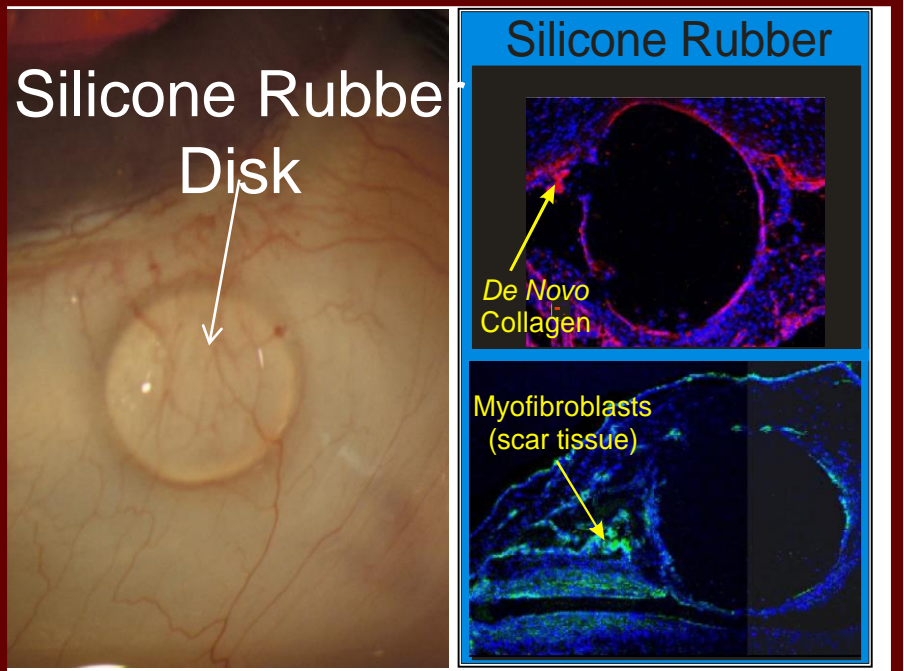
InnFocus Microshunt

- *Ab externo*
- Subkonjunktival filtration
- SIBS
- Som en traditionell shunt utan platta
- <http://innfocusinc.com/>
 - Juli 2016 köpt av Santen

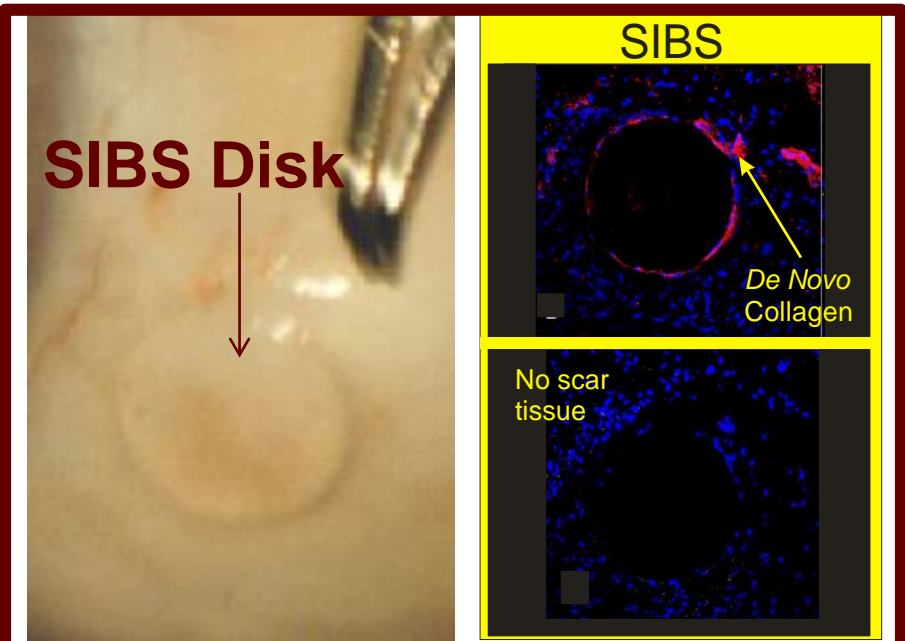
Poly(styrene-block-isobutylene-block-styrene)
"SIBS"



SIBS and silicone rubber implanted sub-Tenon's - 2 month Rabbit Studies at the Bascom Palmer Eye Institute

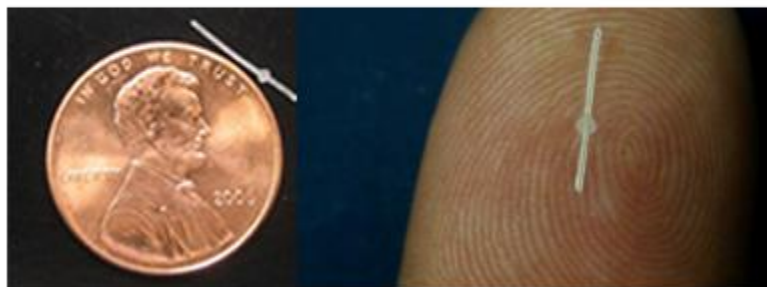
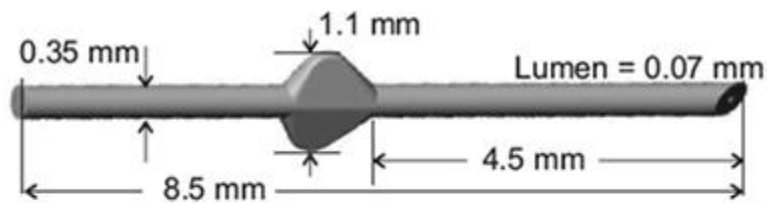
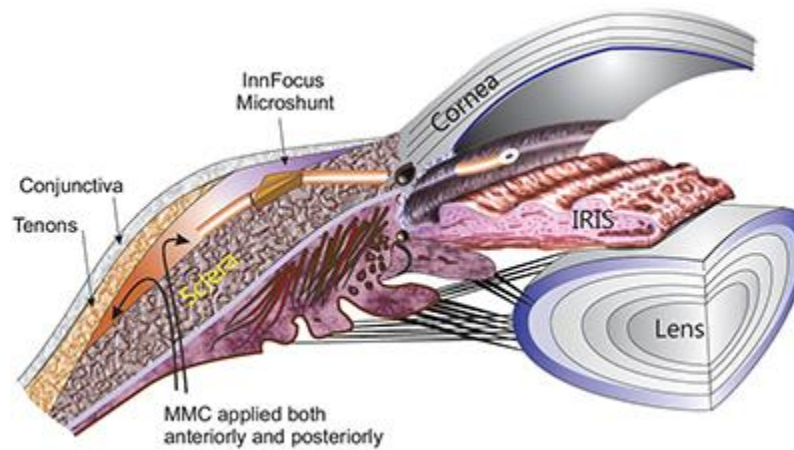


