

XEN-Augmented Deep Sclerectomy: Step-by-step Description of a Novel Surgical Technique for the Management of Open-angle Glaucoma

Laëtitia J Niegowski¹, Kevin Gillmann², J-M Baumgartner³

ABSTRACT

Aim and background: The present case report describes a novel surgical technique combining XEN gel stent implantation and deep sclerectomy: XEN-augmented deep sclerectomy (XEN-DS).

Case description: An active 96-year-old Caucasian woman suffering from pseudoexfoliative glaucoma (PEXG) presented with intraocular pressure (IOP) of 24 mm Hg and a double arcuate visual field defect [mean deviation (MD) −9.6 dB] in her only functional eye despite maximal medical therapy. Considering (1) the magnitude of IOP reduction sought, (2) the risk of complications associated with trabeculectomies and glaucoma drainage devices, and (3) the risk of missed appointments due to the patient's personal and social circumstances, it was decided to tailor the surgical treatment to this patient's specific characteristics combining two existing surgical techniques. Following conjunctival dissection, a superficial scleral flap was lifted 2 mm more posteriorly than in conventional DS, and a XEN gel stent was implanted *ab externo* through the anterior wall of the deep sclerectomy, into the anterior chamber. A mitomycin C-soaked autologous space maintainer was used. No peri- or postoperative complications were observed. Following XEN-DS, her IOP stabilized between 5 mm Hg and 8 mm Hg through 6 months, and her visual field MD improved to −1.5 dB.

Discussion: The present case report is a proof of concept for this novel surgical technique, confirming that XEN-DS has the potential to achieve substantial and persistent IOP reductions in PEXG with a satisfactory safety profile. Clinical studies are warranted to confirm these results.

Keywords: Case report, Glaucoma, Illustrated, Intraocular pressure, Minimally-invasive glaucoma surgery, Non-penetrating, Stent, Surgery, XEN. *Journal of Current Glaucoma Practice* (2021): 10.5005/jp-journals-10078-1311

BACKGROUND

Glaucoma is the leading cause of irreversible blindness worldwide.¹ Intraocular pressure (IOP) reduction is the cornerstone of glaucoma management, with medical therapies and laser trabeculoplasties as the main first-line treatment options. When glaucoma progresses despite the best medical treatment, however, surgical treatment may become essential to halt disease progression.²

Described by Cairns in 1968, trabeculectomy has for many years been the gold standard of filtering surgery. However, despite robust evidence of its efficiency at lowering IOP, trabeculectomy is associated with frequent, potentially sight-threatening, postoperative complications.³ Over the years, new techniques have emerged to overcome these complications.^{4,5} Among these, non-penetrating deep sclerectomy (DS) is regarded as an effective alternative to trabeculectomy⁶ offering similar IOP reduction with a superior safety profile.⁷ Another range of surgical techniques labeled “minimally-invasive glaucoma surgery” (MIGS) have recently gained popularity due to their relatively short recovery periods and low rates of complications. However, their IOP-lowering potentials tend to be less than that of traditional filtering surgeries, making them indicated for milder forms of glaucoma. While often considered a MIGS, XEN gel stents were shown to produce more significant IOP reduction than most minimally invasive approaches.^{8,9} Yet, XEN gel stents are bleb-producing procedures, and as such, they are associated with frequent bleb-related complications, including a need for frequent needling revisions.¹⁰ Building on the respective strengths of DS and XEN gel stents, a new surgical technique was developed: the XEN-augmented deep sclerectomy (XEN-DS).

¹⁻³Department of Ophthalmology, Ophthalmology Network Organisation, Clinique de l'Oeil SA, Onex, Geneva, Switzerland

Corresponding Author: Laëtitia J Niegowski, Department of Ophthalmology, Ophthalmology Network Organisation, Clinique de l'Oeil SA, Onex, Geneva, Switzerland, Phone: +0041784042279, e-mail: laetitia-jessy@outlook.fr

How to cite this article: Niegowski LJ, Gillmann K, Baumgartner JM. XEN-Augmented Deep Sclerectomy: Step-by-step Description of a Novel Surgical Technique for the Management of Open-angle Glaucoma. *J Curr Glaucoma Pract* 2021;15(3):144–148.

