MICROSTENTS IN GLAUCOMA

Dr. Parul Ichhpujani, Dr. Nimisha Nagpal, Dr. Suresh Kumar

Department of Ophthalmology, Government Medical College and Hospital, Chandigarh, India

Minimally Invasive Glaucoma Surgery or 'MIGS' is a term that encompasses surgeries using shunts, stents and techniques that lower intraocular pressure with less surgical risk than the more established penetrating (trabeculectomy) and non-penetrating procedures (deep sclerectomy, canaloplasty, viscocanulostomy etc.) and setons (Ahmed, Baerveldt, or Molteno).

Microstents are emerging as potential noninvasive alternatives to trabeculectomy, and thus likely to play an important role in future for glaucoma management.

Most surgeons believe that MIGS procedures use an ab-interno approach that leave the conjunctiva intact for trabeculectomy or non-penetrating surgery, in future (if required). Recently, many have started using the term 'MIGS' to include surgery that affects the conjunctiva, such as XEN.

A new term, 'Moderately' Invasive Glaucoma Surgery' has also been suggested to include the conjunctiva incising MIGS and possibly even ExPress Glaucoma Filtration Device.

Broadly, available stents can be divided as:

a) Schlemm's canal stents : iStent®, iStent® inject, Hydrus
b) Suprachoroidal stents: CyPass®, iStent® Supra, and
c) Subconjunctival stents: XEN, InnFocus

INDICATIONS AND CONTRAINDICATIONS FOR MICROSHUNTS

Indications

Solo MIGS

- Patients with mild-moderate glaucoma
- Primary open-angle glaucoma, pseudoexfoliation glaucoma, or pigmentary dispersion glaucoma
- Glaucoma uncontrolled with maximum pharmacologic treatment or there are barriers preventing adequate medication dosing
- Age greater than 18 years

Phaco Plus:

- Patients with clinically significant cataract, as surgery may be performed simultaneously.

All patients must undergo a pre-operative comprehensive eye exam including gonioscopy and a detailed medical history.

Contraindications

Relative contraindications for these shunts include angle-closure glaucoma, secondary glaucoma, moderate-advanced glaucoma, previous glaucoma surgery, or severely uncontrolled IOP. Other considerations include patients with previous refractive procedures as well as monocular patients.

SCHLEMM'S CANAL STENTS

iStent®, iStent® inject

iStent is the first generation trabecular bypass device that is manufactured by Glaukos Inc. The device has CE-mark and was approved in 2012 by the FDA.

iStent inject is a smaller second generation model with radial symmetry.

Mechanism of action: Both the devices connect the anterior chamber with Schlemm's canal.

Device Design: The product has a size of 1×0.3 mm, is made from heparin-coated, non-magnetic titanium. The iStent is delivered in an inserter which consists of a 26-gauge disposable instrument which contains the iStent on the tip. There is a right- and left-eye model which are distinguished by the direction of the foot. Once placed, the long leg of the "L" shaped implant resides in Schlemm's canal with the short leg or snorkel protruding into the anterior chamber.

iStent inject (Figure 1) has a length of only 360 µm and a diameter of 230 µm, and is currently the smallest medical implant approved for use in the human body during surgical procedures. The G2-M-IS injector system contains two stents, allowing the insertion of both stents from one injector during the same surgical procedure.

Hydrus

Mechanism of action: The Hydrus micro-stent dilates Schlemm's canal (SC) in the complete nasal quadrant, allowing aqueous humor to bypass the trabecular meshwork through multiple collector channels

Design: It is also called as "intracanalicular scaffold". Hydrus is about 8mm long and made of Nitinol (nickel-titanium alloy), a shape memory alloy; when deformed, it returns to its original shape after being heated (Figure 2). It straddles 3 clock hours of SC (approximately 90 degrees), it access collector channels, without blocking their ostia and dilates the SC.

