

InnFocus MicroShunt®



InnFocus MicroShunt[®] differentiation

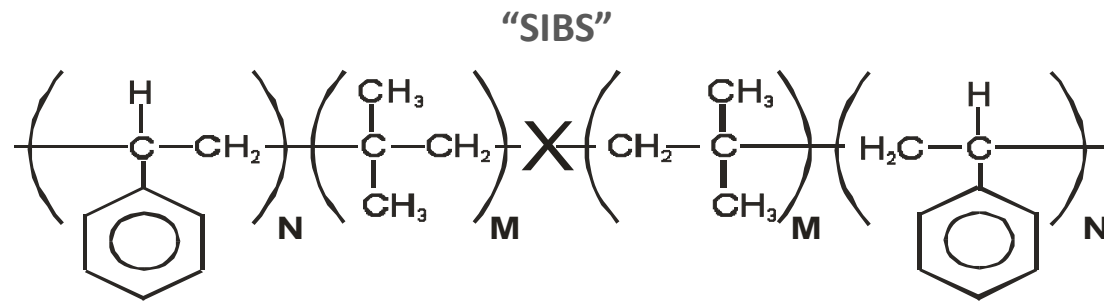
- The MicroShunt[®] is the first and only surgical device/procedure to provide treatment for mild-, moderate-, and severe-stage standalone POAG
 - No requirement to remove the cataract (but this can be done)
 - Standalone procedure allows treatment of the largest population of patients with POAG
 - Clinical outcomes meet AGIS¹ objective (IOP <15 mmHg)
- It is the only device undergoing FDA randomized clinical study vs trabeculectomy
- The intellectual property of the MicroShunt[®] is protected

AGIS, Advanced Glaucoma Intervention Study; FDA, Food and Drug Administration; IOP, intraocular pressure; POAG, primary open-angle glaucoma

1. Ederer F et al. *Control Clin Trials*. 1994;15(4):299–325

The SIBS material

Poly(styrene-*block*-isobutylene-*block*-styrene)



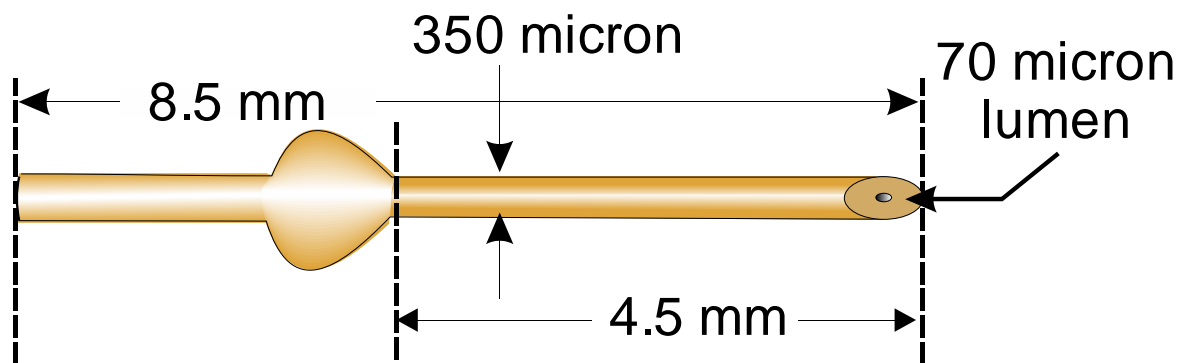
- There is current, real-world experience with SIBS
 - SIBS has been used for over 15 years in >1 million patients as a cardiac-stent coating (TAXUS®)¹
 - It has also been used as an investigational product for over 8 years in the eye²
- SIBS is a stretchy biomaterial that will not provoke scar tissue formation in the eye³
- SIBS has proven biocompatibility⁴
- SIBS is an ultra-stable material and will not degrade in the body⁵
 - No degradation means no chronic inflammation and minimal scarring⁶

SIBS, poly(styrene-*block*-isobutylene-*block*-styrene)

1. Silber S et al. *Circulation*. 2009;120(15):1498–1504; 2. InnFocus data on file; 3. Acosta AC et al. *Arch Ophthalmol*. 2006;124(12):1742–1749;
4. Pinchuk L et al. *Biomaterials* 2008;29(4):448–460; 5. Strickler F et al. *J Biomed Mater Res A*. 2010;92(2):773–782;
6. Pinchuk L et al. *J Biomed Mater Res A*. 2017;105(1):211–221