Source of support: Nil

Conflict of interest: None

This case report constitutes a proof of concept and a detailed description of this surgical technique.

CASE DESCRIPTION

Case Presentation

An active 96-year-old Caucasian woman with pseudoexfoliative glaucoma (PEXG) was referred to our tertiary ophthalmology center with uncontrolled IOP despite maximum medical topical therapy, namely: prostaglandin analog, carbonic anhydrase inhibitor, beta-blocker, and alpha-adrenergic agonist topical eye drops. She presented late due to difficulties traveling to attend medical appointments but reported good treatment compliance. She denied any family history of glaucoma. Upon examination,

Goldmann tonometry confirmed an IOP of 28 mm Hg in her right eye and 24 mm Hg in her left eye. Her best-corrected visual acuity was “counting fingers” in the right eye and 0.2 LogMAR in the left eye. Anterior segment biomicroscopic examination of the left eye demonstrated pseudophakia with pseudoexfoliative material on an atrophic pupillary sphincter and a clear cornea. Gonioscopy confirmed an open iridocorneal angle and a heavily pigmented trabecular meshwork. Fundus examination revealed a cup-to-disc ratio of 0.9 in both eyes and was otherwise unremarkable. Despite the poor visual acuity, a visual field examination was attempted, resulting in a mean deviation (MD) of -27.6 and -9.6 dB in the right and the left eye, respectively, with double arcuate defects.

Surgical Rationale

Based on the above clinical findings, surgical treatment was discussed, and agreed with the patient to attempt to preserve functional vision in the left eye. Considering the amplitude of IOP reduction sought, MIGS options were excluded. Yet, in presence of a monophthalmic patient with extensive visual field defects, it was also decided to avoid glaucoma drainage devices or trabeculectomies to minimize the risk of hypotony and potential wipe-out syndrome. While DS appeared to be the best-suited option, it was feared that her difficulties attending appointments may prevent adequate postoperative follow-up, including laser goniopuncture. Therefore, it was decided to perform XEN-DS to benefit from both DS’ scleral lake and XEN’s standardized outflow control.

Surgical Protocol

Following topical and subconjunctival anesthesia with xylocaine, blunt Westcott scissors and non-toothed Bishop-Harmon forceps were used to open the conjunctiva at the limbus. Conjunctiva and Tenon’s capsule were dissected, and a 5.5×5.0 mm superficial scleral flap was created 2 mm more posteriorly than in conventional DS (Fig. 1A), so that the dissection of the deep flap would terminate

2 mm away from the scleral spur. Corneal tissue, therefore, remained untouched. Once the deep scleral flap was excised (Fig. 1B), a scleral section was removed and soaked in mitomycin C (MMC) 0.4 mg/mL for 5 minutes. Mitomycin C-soaked sponges were applied to the deep scleral bed for 2 minutes, and the MMC-soaked scleral section was positioned perpendicular to the limbus and secured to the deep scleral bed with 10-0 Dermalon sutures. The XEN gel stent was then implanted ab externo into the anterior wall of the DS so that 1 mm lies within the anterior chamber and 3 mm rest on the deep scleral bed next to the space maintainer (Fig. 1C). The superficial flap was repositioned and secured with two 10-0 Dermalon sutures to its distal corners. The conjunctiva and Tenon’s layer were closed at the limbus with two 8-0 Safil resorbable suture (Fig. 1D). No perioperative complications were observed.

Surgical Outcome

Postoperatively, all anti-glaucoma medications were withdrawn and combined topical corticosteroid and antibiotic therapy (Spersadex comp, Théa PHARMA SA) was prescribed for 4 weeks. Postoperative unmedicated IOP was 5 mm Hg at day-1, and gradually increased to 8 mm Hg through to 6 months (Fig. 2).