Figure 1: *iStent inject with its injector*

Table 1: Scientific evidence for efficacy and safety of iStent and iStent inject

S No.	Author	Study design	MIGS used	Comparator	No. of Eyes	Follow up (Months)	IOP reduction (%) Mean ± SD	Medication reduction at 12 months	Vision loss	Post operative complications	Reoperations needed
Combined iStent (1 iStent)											
1	Arriola-Villalobos, 2012	BEF-AFT Study (Before After)	iStent (1) Combined	None	19	60	11.0 ± 19.2	1.15	None	IOP spike 4/19	None
2	Craven B , 2012	RCT	iSent (1) Combined	Phaco alone	116	24	(iStent + Phaco): 8.6 ± 23.5 Phaco alone): 5.0 ± 24.1	1.20/1.10	None	IOP spike 5/116 Device related 5/116	1/116
3	Fea, 2015	RCT	iSent (1) Combined	Phaco alone	10	48	(iStent + Phaco):17.4 ± 16.8 (Phaco alone):6.6c19.3	1.50/O.80	None	None	None
4	Spiegel, 2009	BEF-AFT	iStent (1) Combined	None	12	12	19.8 ± 23.5	1.20	None	IOP spike 1/58 Device related 7/58	2/58
Combined iStent (2 iStents)											
5	Arriola-Villalobo Se, 2016 (INJECT)	BEF-AFT	(2) iStent Combined (Inject)	None	20	60	16.0 ± 21.7	1.00	None	IOP spikes (3/20) Device related (1/20)	None
6	Belovayf , 2012	NRS	(2) iStent Combined (Inject)	Phaco+3 iStent	28	12	20.2 ± 30.4	1.80	None	None	None
7	Fernandez-Barrientos, 2010	RCT	(2) iStent Combined	Phaco alone	17	12	(2 iStent + Phaco): 27.3 ± 13.8 Phaco alone:6.1 ± 11.6	1.20 / 0.50	None	None	None
8	Gonnermanna, 2017 (INJECT)	NRS	(2) iStent Combined	Trabectome combined	27	12	(2 iStent + Phaco):30.0 ± 23.2 (Phaco + Trabectome): 34.3 ± 22.1	0.67/0.76	None	None	2/27
SOLO iStent (1 iStent / 2 AND 3 iStents)											
9	Katz, 2015	RCT	SOLO iStent	2 and 3 iStent	36	18	iStent :21.2 ± 10.2 2/3 iStents :40.7 ± 10.7	1.52/1.83	None	None	None
SOLO iStent (2 iStents)											
10	Ahmed, 2014	BEF-AFT	iStent Inject Solo	None	39	18	46.9 ± 13.1	1.0	None	Hypotony 1/39	None
11	Donnenfeld, 2015	BEF-AFT	iStent Inject Solo	None	39	36	34.5 ± 14.4	NA		IOP spike 1/39	1/39
12	Fea, 2014 (INJECT)	RCT	2 iStent	2 Medications	94	12	iStent Inject: 38.4 ± 13.6 2 Medications:36.2 ± 13.0	0.96 / NA		IOP spike 1/94 Device related (1/94)	None
13	Lindstrom, 2016 (INJECT)	BEF-AFT	iStent Inject	None	57	18	27.2 ± 12.4	1.00	NA	NA	NA
14	Vold, 2016	RCT	2 iStent	Medication	54	24	2 iStent : 46.3 ± 12.4 Medications :44.6 ± 19.5 0	NA/NA	None	None	None
15	Voskanyan, 2014 (INJECT)	BEF-AFT	iStent Inject	None	99	12	29.0 ± 23.2	NA	None	IOP spike 10/99 Device related 4/99	4/99

