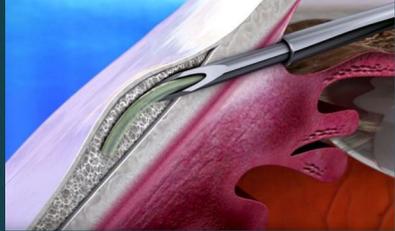




Efficacy and Safety of XEN[®] Gel Stent as Primary Surgical Procedure in Korean Glaucoma Patients

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XEN[®] GEL STENT



- 6-mm hydrophilic tube with 45- μ m inner lumen \varnothing
- Drainage shunt connecting AC and SC space
- Via 'ab interno' stent insertion technique
- Collagen-derived gelatin, cross-linked with glutaraldehyde

PURPOSE

To evaluate the safety and efficacy of the ab interno subconjunctival gelatin implant (XEN[®] Gel Stent) as primary surgical procedure in Korean eyes with medically uncontrolled glaucoma

PATIENTS AND METHODS

- Retrospective, open-label, single-center, and consecutive series study
- Inclusion criteria
 - 43 eyes of 39 Korean glaucoma patients with uncontrolled IOP or glaucomatous VFD progression
 - XEN[®] Gel Stent implantation between November 2018 and May 2019 at the Central Seoul Eye Center
 - No history of previous glaucoma surgery before the stent insertion
 - Minimum follow-up period of 3 months (maximum F/U up to 9 months)

▪ Surgical procedure details

- **Technique 1 (14 eyes)**
 - : XEN implantation with pre-XEN MMC 4 μ g/ml 0.1cc
- **Technique 2**
 - : XEN implantation with pre-XEN air & OVD dissection and post-XEN MMC
 - * 2-1 (20 eyes): MMC 2 μ g/ml 0.1cc
 - * 2-2 (9 eyes): MMC 4 μ g/ml 0.1cc

▪ Primary measured outcomes

- Intraocular pressure (IOP)
- Number of glaucoma medications
- BCVA (Snellen chart)
- Baseline, postoperative 1 day, 1 and 2 weeks, and 1, 3, 6, and 9 months.

▪ Intra- and post-operative complications were also assessed.

▪ Bleb assessment was performed with swept-source AS-OCT (CASIA2, Tomey, Japan).

RESULTS

▪ Demographics

- Total 43 eyes (M:F = 26:17)
- Age = 52.9 \pm 13.7 years
- OD: OS = 24: 19
- POAG: PACG: Uvetic glaucoma = 35: 1: 7
- Phakic: Pseudophakic = 31: 12
- SLT Hx: 18/43