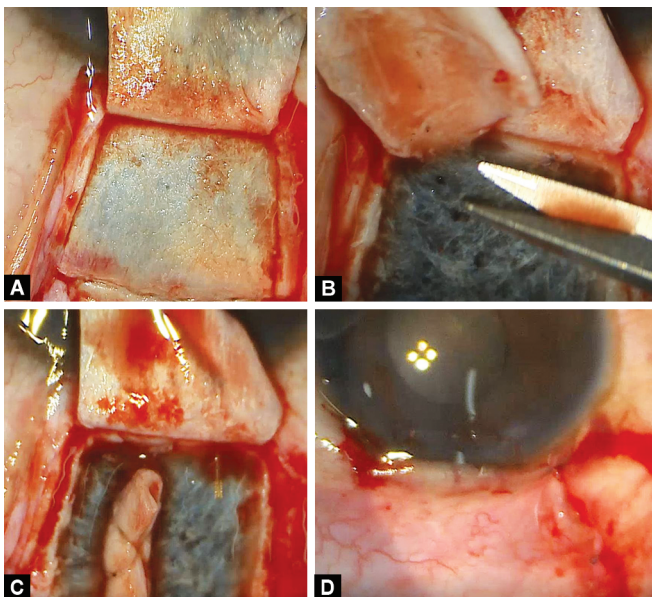
The XEN gel stent remained stable within the anterior chamber and the filtration bleb remained healthy and diffuse through to 6 months (Fig. 3). Ultrasound biomicroscopy revealed a patent intrascleral lake (Fig. 4).

No postoperative complications were observed, and no needling revision or subsequent surgical intervention was required. Interestingly, while the best-corrected visual acuity remained unchanged, visual field MD showed a marked improvement from -9.6 to -1.5 dB after 6 months (Fig. 5).

DISCUSSION

This case report constitutes a proof of concept for XEN-DS, achieving significant IOP and treatment reduction without any postoperative complication, in a patient at risk of glaucoma progression and complications. The concept of XEN-DS stemmed from several observations on DS and XEN gel stents’ strengths and weaknesses.

The intrascleral space and novel intrascleral venous outflow achieved through traditional DS were shown to contribute to long-term IOP reduction.¹¹ Yet, while relatively safe compared with



Figs 1A to D: Illustration of the XEN-augmented deep sclerectomy surgical technique: (A) Dissection of a 5.5×5.0 mm superficial scleral flap 2 mm posterior to the limbus; (B) Excision of the deep scleral flap 2 mm posterior to the scleral spur; (C) Implantation of the XEN gel stent through the anterior wall of the sclerectomy and suturing of the autologous space maintainer to the deep scleral bed; (D) Conjunctival and Tenon’s capsule closure