MicroShunt[®] design

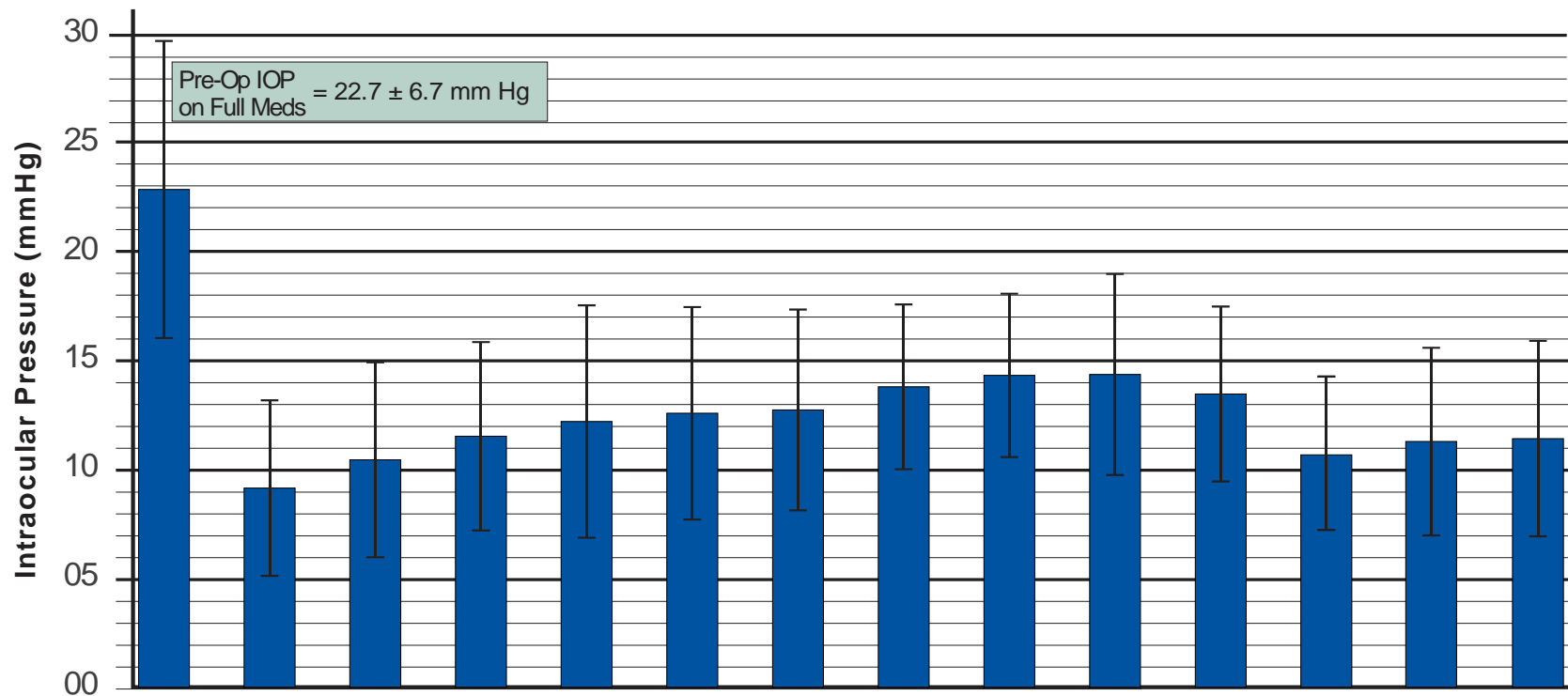
- Soft to conform to the curvature of the eye
- Lumen sufficiently large to allow cells to pass; yet, small and long enough to prevent hypotony¹
- Fin to prevent migration and leakage around the outside of the tube²



