A Comparison of Clinical Outcomes After XEN Gel Stent and EX-PRESS Glaucoma Drainage Device Implantation

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Precis: Although the XEN stent offers a lower risk of hypotony and choroidal effusions with fewer clinic visits postoperatively, its surgical success rate was inferior to the EX-PRESS shunt.

Purpose: To compare the clinical efficacy and safety outcomes of the XEN stent and EX-PRESS glaucoma drainage device in glaucomatous eyes.

Materials and Methods: One hundred eyes from 88 patients underwent ab interno XEN stent or EX-PRESS shunt implantation (52 XEN and 48 EX-PRESS) for uncontrolled glaucoma at the University of Colorado Eye Center. The primary outcome was surgical success defined as intraocular pressure (IOP) ≥ 6 and ≤ 18 mm Hg, without reoperation for uncontrolled glaucoma, loss of light perception, or use of glaucoma medications (complete success). Secondary outcomes were the same requirements allowing for medications (qualified success), mean IOP, medication use, adverse events, and number of postoperative clinic visits in the first 3 months.

Results: Baseline characteristics including glaucoma type and severity were similar between groups, with the exception of XEN patients having fewer men (17% vs. 46%), older patients (median age, 78 vs. 68), and a higher percentage of white patients (89% vs. 69%). Adjusted hazard ratio of failure of XEN relative to EX-PRESS was 3.94 (95% confidence interval, 0.40-6.38, P = 0.001) for complete success and 1.61 (95% confidence interval, 0.40-6.38, P = 0.501) for qualified success. There were significantly fewer postoperative clinic visits during the first 3 months in the XEN group (5.3 vs. 9.1 visits, P < 0.001). The incidence of serous choroidal effusions and hypotony was significantly less after XEN compared with EX-PRESS (1 vs. 9, P = 0.023 and 15 vs. 25, P = 0.023, respectively). Three XEN stents (5.8%) required removal.

Conclusions: In this population, although the XEN stent offers a better safety profile and fewer postoperative clinic visits, complete surgical success was inferior to the EX-PRESS shunt.

Glaucoma is a disease characterized by progressive deterioration of the optic nerve and concomitant visual field loss. It remains the leading cause of irreversible blindness worldwide.¶ Surgical intervention for glaucoma has focused on increasing aqueous outflow to lower intraocular pressure (IOP). Traditionally, this has been through the creation of a fistulous pathway between the anterior chamber (AC) and the subconjunctival space generating a filtration bleb. Since the late 1960s, trabeculectomy has been the standard filtering procedure to accomplish this. Although effective, trabeculectomy has a number of limitations including bleb fibrosis and failure, need for subsequent wound modifications, and vision-threatening complications including hypotony, choroidal detachments, and endophthalmitis.¶

Approved by the Food and Drug Administration in 2002, the EX-PRESS glaucoma drainage device (Alcon, Fort Worth, TX) was introduced as a filtration surgery alternative to trabeculectomy.¶ It was a nonvalved stainless steel shunt with a 50- or 200-μm lumen designed to be implanted underneath the conjunctiva to establish a consistent opening between the AC and the subconjunctival space. However, initial use of the device alone failed to prevent hypotony prompting an alteration of technique whereby a 50-μm lumen device is implanted under a partial-thickness scleral flap. This current technique is often seen as a modification of traditional trabeculectomy rather than a distinct surgical procedure. Clinical studies have found the EX-PRESS shunt can achieve similar IOP-lowering efficacy to trabeculectomy, with some studies suggesting a mild safety benefit.¶

The XEN stent (Allergan, Irvine, CA) is a porcine gelatin stent designed to establish a subconjunctival filter for aqueous through a less invasive, ab interno approach.¶ The stent dimensions of an internal diameter of 45 μm and length of 6 mm were uniquely designed to be flow limiting on the basis of the Hagen-Poiseuille equation.¶ The stent is therefore theoretically capable of preventing hypotony without the need for sutures, a scleral flap, or a valve mechanism. The XEN stent was approved for use in the United States in 2016 and is implanted through a 27-G needle without the need for conjunctival dissection or creation of an iridectomy or ostomy.¶ Initial clinical reports have found significant IOP reductions with a favorable safety profile compared with trabeculectomy. However, the need for postoperative revision of the XEN stent because of...
fibrosis is common. To date, only 3 studies have been published that define the XEN stent’s utility in reducing IOP and its risk profile in the treatment of glaucoma compared with trabeculectomy, and none have compared it with the EX-PRESS device. This study aims to compare the clinical efficacy and adverse outcomes of the XEN stent and EX-PRESS device in patients with glaucoma.