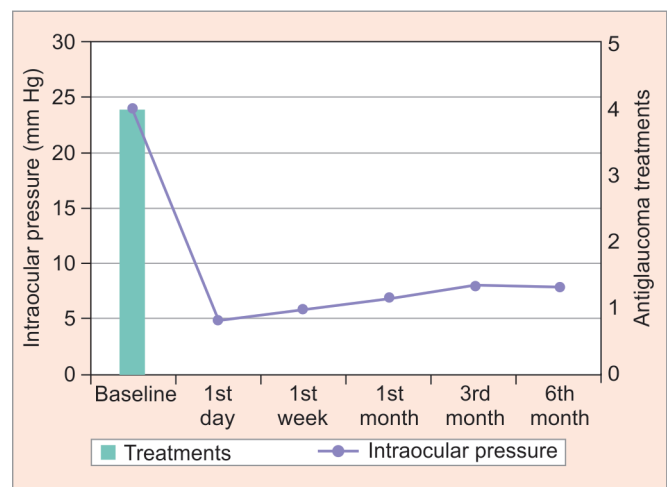
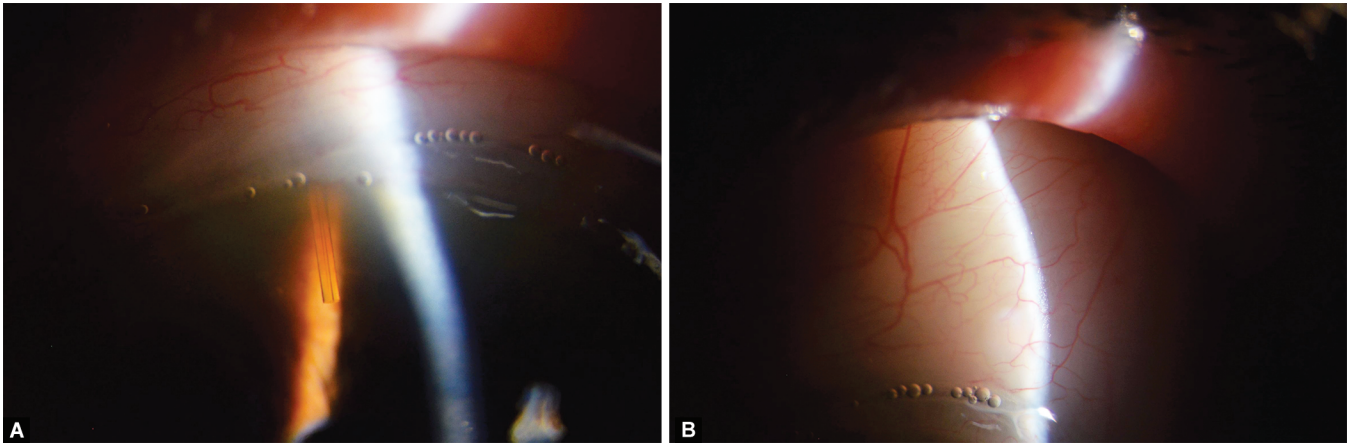
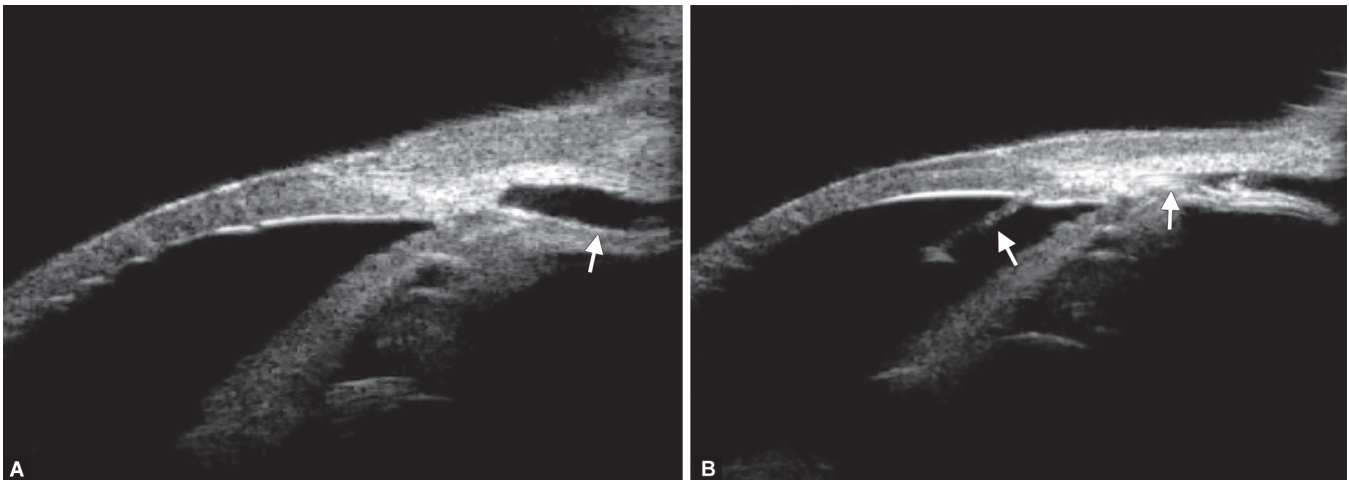


Fig. 2: Postoperative progression of intraocular pressure and number of treatments through to 6 months



Figs 3A and B: Postoperative biomicroscopic examination: (A) A segment of XEN gel stent is visible within the anterior chamber; (B) Filtration bleb is diffuse and healthy-looking



