BACK TO THE FUTURE

ITERATIONS IN TOOLS AND TECHNIQUE OVER TIME

Exploring the outcomes of stent designs and implantation.

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The Xen Gel Stent (Allergan) was designed using the Hagen-Poiseuille equation, which enables the calculation of resistance to flow through a tube. Several variables are included in the equation, such as the length and diameter of the tube, both of which affect the final resistance. To explore varying levels of IOP control, three models of the Xen were initially developed, with internal lumen diameters of 45, 63, and 140 µm. Ultimately, the smallest, Xen 45, was approved by the FDA in 2016.

Several investigations of the Xen 63 have been conducted, and others are underway. This article reviews some of the outcomes found to date with this larger-lumen implant.

A LOOK AT THE DATA

In 2019, Lenzhofer et al[1] published the results of a prospective, nonrandomized, multicenter study with sites in Austria, Canada, and Germany. A total of 64 patients with open-angle glaucoma underwent implantation of the Xen 63 without the use of mitomycin C (MMC). The investigators found that mean best-medicated IOP decreased from 22.5 ±4.2 mm Hg at baseline to 13.4 ±3.1 mm Hg at 4 years postoperatively (-40%; n = 34; P = .001). The mean number of IOP-lowering medications decreased significantly from 2.4 ±1.3 preoperatively to 1.2 ±1.3 postoperatively (-50%; n = 34; P < .001). Visual field mean deviation showed no significant change between preoperative and postoperative examinations. The complete surgical failure rate per year was 10%, which is comparable to that of other filtration surgeries.

In 2020, Fernández-Garcia et al[2] published the results of a retrospective comparison of 40 patients who received the Xen 45 and 34 patients who received the Xen 63, with MMC used as an adjunctive agent (0.1 mL of a concentration of 0.02 mg/mL). The investigators found that, in the Xen 45 group, IOP decreased from 18.02 ±5.23 mm Hg preoperatively to 13.81 ±1.88 mm Hg, 14.80 ±2.23 mm Hg, and 14.62 ±1.90 mm Hg at 1, 2, and 3 years, respectively (P < .001). In the Xen 63 group, IOP decreased from 19.00 ±6.11 mm Hg preoperatively to 15.47 ±2.45 mm Hg, 14.66 ±2.45 mm Hg, and 15.46 ±2.48 at 1, 2, and 3 years, respectively (P < .001). The number of glaucoma medications decreased postoperatively in both groups. The mean reductions in medication use at 1, 2, and 3 years amounted to 70%, 74.3%, and 37.5%, respectively, in the Xen 45 group and 75%, 79.8%, and 71.9%, respectively, in the Xen 63 group. The study authors stated, "When comparing the outcomes for the two groups, the differences did not prove to be statistically significant. More than 90% of the procedures included in the study (using either gel-stent device) were completed without any noteworthy complications."

In 2021, Lavin-Dapena et al[3] conducted a prospective, nonrandomized, single-center study of 11 eyes of 11 patients with open-angle glaucoma who underwent implantation of the Xen 63 and were observed for 5 years. Two eyes (18.2%) underwent Xen

AT A GLANCE

- To explore varying levels of IOP control, three models of the Xen Gel Stent (Allergan) were initially developed, with internal lumen diameters of 45 µm, 63 µm, and 140 µm. Ultimately, the smallest, Xen 45, was approved by the FDA.
- Changes to the implantation procedure for the Xen Gel Stent have been made over time, primarily related to the injector, the use of mitomycin C, and the surgical technique itself.
- Several investigations of Xen 63 implantation using the modern approach have been conducted, and others are underway.

implantation alone, and nine eyes (81.8%) underwent Xen implantation combined with cataract extraction without the use of MMC. The investigators found that the median IOP reduction was 17.7% (-13.3% to 34.9%). At the conclusion of the study, nine eyes (81.8%) had an IOP of 18 mm Hg or less, six of them on no medication. Six eyes (54.6%) achieved an IOP reduction of 20% or more. Compared to baseline, a significant reduction in the number of ocular hypotensive drugs occurred (P = .0039). No treatment-related serious adverse events were reported. Early postoperative complications included diplopia (1 eye), blood in epithelium (2 eyes), ocular hypertension (one eye), corneal edema (1 eye), folds in Descemet membrane (1 eye), and contact between the implant and the iris (1 eye). All the adverse events were successfully resolved without sequalae. One eye required bleb needling.

CURRENT TECHNIQUE AND DATA

Several changes to the implantation of the Xen Gel Stent have been made over time, primarily related to the injector, the use of MMC, and the surgical technique itself. Some evidence on the outcomes of Xen 63 implantation using the current approach is available.

In June, Fea et al[4] published 18-month clinical outcomes of a retrospective clinical study of consecutive patients who underwent implantation of the Xen 63, either as a standalone procedure or in conjunction with phacoemulsification. MMC was used in all cases. Twenty-three eyes of 23 patients were included in the analysis. The investigators found that IOP was significantly lowered in these patients, from 27.0 ±7.8 mm Hg preoperatively to 14.1 ±3.4 mm Hg postoperatively. A total of 14 eyes (77.8%) and 11 eyes (61.1%) had an IOP of 16 mm Hg or less and 14 mm Hg or less, respectively, without glaucoma medication. The mean number of glaucoma medications was significantly reduced from 2.3 ±0.9 at baseline to 1.0 ±1.4 at 18 months (P = .0020). Four eyes (17.4%) underwent a needling procedure, and four eyes (17.4%) underwent additional surgeries.

In an earlier analysis of their 3-month data, Fea et al[5] commented on the outer and inner diameters of the initial Xen 63 compared with the "new" Xen 63 (implanted with the current technique) and the Xen 45. They noted, "The former Xen 63 device was inserted by using a 25-gauge needle injector (with an outer diameter of 0.5144 mm), while the new Xen 63 device is inserted by using a 27-gauge needle injector (with an outer diameter of 0.4128 mm, which is 19.8% smaller). As compared to [the] Xen 45 implant, the outer diameter of [the] Xen 63 is only 12% greater, while the inner diameter is 1.4 times greater. Since the new Xen 63 and the Xen 45 devices are inserted by using a [27-gauge] injector needle, the side flow with the Xen 63 is reduced compared with the Xen 45." ■

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