1 Arriola-Villalobos P, MartõÂnez-de-la-Casa JM, DõÂaz-Valle D, et al. Combined iStent trabecular micro-bypass stent implantation and phacoemulsification for coexistent open-angle glaucoma and cataract: a long-term study. Br J Ophthalmol. 2012; 96(5):645±649.
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3 Fea AM, Consolandi G, Zola M, et al. Micro-Bypass Implantation for Primary Open-Angle Glaucoma Combined with Phacoemulsification: 4-Year Follow-Up. J Ophthalmol.2015; 2015:795357.
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11 Donnenfeld ED, Solomon KD, Voskanyan L, Chang DF, Samuelson TW, Ahmed II, et al. A prospective 3-year follow-up trial of implantation of two trabecular microbypass stents in open-angle glaucoma. Clin Ophthalmol. 2015; 9:2057-2065.
12 Fea AM, Belda JI, Rękas M, JuËnemann A, Chang L, Pablo L, et al. Prospective unmasked randomized evaluation of the iStent inject (®) versus two ocular hypotensive agents in patients with primary open angle glaucoma. Clin Ophthalmol. 2014; 8:875-882
13 Lindstrom R, Lewis R, Hornbeak DM, et al. Outcomes Following Implantation of Two Second-Generation Trabecular Micro-Bypass Stents in Patients with Open-Angle Glaucoma on One Medication: 18-Month Follow-Up. Adv Ther. 2016; 33(11):2082-2090.
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Scientific evidence for efficacy and safety

Table 1 enlists some salient studies highlighting efficacy and safety profile of iStent and iStent inject.

Pfeiffer et al carried out a RCT, where 100 cases were randomised to cataract surgery alone or combined cataract surgery with Hydrus.Glaucoma medications were washed out and the results were presented off glaucoma medications. At 24 months, a significantly greater proportion of the combined surgery cases reached the endpoint of a 20% reduction in diurnal IOP (80% versus 46%, p = 0.0008). The IOP was also significantly lower in the combined surgery group (16.9 ± 3.3 versus 19.2 ± 4.7 mmHg, p = 0.0093), and there was a significant reduction in cases without ocular hypotensive medications in the combined surgery group (73% versus 38%, p = 0.0008).

The HORIZON study is the largest prospective, randomized, controlled trial conducted to date for a MIGS device. The study was conducted at 38 centers in nine countries and enrolled 556 patients. The trial compared reductions in IOP and anti glaucoma medication use in patients having cataract surgery, with and without the Hydrus Microstent.

The 24 month US cohort data (331 patients), showed that 79 percent of Hydrus Microstent patients achieved a > 20 % reduction in IOP, compared to 55 % in the cataract only group. Hydrus Microstent reduced IOP 50 percent more than cataract surgery alone (7.9 mmHg vs. 5.2 mmHg, a difference of 2.7 mmHg). Table 2 shows some studies showing outcome of Hydrus.

SUPRACHOROIDAL STENTS

Targeting suprachoroidal space is likely to be beneficial as prostaglandins, exert their effect via this route. A negative pressure gradient exists that drives aqueous humor in the direction of the suprachoroidal space. Therefore suprachoroidal stents were created to exploit these characteristics.

CyPass

Cypass Microstent (Alcon) is a micro-implantable device made from a biocompatible material (polyimide). It allows for an ab interno surgical approach, which spares the conjunctiva, does not penetrate the sclera and leaves the trabecular meshwork intact.

Mechanism of action: The device is inserted into the supraciliary space, thereby creating a permanent conduit between the anterior chamber and the supraciliary space. It enables aqueous drainage through the uveoscleral pathway.

Device Design: This flexible device is 6.3 mm in length and 0.5 mm wide and is introduced by a curved guidewire (Figure 3). It bends to conform to the curved scleral contour during implantation into the supraciliary space. The device has proximal retention rings, that are visible under a goniolens and provide guidance for proper insertion and depth.

Scientific evidence for efficacy and safety

The COMPASS study demonstrated a statistically significant reduction in IOP at two years after cataract surgery combined with the CyPass Micro-Stent implantation vis-a-vis subjects undergoing cataract surgery alone. At two years post-surgery, there was little difference in endothelial cell loss between the CyPass Micro-Stent and cataract surgery-only groups.