Figs 4A and B: Ultrasound biomicroscopic examination: (A) A deep intrascleral lake is visible (arrow), with no direct anterior chamber communication; (B) XEN gel stent is visible within the anterior chamber (arrow) and is tracked through the sclera

trabeculectomy, DS is a challenging technique, and reported rates of accidental perforation are as high as 30%.¹² These may have serious consequences such as iris incarceration and IOP spikes,^{13,14} or profound hypotony.¹² Other groups reported hypotony in as much as 37.0% of cases.^{12,15} Furthermore, while postoperative follow-up is important after all glaucoma procedures, it may be even more crucial following DS.⁵ Indeed, after DS, most eyes experience IOP elevation due to thickening of the trabeculo-Descemet's membrane, requiring diagnosis and laser goniopuncture.¹⁶

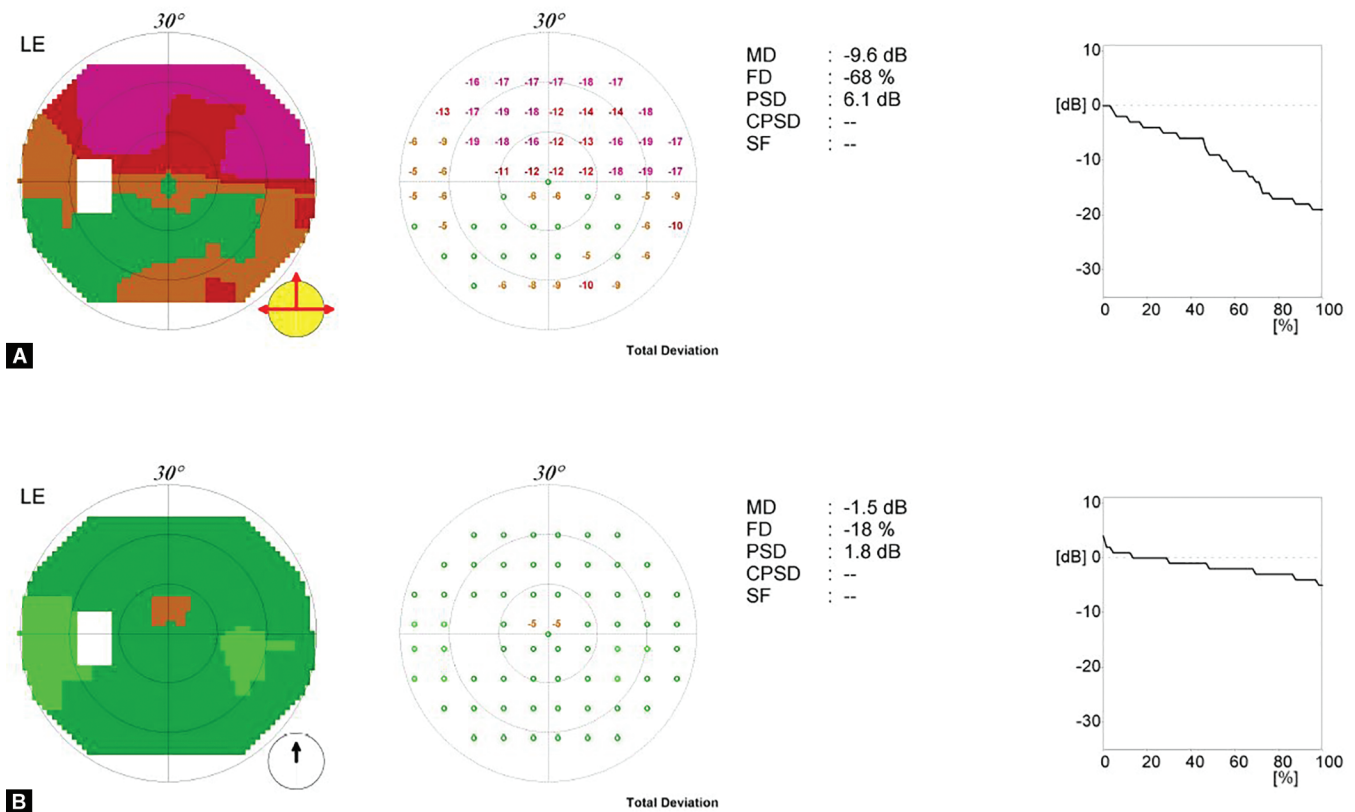
On the other hand, several studies confirmed XEN gel stents' superior safety profile, with barely any reported perioperative complications,¹⁷ and low rates of postoperative hypotony.¹⁸ Furthermore, XEN gel stents were shown to produce healthier filtration blebs than filtering procedures and promote posterior fluid diffusion. This is suspected to be due to the intrinsic characteristics of the stents, the 45- μ m lumen of which restricts the flow of inflammatory aqueous humor draining into the subconjunctival space, thus minimizing fibrosis and leading to wider-based blebs.^{19–23} Yet, while the IOP-reduction potential of XEN gel stents is supposedly greater than that of most MIGS, it was shown to be less