Surgical Videos

Technique 1

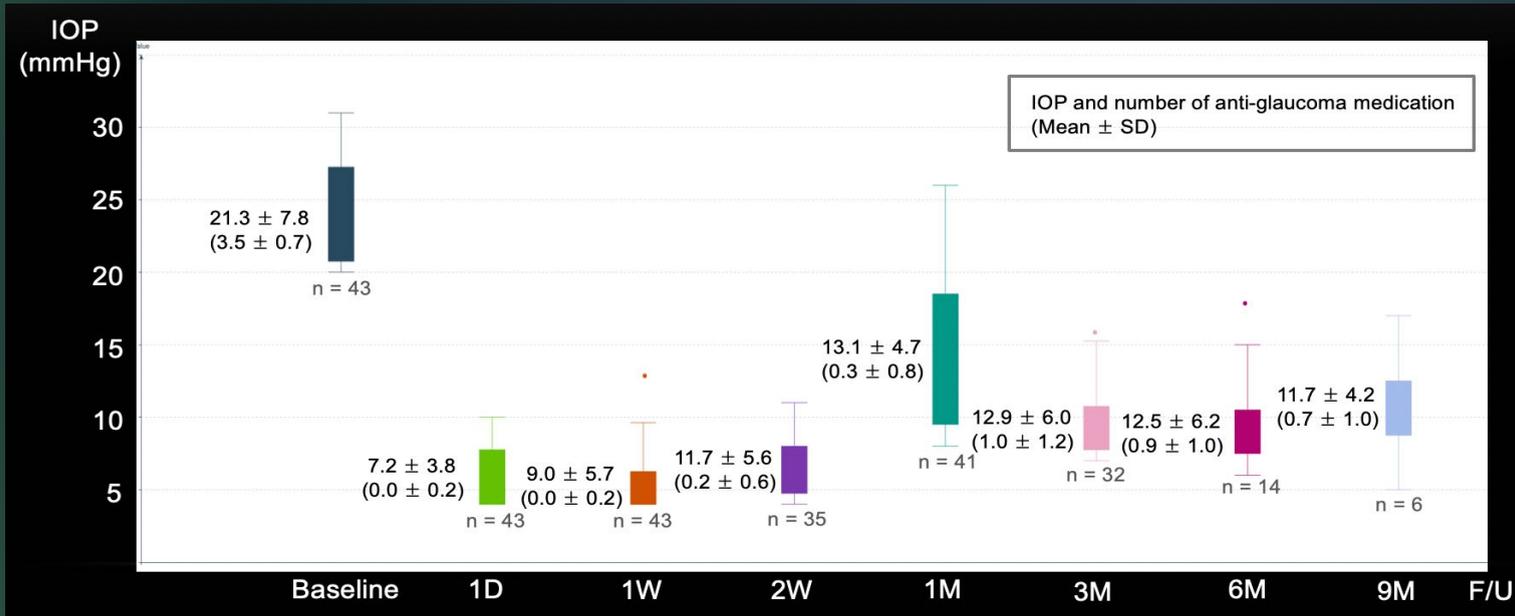


Technique 2



RESULTS (Continued)

Efficacy



Safety I: BCVA loss and postop complications

BCVA loss > 2 lines

- 1W: 12 (27.9%)
- 2W: 4 (9.3%)
- 1M: 2 (4.7%)
 - : 1 d/t choroidal effusion
 - AMD aggravation
 - 1 d/t cataract progression

- Flat AC: 0
- Shallow AC: 2
- Chemosis ≥ 1W: 3
- Hyphema: 4
- Tenon's cyst: 2

Hypotony (≤ 5mmHg)

- 1W: 11 (25.6%)
- 2W: 3 (7.0%)
- 1M: 0 (0%)

- Iris incarceration into the corneal wound: 1
- Choroidal effusion: 1
- Stent dislocation: 1
- Cataract worsening: 2

Safety II: secondary interventions - overall

Postoperative surgical procedures

- 5FU injection + bleb needling: 17/ 43 (39.5%)
- Open revision: 3/ 43 (7.0%)
- XEN reposition (d/t dislocation into AC) : 1 (2.3%)

Secondary glaucoma surgical intervention

- GDD: 1 (2.3%)
- Micropulse CPC: 1 (2.3%)

Comparison among different techniques

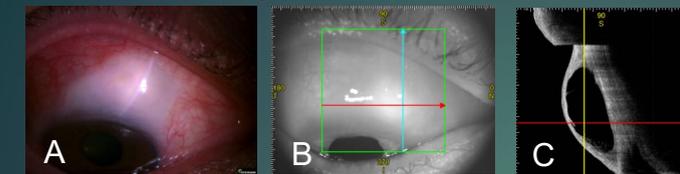
Secondary surgical intervention

	Technique 1	Technique 2-1	Technique 2-2
	Pre-XEN MMC 0.02%	Pre-XEN air & OVD Post-XEN MMC 0.02%	Pre-XEN air & OVD Post-XEN MMC 0.04%
Bleb needling	9/14 (64.3%)	9/20 (45%)	3/13 (23.0%)
Open revision	1/14 (2.3%)	2/14 (14.2%)	1/14 (7.6%)
Open revision with 2 nd XEN implantation	1/14 (2.3%)	-	-
GDD	1/14 (2.3%)	-	-
Micropulse laser CPC	1/14 (2.3%)	-	-

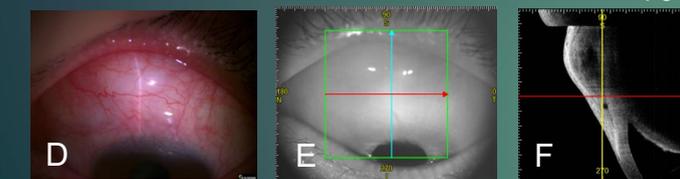
* Combination of pre-XEN air/OVD dissection and post-XEN MMC 4 µg/ml 0.1cc injection tends to have relatively lower incidence of secondary bleb intervention procedures.