The COMPASS-XT study was carried out to gather safety data on the subjects who participated in the COMPASS study for an additional three years, with analysis of the completed data set at five years post-surgery. At five years, the CyPass Micro-Stent group experienced statistically significant endothelial cell loss compared to the group who underwent cataract surgery alone. Therefore, Alcon has recently withdrawn CyPass from global market.

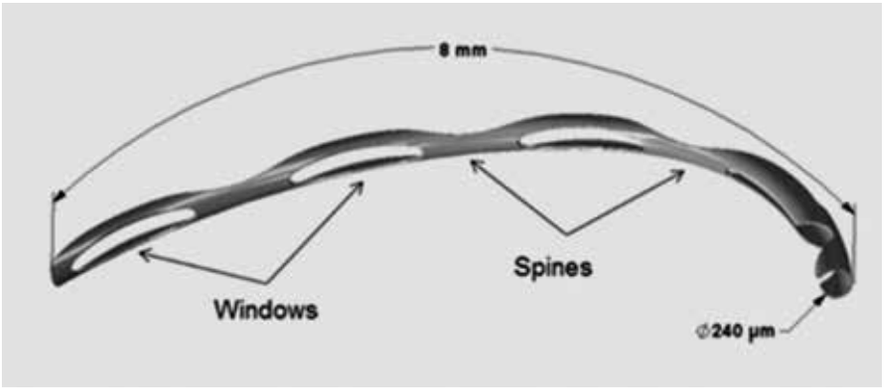

Figure 2: *Hydrus implant*

Figure 3: *CyPass Microstent*

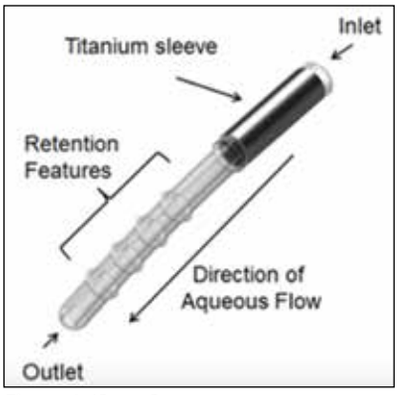

Figure 4: *iStent Supra*

iStent Supra

Device Design: The iStent Supra (Model G3) is made of a biocompatible polymer with a titanium sleeve. It is a 4mm long curved stent with a lumen of 0.165mm (Figure 4).

SUBCONJUNCTIVAL STENTS

The subconjunctival space is the traditional outflow pathway for glaucoma drainage surgery. Continued patency of this pathway for aqueous, and the scarring response in the conjunctiva, determine the successful outcome.

InnFocus

Device design: The InnFocus MicroShunt is made of an ultra-stable synthetic polymer of poly (styrene-block-isobutyl- ene-block-styrene) or SIBS (Figure 5). The MIDI-Arrow or InnFocus MicroShunt, is 8.5 mm long with a 70 mm lumen and a 1.1 mm wide attached fin located 4.5 mm from the anterior tip, which helps secure the device location.

Table 2: Scientific evidence of efficacy and safety of Hydrus

S.No.	Author	Study design	MIGS used	Comparison	No. of Eyes	Follow up	IOP reduction (%) Mean ± SD	Medication reduction at 12 months	Vision loss	Post operative complications	Reoperations needed
Hydrus (Combined)											
1	Pfeiffer, 2015	RCT	HYDRUS combined	Phaco alone	50	24	Hydrus + Phaco: 14.8 ± 23.7 Phaco alone: 14.0 ± 25.5	1.50/ 1.20	None	IOP spikes : 2/50	1/50
Hydrus (Solo)											
2	Gandolfi, 2016	NRS	HYDRUS	Canaloplasty Ab Externo	21	24	37.5 ± 28.0	0.9	None	IOP spike 1/21 Device related 2/21	4/21
3	Fea, 2016	NRS	HYDRUS	SLT	31	12	Hydrus solo: 28.6 ± 24.8 SLT : 31.4 ± 14.2	1.40/ 0.40	None	None	None