Benefits to the glaucoma surgeon

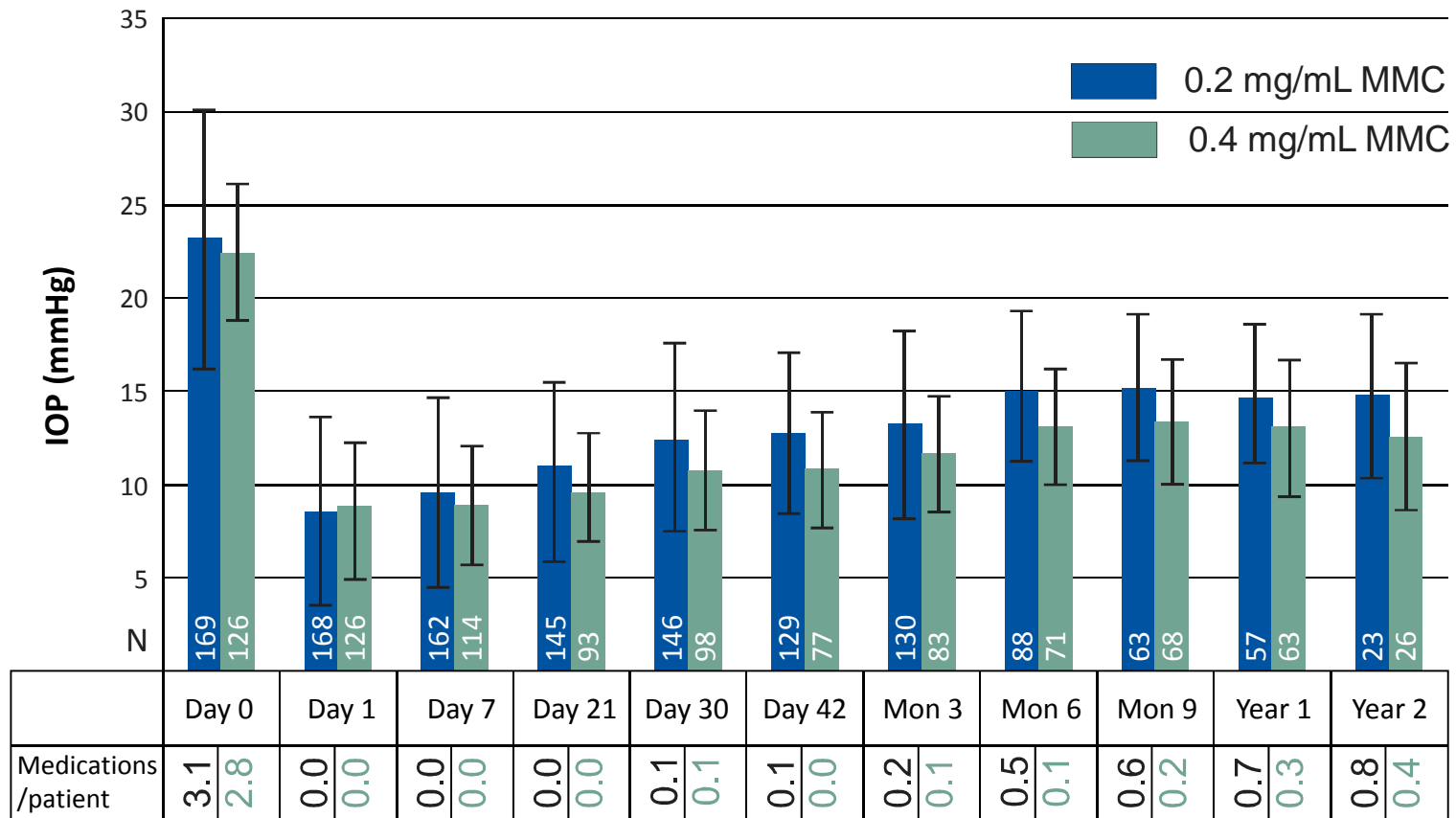
- Potential replacement product for trabeculectomy and tubes
 - Advantage in safety and operating time
- Potential advantage in post-operative patient follow up compared with trabeculectomy
- A potential replacement for some laser procedures that only deliver temporary relief¹
- May reduce or remove the need for patients to administer multiple eye drops sooner compared with other procedures²
- A procedure that may halt the progression of the patient towards blindness^{2,3}

Change in mean IOP over time



Time	Pre-Op	Day-1	Week-1	Week-3	Week-4	Week-6	Month-3	Month-6	Month-9	Year-1	Year-2	Year-3	Year-4	Year-5
N	373	302	341	281	299	240	270	242	142	148	51	22	21	20
IOP %Rdctn	n/a	61	60	54	48	46	44	39	37	36	40	53	51	50
Meds/Pt	3.0±1.3	0	0.1±0.4	0	0.1±0.5	0.1±0.5	0.2±0.6	0.4±0.9	0.4±0.9	0.5±1.0	0.6±1.0	0.9±1.4	1.1±1.7	0.8±1.4
%Off Meds	9	99	98	98	93	96	90	82	79	75	68	64	65	61
%< 5 mmHg	n/a	15.	7.8	3.6	2.1	0.8	1.2	0	0	0	2.0	0	5.0	0
Failures	n/a	0	0	0	1	0	1	3	2	8	4	1	0	1
Kaplan/Meier	100	100	100	100	99.7	99.5	99.2	98.4	97.9	95.7	94.6	94.4	94.4	94.1