than that of filtering surgeries²⁴ and to require frequent revisions to maintain adequate filtration.¹⁰

Combining traditional DS' intrascleral outflow with XEN gel stents' ease of implantation, outflow control, and bleb morphologies resulted in the design of this novel technique, which seems viable and, in this specific example, achieved its aim. However, there are reports, in the literature, of specific XEN-related complications such as stent displacement or obstruction, which may affect the outcomes of this procedure. These are relatively rare and dedicated studies are warranted to confirm the efficacy and safety profile of this novel procedure.

CONCLUSION

The present case report proves the viability of XEN-DS surgery in a patient at risk of glaucoma progression and complications. No peri- or postoperative complications were observed and sustained IOP reduction was observed through to 6 months. XEN-DS might therefore be a promising novel technique in the management of moderate-to-advanced open-angle glaucoma. A longer-term study involving several patients is currently in progress.



Figs 5A and B: Visual field showed clear improvement between the preoperative examination (A) and the 6-month postoperative examination (B)

REFERENCES

- Kingman S. Glaucoma is second leading cause of blindness globally. *Bull World Health Organ* 2004;82(11):887–888. DOI: /S0042-96862004001100019.
- Thakur S, Ichhpujani P, Kumar S. Grafts in glaucoma surgery: a review of the literature. *Asia Pac J Ophthalmol (Phila)* 2017;6(5):469–476. DOI: 10.22608/APO.2016123.
- Gedde SJ, Herndon LW, Brandt JD, et al. Postoperative complications in the tube versus trabeculectomy (TVT) study during five years of follow-up. *Am J Ophthalmol* 2012;153(5):804–814.e1. DOI: 10.1016/j.ajo.2011.10.024.
- Roy S, Mermoud A. Deep sclerectomy. *Dev Ophthalmol* 2017;59:36–42. DOI: 10.1159/000458484.
- Kalala A, Gillmann K, Mermoud A. Prospective evaluation of penetrating deep sclerectomy in advanced open-angle glaucoma: filtration surgery adapted to resource scarcity in developing countries. *J Fr Ophtalmol* 2020;43(3):228–236. DOI: 10.1016/j.jfo.2019.07.024.
- Klemm M. Deep sclerectomy. An alternative to trabeculectomy. *Ophthalmologe* 2015;112(4):313–318. DOI: 10.1007/s00347-014-3161-6.
- Rulli E, Biagioli E, Rivali I, et al. Efficacy and safety of trabeculectomy vs non-penetrating surgical procedures: a systematic review and meta-analysis. *JAMA Ophthalmol* 2013;131(12):1573–1582. DOI: 10.1001/jamaophthalmol.2013.5059.
- Gillmann K, Mansouri K. Minimally invasive glaucoma surgery: where is the evidence? *Asia Pac J Ophthalmol (Phila)* 2020;9(3):203–214. DOI: 10.1097/APO.0000000000000294.
- Buffault J, Baudouin C, Labbé A. XEN® gel stent for management of chronic open angle glaucoma: a review of the literature. *J Fr Ophtalmol* 2019;42(2):e37–e46. DOI: 10.1016/j.jfo.2018.12.002.
- Gillmann K, Bravetti GE, Rao HL, et al. Combined and stand-alone XEN 45 gel stent implantation: 3-year outcomes and success predictors. *Acta Ophthalmol* 2020;99(4):e531–e539. DOI: 10.1111/aos.14605.