1 Pfeiffer N, Garcia-Feijoo J, Martinez-De-La-Casa JM, et al. A randomized trial of a Schlemm's canal microstent with phacoemulsification for reducing intraocular pressure in open-angle glaucoma. Ophthalmology. 2015;122:1283–93.

2 Gandolfi SA, Ungaro N, Ghirardini S, Tardini MG, Mora P. Comparison of surgical outcomes between canaloplasty and Schlemm's canal scaffold at 24 months' follow-up. J Ophthalmol. 2016; 5.Article ID 3410469.

3 Fea AM, Ahmed IIK, Lavia C, et al. Hydrus microstent compared to selective laser trabeculoplasty in primary open angle glaucoma: one year results. Clin Exp Ophthalmol. 2016;45(2):120–7.

Figure 5: *InnFocus MicroShunt*

Figure 6: *XEN implant in place*

Figure 7: *ExPRESS Glaucoma filtration device*

The InnFocus MicroShunt has been approved in Europe since 2012, but is not yet FDA approved in the USA.

As a fornix-based conjunctival flap and dissection of a shallow scleral pocket is required, it resembles conventional trabeculectomy.

Xen Gel stent

Mechanism of action: XEN is placed in a scleral tunnel created by its beveled needle applicator and terminating just under the conjunctiva. Aqueous humor flows from the anterior chamber through the stent and forms a filtering bleb under the conjunctiva (Figure 6), thus its mechanism of action is akin to trabeculectomy.

Device Design: The Xen Gel Stent is produced from porcine gelatin cross-linked with glutaraldehyde. Three Xen models have been designed, which are all 6 mm in length: Xen140, Xen63, and Xen45 with 140, 63, and 45 mm internal lumen diameters, respectively. The Xen140 offers minimal flow resis- tance and essentially relies entirely on subconjunctival resistance. The Xen63 and Xen45 provide 2–3 mmHg and 6–8 mmHg of outflow resistance, respectively. Xen45 is the primary

Table 3: Some Scientific Evidence for Efficacy and Complications of Xen Implants

S No	Author	Study design	XEN design used	Eyes	Success definition	Complete success	IOP reduction	Medication reduction at 12 months	Vision loss	Intraoperative complications	Post operative complications	Reoperations needed
1	Galal et al.	Prospective, interventional study	XEN45 +MMC : standalone XEN	13	XEN ≥20% IOP reduction without medication/ ≥20% IOP reduction with medication 41.7%	41.7 %	16 ± 4 to 12 ± 3 mmHg (p ≤ 0.01	1.9 ± 1 to 0.3 ± 0.49 (p = 0.003)	None	None	Choroidal detachment (2/13) (transient, resolved at 1 month with medical treatment) Implant extrusion (1/13) (repositioned with conjunctival suturing)	2/13(Trab)
2	De Gregoria et al	Nonrandomised, Prospective, interventional study	XEN45+ MMC Phaco + XEN	41	≤18 mmHg without medication / ≤18 mmHg with medications	80.4 %	16 ± 4 to 12 ± 3 mmHg (p ≤ 0.01)	1.9 ± 1 to 0.3 ± 0.49 (p = 0.003	None	Subcon haem (15/41) Transient ac bleed (10/41) Incorrect position(5/41)	Obstruction/explant (1/41) XEN migration (1/41) Transient hypotony on day 1 (1/41) Transient choroidal detachment with spontaneous resolution at 1 week (1/41)	1/41 (Trab)
3	Fea et al.	Prospective, interventional study	XEN45+ MMC 10: Stand-alone XEN, 2: Phaco + XEN ≤18	12	≤18 mmHg without medication / ≤18 mmHg with medications	50 %	21.8 ± 2.8 to 1414.9 ± 2.1 mmHg (p < 0.001)	2.92 ± 1.16 to 0.50 ± 0.53 (p < 0.001)	None	None	None	1/12 (Trab)
4	Pérez-Torregrosa et al.	Nonrandomised, Prospective, interventional study	XEN45+ MMC Phaco + XEN	30	≤18 mmHg without medication	90 %	21.2 ± 3.4 to 15.03 ± 2.47 mmHg (p < 0.001)	3.07 ± 0.69 to 0.17 ± 0.65 (p < 0.001)	None	Subconjunctival hemorrhage (26/30) AC bleed (26/30) hemorrhage at scleral exit point (27/30) XEN relocation (6/30) XEN reimplantation (1/30)	Encapsulation of filtration bleb (1/30)	None
5	Sheybani et al	Nonrandomised, Prospective, multicentre, cohort trial	XEN140; No MMC Stand-alone XEN	49	≤18 mmHg without medication / ≤18 mmHg with medications	40 %	23.1 ± 4.1 to 14.7 ± 3.7 mmHg (p < 0.001)	3.0 to 1.3 (p < 0.001	None	None	Trace corneal edema (1/13) Shallow AC requiring AC fill (4/49	None

