Pivotal Trials for FDA Approved Micro-Invasive Glaucoma Surgery*

Study	Year	Journal	FDA	Study Design	No. of Eyes	Follow-up (yrs)	IOP≤ 21 mm Hg no meds	↓IOP 20% no meds	Postop Mean # meds	Mean IOP reduction (mm Hg)	Conclusions
Samuelson, iStent Study Group (2)	2011	Ophthalmology	PMA	RCT	111/122	1 yr. (233)	72%/50% (p<0.001)	66%/48% (p=0.003)	0.2/0.4 (p=0.011)	8.4/8.2 (p=NS)	Pressure reduction on fewer medications was clinically and statistically significantly better 1 year after stent plus cataract surgery versus cataract surgery alone, with an overall safety profile similar to that of cataract surgery alone.
Craven, iStent Study Group 2 yr. follow-up (3)	2012	J Cataract Refract Surg	PMA	RCT	98/101	2yr. (199)	61%/50% (p=0.036)	53%/44% (p=0.09)	0.3/0.5 (p=NS)	8.4/7.5 (p=NS)	Patients with combined single trabecular micro-bypass stent and cataract surgery had significantly better IOP control on no medication through 24 months than patients having cataract surgery alone. Both groups had a similar favorable long-term safety profile.
Vold, COMPASS Cypass Study Group (4)	2016	Ophthalmology	PMA	RCT	374/131	2yr. (480)		77%/60% (p=0.001)	0.2/0.6 (p<0.001)	7.4/5.3 (p<0.001)	This RCT demonstrated safe and sustained 2-year reduction in IOP and glaucoma medication.
Grover (17)	2017	Am J Ophthalmology	510K	prospective, multicenter, single-arm, open label	65 (stent alone)	1 yr. (61)		75.4% (95% CI: 62.7%, 85.5%) on fewer or same meds	1.7 (excludes nonresponders (9) and patients with missing data (4))	6.2 (95% CI: -8.5, -3.9)	The gelatin stent reduced IOP and medication use without raising unexpected safety concerns, offering a minimally invasive surgical option for refractory glaucoma patients.
Samuelson, HORIZON Investigators (24)	2018	Ophthalmology	PMA	RCT	369/187	2 yr. (528)	78%/48% (p<0.001)	77%/58% (p<0.001)	0.3/0.7 (p<0.001)	7.6/5.3 (p<0.001)	This 24-month multicenter randomized controlled trial demonstrated superior reduction in MDIOP and medication use among subjects with mild-to-moderate POAG who received a Schlemm canal microstent combined with phacoemulsification compared with phacoemulsification alone.

*all results are depicted in the format (study group/control group)