Mean change in IOP over time by Mitomycin C dose

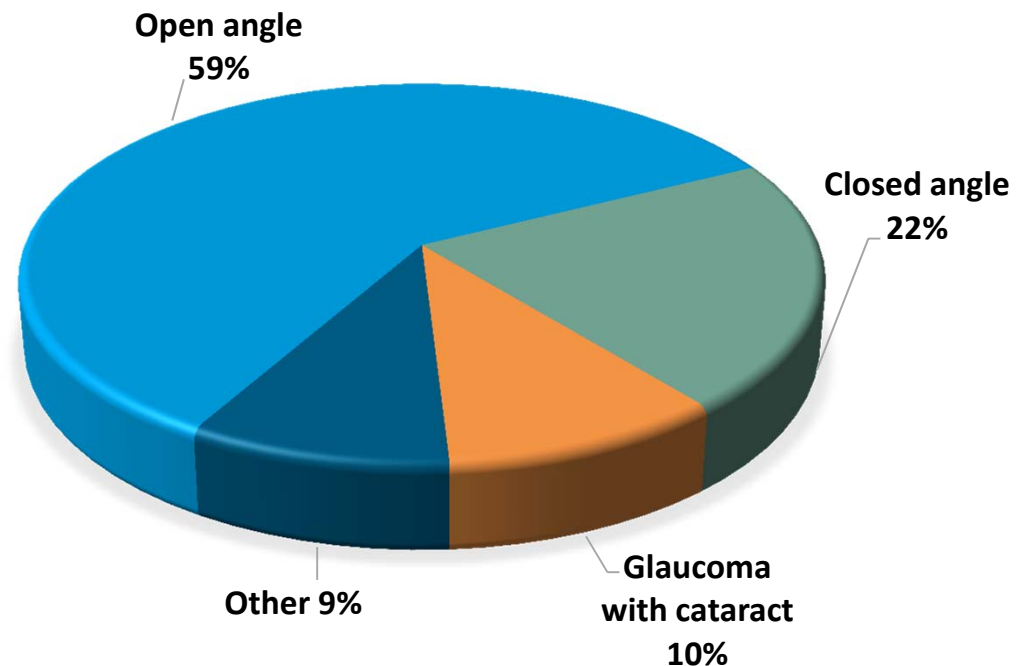


Higher MMC concentration results in lower IOP and fewer medications/patient (P <0.05 from Day 21 to Year 1)

US glaucoma surgical market

- InnFocus have focused on the total glaucoma surgical market
 - Competitors¹ have mainly focused only on niche cataract with glaucoma (~10%)
- US potential procedure market was estimated to be 7 million USD in 2014²
- Projected >40% CAGR for glaucoma surgical procedures from 2015 to 2020²
 - This represents the largest growth opportunity in ophthalmology

Glaucoma surgical procedure market²



InnFocus provides 5 times the market opportunity vs the competitors

CAGR, compound annual growth rate; USD, United States dollars

1. Glaukos, Transcend, Ivantis; 2. Market Scope 2014

MicroShunt[®] competitive advantage

- Bio-inert material with real world use
 - SIBS material is ultra-stable; no evidence of degradation¹
 - >1 million in-patient device implants (TAXUS[®] Stent)²
 - Over 15 years in-human use – 8 years in eyes
 - Dr. Paul Palmberg³ – “The eye doesn’t know this material is in the eye”
- Design shown to prevent chronic hypotony^{4,5}
 - Outer diameter (350 μ m), lumen diameter (70 μ m), length (8.5 mm)



SIBS, poly(styrene-*block*-isobutylene-*block*-styrene)

1. Strickler F et al. *J Biomed Mater Res A*. 2010;92(2):773–782; 2. Silber S et al. *Circulation*. 2009;120(15):1498–1504;

3. University of Miami, Miller School of Medicine, Bascom Palmer Eye Institute, Miami, FL;

4. Arrieta EA et al. *Ophthalmic Surg Lasers Imaging*. 2011;42(4):338–345; 5. Batlle JF et al. *J Glaucoma*. 2016;25(2):e58–65

InnFocus MicroShunt[®] summary

- Standalone procedure allows access to largest patient population
- First and only surgical device/procedure to provide treatment for mild-, moderate-, and severe-stage standalone POAG
- Clinical data shows IOP lowering capabilities with acceptable safety and tolerability profile
- MicroShunt[®] is the only device undergoing FDA randomized clinical study vs trabeculectomy
- Unique patented material as a glaucoma product with long-term material biocompatibility



THANK YOU



Santen