1. Galal A, Bilgic A, Eltanamly R, et al. XEN glaucoma implant with mitomycin C 1-year follow-up: result and complications. J Ophthalmol. 2017;2017:5457246.
2. De Gregoria A, Pedrotti E, Russo L, et al. Minimally invasive combined glaucoma and cataract surgery: clinical results of the smallest ab interno gel stent. Int Ophthalmol. 2017. doi: 10.1007/s/0792- 017-0571-x
3. Fea AM, Spinetta R, Cannizzo PML, et al. Evaluation of bleb morphology and reduction in IOP and glaucoma medication following implantation of a novel gel stent. J Ophthalmol. 2017;2017:9364910.
4. Pérez-Torregrosa VT, Olate-Pérez Á, Cerdà-Ibáñez M, et al. Combined phacoemulsification and Xen45 surgery from temporal approach and 2 incisions. Arch Soc Esp Oftalmol. 2016 Sep;91:415–421.
5. Sheybani A, Dick B, Ahmed IIK. Early clinical results of a novel ab interno gel stent for the surgical treatment of open-angle glaucoma. J Glaucoma. 2016;25:e691–e696

Table 4: Some Scientific Evidence for Efficacy and Complications for Express Glaucoma Filtration Device

S.No.	Author Year(s) Journal(s)	Study design	Eyes per treatment group	Patient population	EX-PRESS model implanted or trabe-culectomy	Follow up	Success definition, upper limit	IOP success outcomes (complete success without medications)	Visual Acuity results		Post- op Complications	
									Device group	Trabe-culectomy group	Device group	Trabe-culectomy group
1	Dahan 2012 Eye	Prospective, randomized, fellow eye	30	Medically uncontrolled POAG	X-200 Trabe-culectomy	Mean 23.6 ± 6.9 mths	<18 mmHg	Hazard ratio=0.27 (favouring device) P=0.002	Remained stable compared to pre -operative values		Wound leak (7%) Shallow anterior chamber (13%) Hypertony (0%) Hyphema (0%) High avascular bleb (0%) ≥1 complications per eye (20%)	Wound leak (0%) Shallow anterior chamber (20%) Hypertony (20%) Hyphema (7%) High avascular bleb (7%) ≥1 complications per eye(33%)
2	de Jong 2009 Adv Ther, De Jong 2011 Clin Ophthalmol	Prospective, randomized, parallel group	70	Un-controlled open-angle glaucoma; did not have previous ocular surgery (except cataract surgery)	R-50 Trabe-culectomy	3 years 5 years	≤18 mmHg ≤18 mmHg	Device vs trabe-culectomy = 67% vs 41%. P=0.02 Device vs trabe-culectomy = 41% vs 53.9%. P=NS	Improved = 24% Unchanged= 62% Declined= 14%	Improved = 18% Unchanged = 66% Declined = 16%	Shallow anterior chamber (20%) Choroidal detachment (7.5%) Flat anterior chamber (2.5%) Bleb leak (2.5%) Hyphema (0%) IOP spike (0%)	Shallow anterior chamber (12.5%) Choroidal detachment (2.5%) Flat anterior chamber (0%) Bleb leak (5%) Hyphema (5%) IOP spike (2.5%)