Swept-source AS-OCT

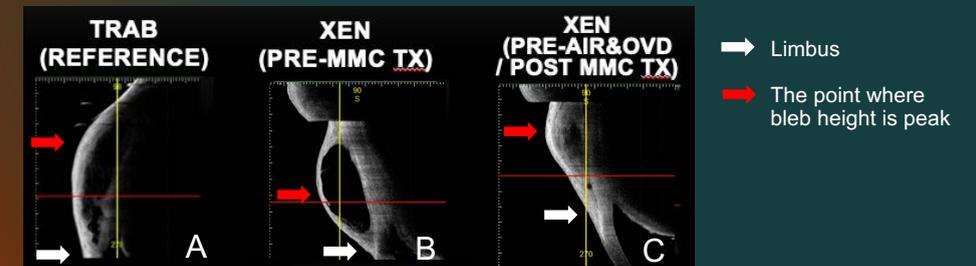
Pre-XEN MMC 4 µg/ml 0.1cc



Pre-XEN air & OVD dissection / Post-XEN MMC 4 µg/ml 0.1cc



* 6-month representative photos of a patient who had XEN surgeries in both eyes. More diffuse and less avascular bleb formation was observed in the left eye which underwent Technique 2-2 (D-F) than in the right eye which underwent Technique 1 (A-C).



* Comparison of AS-OCT vertical section among different surgical techniques. More posterior and low lying bleb was noted in the left eye which underwent Technique 2-2 (C) than in the right eye which underwent Technique 1 (B).

DISCUSSIONS

• Efficacy & Safety

Overall, our data showed a 38.5%, 39.4%, 41.3%, and 45.0% reduction in mean IOP from the baseline at the 1, 3, 6, and 9-month timepoint on a mean use of 0.3, 1.0, 0.9, and 0.7 antihypertensive medications.

One potential benefit of minimally invasive procedure is the rapid improvement in vision. Our results show that the proportion of the patients who had BCVA loss more than 2 lines were 27.9% at 1 week, and 4.7% (2 eyes) at 1 month. One eye had choroidal effusion and aggravation of pre-existing AMD, and the other eye had cataract progression. These two patients also recovered their vision after the resolution of choroidal effusion followed by anti-VEGF injection and cataract surgery.

Secondary bleb intervention rate was quite high. Needling was required by 39.5% of patients, and open revision by 7.0% of patients by 9 month. 4.6% of patients needed secondary glaucoma surgery.

IOP lowering efficacy was satisfactory in most patients. However, high proportion of secondary surgical intervention implies that the wound healing modulation skills and the ability to perform traditional glaucoma surgery when needed are essential for long-term XEN success.

• Comparison among different techniques

Various surgical modifications have been applied for the XEN implantation by many surgeons.

1. For the concentration of MMC, it may differ among surgeons. Some prefer 2 $\mu\text{g/ml}$ concentration, while others do 1 or 4 $\mu\text{g/ml}$.
2. For the time of MMC injection, most doctors inject MMC prior to XEN implantation, while others do it following XEN implantation.
3. Dissecting conjunctiva from Tenon's capsule using air and dispersive OVD injection may be incorporated in the surgical procedure to enhance the outcome.

In our study, we could observe that postoperative surgical interventions were less frequent in the group who underwent Technique 2 (the combination procedure of pre-XEN air & OVD dissection and post-XEN MMC) than in the group with Technique 1.

Swept-source AS-OCT analysis also revealed that more posterior and diffuse bleb may be associated with Technique 2-2.

Further randomized and longitudinal studies are required to seek the associations between different surgical procedure and the clinical outcome.

CONCLUSION

- The XEN® Gel Stent effectively reduced IOP and the need of medication as a primary surgical procedure in Korean patients with medically uncontrolled glaucoma.
- The postoperative safety profile seems to be acceptable. No irreversible vision-threatening complications such as persistent symptomatic hypotony was noted in our series of study.
- Secondary surgical intervention rate is quite high. Researches on unique wound healing process and proper XEN surgical technique should be performed in future.
- Bleb morphology can be assessed more accurately using the assistance of swept-source AS-OCT.