Silicone Rubber provokes neovascularization and pseudocapsule formation



SIBS does not provoke neovascularization and pseudo capsule formation
No Myofibroblasts

Courtesy: Edgar Espana, MD & A Carolina Acosta, MD

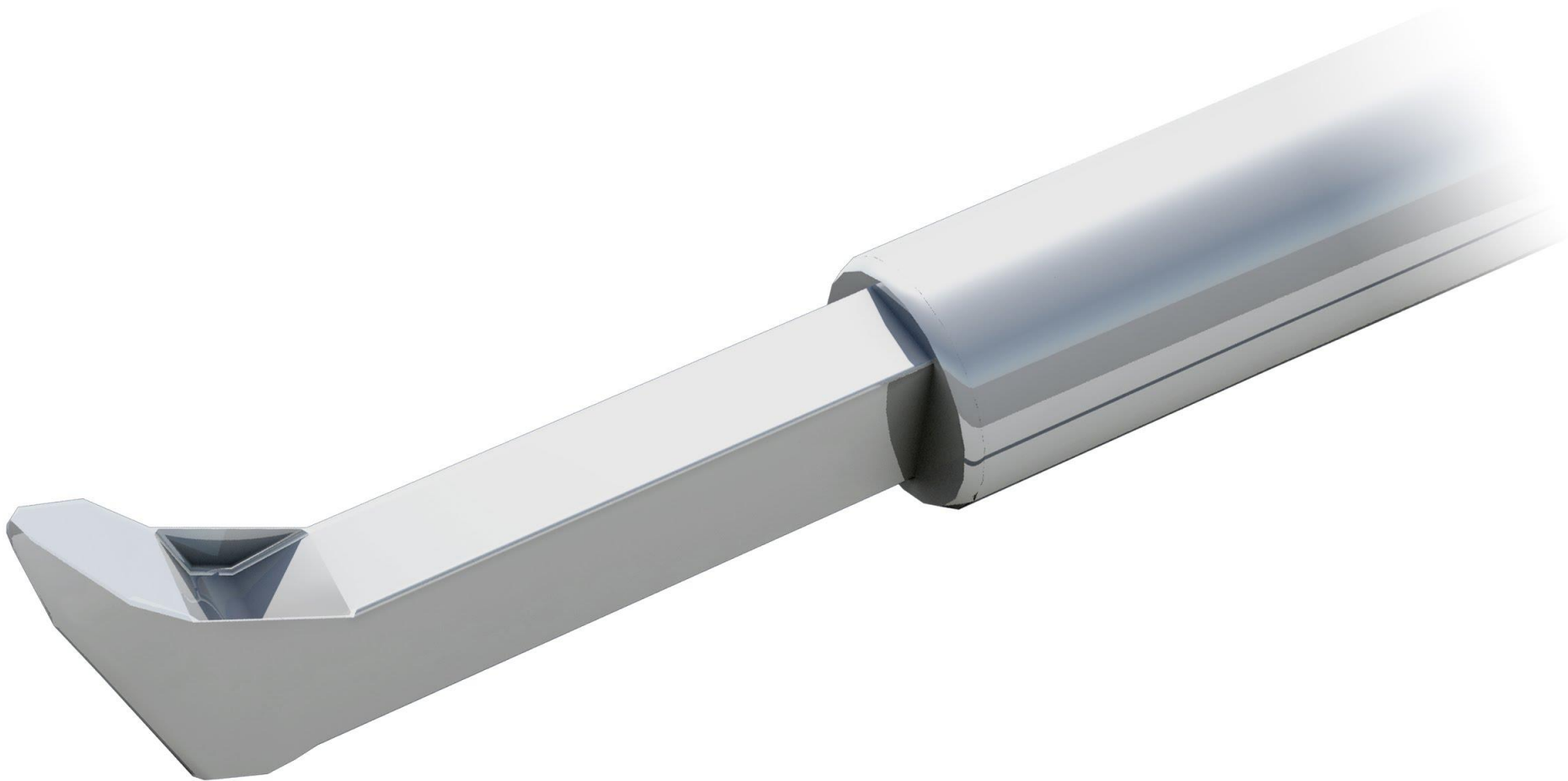


InnFocus Microshunt

- Lanseras i Sverige nästa år?
- Inte riktig MIGS
 - Konjunktiva öppnas

Kahook Dual Blade (KDB)





KDB

- Tillgänglig i bl.a. Sverige
- Uddevalla, Stockholm, fler?



Tack från
Malmö



och
Lund