3	Beltran-Agullo 2013 Wagschal 2013 J Glaucoma	Prospective, randomized, controlled	64	Un-controlled open-angle glaucoma and trabe-culectomy as planned procedure	P-50 Trabe-culectomy	1 year	NR	Device vs trabe-culectomy = 70% vs 57%. P=NS	Declined in 1st 2 weeks, recovered to baseline at 1 year	Declined wrt baseline	Choroidal effusion (0%) Membrane over tube(3%) Hyphaema (0%) Shunt completely entered AC (3%) Lens opacity (3%) Encapsulated bleb (0%) Epiretinal membrane (0%) CRVO (0%)	Choroidal effusion (3.2%) Membrane over tube (0%) Hyphaema (16%) Shunt completely entered AC (0%) Lens opacity (13%) Encap-sulated bleb (3.2%) Epiretinal membrane (3.2%) CRVO (3.2%)
4	Netland 2014 Am J Ophthalmo	Prospective, randomized, comparative	120	Open-angle glaucoma, history of laser trabe-culoplasty or cataract phaco-emulsion at least 2 months prior to study	P-50 Trabe-culectomy	Upto 2 years	5-18 mmHg	NR	Recovered to baseline in 0.7 months (median time)	Recovered to baseline in 2.2 months (median time)	Shallow AC & choroidal effusion(6.8%) Surgically treated cataract(5.1%) Hyphaema(0%) Early wound leak (3.3%)Dellen (1.7%) Late bleb leak (1.7%) End-ophthalmitis (0%)	Shallow AC & choroidal effusion (11.5%) Surgically treated cataract (11.5%) Hyphaema (9.8%) Early wound leak (4.9%) Dellen (0%) Late bleb leak (1.6% End-ophthalmitis (1.6%)

version utilized worldwide and the only version available in the USA. It softens on contact with water within 1–2 min, meaning that it can bend and conform to tissue, reducing the risk of erosion.

Scientific evidence for efficacy and safety

Table 3 elucidates several studies that show the efficacy and safety profile of XEN.

Transient hypotony, AC shallowing, and choroidal detachment have been reported in few cases, but these are either self resolving or resolve with medication, without any impact on vision. Conjunctival exposure of the XEN Gel Stent is a serious complication, which can be avoided using a meticulous surgical technique to implant the device.

Where does the ExPress Glaucoma Filtration Device fit?

Ex-PRESS glaucoma filtration device

(Alcon Laboratories, Fort Worth, TX, USA) was created to mimic trabeculectomy's IOP control and improve its safety.

Mechanism of action: This non-valved device drains aqueous fluid from the anterior chamber to the subconjunctival space and forms a filtration bleb.

Device Design: Ex-PRESS glaucoma device is made of biocompatible stainless steel with a spur to prevent extrusion of the device and an external backplate to prevent intrusion. The backplate and spur are designed to conform to angle anatomy, and the distance between them approximates that of the scleral tract created by the device (Figure 7).

Ex-PRESS glaucoma device is currently available in two models: an R-model and a P-model.

R-model: It has a beveled tip, an external diameter of 400 microns (27-gauge), an internal lumen of 50 microns, a total device length of 2.96 mm and a uniform back plate.