- Kaluźny JJ, Grzanka D, Wiśniewska H, et al. Intrasclear outflow after deep sclerectomy with absorbable and non-absorbable implants in the rabbit eye. *Med Sci Monit* 2012;18(10):BR402–BR408. DOI: 10.12659/msm.883480.
- Sanchez E, Schnyder CC, Mermoud A. Comparative results of deep sclerectomy transformed to trabeculectomy and classical trabeculectomy. *Klin Monatsbl Augenheilkd* 1997;210(5):261–264. DOI: 10.1055/s-2008-1035050.
- Hyams M, Geyer O. Iris prolapse at the surgical site: a late complication of nonpenetrating deep sclerectomy. *Ophthalm Surg Lasers Imag* 2003;34(2):132–135. DOI: 10.3928/1542-8877-20030301-10.
- Eldaly MA, Bunce C, Elsheikha OZ, et al. Non-penetrating filtration surgery versus trabeculectomy for open-angle glaucoma. *Cochrane Database Syst Rev* 2014(2):CD007059. DOI: 10.1002/14651858.CD007059.pub2.
- Gabai A, Cimarosti R, Battistella C, et al. Efficacy and safety of trabeculectomy versus nonpenetrating surgeries in open-angle glaucoma: a meta-analysis. *J Glaucoma* 2019;28(9):823–833. DOI: 10.1097/IJG.0000000000001323.
- Holmes D, Hui MMP, Clement C. Comparison of early versus late laser goniopuncture following deep sclerectomy for the management of open-angle glaucoma. *Br J Ophthalmol* 2020;104(10):1384–1389. DOI: 10.1136/bjophthalmol-2019-315392.
- Mansouri K, Bravetti GE, Gillmann K, et al. Two-year outcomes of XEN gel stent surgery in patients with open-angle glaucoma. *Ophthalmol Glaucoma* 2019;2(5):309–318. DOI: 10.1016/j.ogla.2019.03.011.
- Gillmann K, Bravetti GE, Mermoud A, et al. XEN gel stent in pseudoexfoliative glaucoma: 2-year results of a prospective evaluation. *J Glaucoma* 2019;28(8):676–684. DOI: 10.1097/IJG.0000000000001295.
- Teus MA, Paz moreno-Arrones J, Castaño B, et al. Optical coherence tomography analysis of filtering blebs after long-term, functioning trabeculectomy and XEN® stent implant. *Graefes Arch Clin Exp*

- Ophthalmol 2019;257(5):1005–1011. DOI: 10.1007/s00417-019-04272-8.
20. Hamanaka T, Omata T, Sekimoto S, et al. Bleb analysis by using anterior segment optical coherence tomography in two different methods of trabeculectomy. *Invest Ophthalmol Vis Sci* 2013;2013(54):6536–6541. DOI: 10.1167/iops.13-12439.
 21. Tominaga A, Miki A, Yamazaki Y, et al. The assessment of the filtering bleb function with anterior segment optical coherence tomography. *J Glaucoma* 2010;19(8):551–555. DOI: 10.1097/IJG.0b013e3181ca76f3.
 22. Yu DY, Morgan WH, Sun X, et al. The critical role of the conjunctiva in glaucoma filtration surgery. *Prog Retin Eye Res* 2009;28(5):303–328. DOI: 10.1016/j.preteyeres.2009.06.004.
 23. Lee YS, Wu SC, Tseng HJ, et al. The relationship of bleb morphology and the outcome of needle revision with 5-fluorouracil in failing filtering bleb. *Med (Baltimore)* 2016;95(36):e4546. DOI: 10.1097/MD.00000000000004546.
 24. Wagner FM, Schuster AK, Emmerich J, et al. Efficacy and safety of XEN®-implantation vs. trabeculectomy: data of a “real-world” setting. *PLoS ONE* 2020;15(4):e0231614. DOI: 10.1371/journal.pone.0231614.