P-model: This model has a decreased bevel angle; an external diameter of 400 microns, a total device length of 2.64 mm and a vertical channel back plate. It is available in both a 50-micron and 200-micron internal lumen size.

Scientific evidence for efficacy and safety

Compared with trabeculectomy, the EX-PRESS device eliminates the need for both peripheral iridectomy and removal of a deep corneoscleral tissue block, but these advantages are counterbalanced by the need to align the device properly to avoid contact with either the cornea or the iris.

Table 4 shows the compiled data from the four randomised controlled trials comparing EX-PRESS device with trabeculectomy.

Of the four randomized prospective studies comparing IOP-lowering efficacy of the EX-PRESS device with trabeculectomy, only one demonstrated lower long-term IOP with EX-PRESS device implantation.In that study, there was a significant difference in mean IOP between groups up to 3 years, but this difference was no longer significant at years 4 and 5 of follow-up.

The Ex-PRESS device relies on nonphysiologic subconjunctival flow as its mechanism of IOP lowering. As a result, all of the issues that limit trabeculectomy and the complication profile associated with blebs accompany the Ex-PRESS shunt too, but to a much lesser extent.

In a nutshell, Minimally invasive glaucoma surgeries fill a gap that has existed in the treatment algorithm for glaucoma between medical therapy and laser at one end of the spectrum and traditional filtering glaucoma surgeries at the other.

SUGGESTED READING

1. Agrawal P, Bradshaw SE. Systematic Literature Review of Clinical and Economic Outcomes of Micro-Invasive Glaucoma Surgery (MIGS) in Primary Open-Angle Glaucoma.Ophthalmol Ther. 2018 Jun;7(1):49-73.
2. Fingeret M, Dickerson JE Jr. The Role of Minimally Invasive Glaucoma Surgery Devices in the Management of Glaucoma. Optom Vis Sci. 2018 Feb;95(2):155-162.
3. Pfeiffer N, Garcia-Feijoo J, Martinez-de-la-Casa JM, Larrosa JM, Fea A, Lemij H, Gandolfi S, Schwenn O, Lorenz K, Samuelson TW. A Randomized Trial of a Schlemm's Canal Microstent with Phacoemulsification for Reducing Intraocular Pressure in Open-Angle Glaucoma. Ophthalmology. 2015 Jul; 122(7):1283-93.
4. https://www.prnewswire.com/news-releases/new-data-from-the-horizon-trial-of-the-hydrus-microstent-shows-significantly-lower-iop-and-medication-use-at-24-months-in-a-us-patient-cohort-300628514.html
5. Hoeh H, Vold SD, Ahmed IK, et al. Initial clinical experience with the CyPass micro-stent: safety and surgical outcomes of a novel supraciliary microstent. J Glaucoma. 2016;25(1):106–112.
6. Vold S, Ahmed II, Craven ER, Mattox C, Stamper R, Packer M, Brown RH, Ianchulev T, CyPass Study Group. Two-Year COMPASS Trial Results: Supraciliary Microstenting with Phacoemulsification in Patients with Open-Angle Glaucoma and Cataracts. Ophthalmology. 2016 Oct; 123(10):2103-12.
7. https://www.accessdata.fda.gov/cdrh_docs/pdf15/p150037b.pdf
8. Myers JS, Masood I, Hornbeak DM, Belda JI, Auffarth G, Jünemann A, Giamporcaro JE, Martinez-de-la-Casa JM, Ahmed IIK, Voskanyan L, Katz LJ. Prospective Evaluation of Two iStent® Trabecular Stents, One iStent Supra® Suprachoroidal Stent, and Postoperative Prostaglandin in Refractory Glaucoma: 4-year Outcomes. Adv Ther. 2018 Mar;35(3):395-407.

Correspondence to:
Dr. Parul Ichhpujani
Department of Ophthalmology,
Government Medical College and Hospital,
Chandigarh, India