MATERIALS AND METHODS

Approval for this study was obtained from the Colorado Multiple Institutional Review Board and the protocol adhered to the tenets of the declaration of Helsinki. A retrospective chart review was performed on all patients who underwent XEN stent or EX-PRESS shunt implantation between February 2017 and June 2019 for uncontrolled glaucoma at the Sue Anschutz-Rodgers Eye Center at the University of Colorado School of Medicine. Glaucoma severity was classified on the basis of the International Classification of Diseases, 10th revision (ICD-10) staging system. All surgeries were performed by 1 of 5 glaucoma fellowship-trained and board-certified ophthalmologists. The indications for surgery in all cases were uncontrolled IOP despite maximally tolerated medications or confirmed progression of glaucomatous disease. Cases were identified using procedure billing codes and confirmed during manual chart review. Preoperative baseline characteristics including patient demographics and ocular history were collected and follow-up data was collected. Inclusion criteria included any eye undergoing XEN or EX-PRESS implantation as a standalone procedure or in combination with cataract surgery. Exclusion criteria included lack of at least 1 month of follow-up or other additional surgeries performed at the same time.

For the XEN procedure, topical anesthesia was administered in the form of topical proparacaine, followed by 2% lidocaine gel, and balbar paracentesis was placed to the AC deepened with viscoelastic. A second inferotemporal wound was placed and the inserter needle with implant was introduced into the AC through the main wound and advanced to the superonasal angle. The needle was then passed through the scleral wall until noted in the subconjunctival space. The implant was then deployed by advancing the inserter sliding mechanism. All implants were placed through this ab interno approach according to manufacturer guidelines as described previously. Following implantation, 0.2 mL of a 50:50 mixture of 2% lidocaine and 0.4 mg/mL mitomycin C was injected into the subconjunctival/subtenons space superiorly. Finally, the viscoelastic was irrigated from the AC and the wounds were sealed. Prednisolone acetate 1% was used 4 times daily for one week, and then tapered over 4 to 8 weeks according to the resolution of inflammation

acetate 1% 4 to 6 times daily for 1 week, and then tapered over 6 to 12 weeks according to the resolution of inflammation.

For both procedures postoperatively, a topical fluoroquinolone antibiotic was used 4 times daily for a total of 1 week. Glaucoma medications were restarted on the basis of disease severity and target IOP at the surgeon’s discretion.

In accordance with the World Glaucoma Association’s guidelines, each subject’s visual acuity (VA), IOP, glaucoma medications, and complications were recorded for day 1, week 1, month 1, month 3, month 6, and year 1 after surgery. The primary outcome was surgical success defined as an IOP ≥6 and ≤18 mm Hg, without reoperation for uncontrolled glaucoma, loss of light perception, device removal, or use of glaucoma medications (complete success). An IOP outside this range for ≥2 consecutive study visits was considered failure.

Secondary outcomes were the same requirements allowing for medications (qualified success), mean IOP, IOP reduction, medication use, complications, postoperative interventions, and number of clinic visits in the first 3 months and 1 year postoperatively. Complications recorded included choroidal effusion, hyphema, hypotony (≥1 visit with an IOP <6 mm Hg), persistent hypotony (>2 study visits with IOP <6 mm Hg), wound leak, device exposure, shallow AC requiring reformation, and vision loss >2 lines.

VA was defined as best-corrected visual acuity when present, and pinhole VA when VA with correction was missing. For postoperative interventions, “needling” referred to the inoffice revision of bleb for scarring and fibrosis, whereas “bleb revision” referred to a return to the operating room for surgical revision of scarring, wound leak, or need for other wound revision, neither of which precluded surgical success.

Patient and ocular baseline characteristics were compared between the XEN and EX-PRESS devices. Statistical analysis was performed using SAS software (version 9.4, SAS Institute Inc., Cary, NC), and figures were generated using GraphPad Prism (version 8.3.0, GraphPad Software, San Diego, CA). A logistic regression model with generalized estimating equations was used to compare the 2 groups and account for the fact that a patient could have 2 eyes included in the study. Kaplan-Meier curves were constructed for each type of procedure. Patient values were censored when patients were lost to follow-up before 1-year postoperatively. Crude and adjusted hazard ratios (HRs) were estimated using Cox proportional hazards modeling with a sandwich variance estimate to account for the potential of 2 eyes per subject. Because our 2 surgery groups differed in terms of demographic characteristics and prior surgery, a sensitivity analysis was performed for our main outcomes of complete and qualified success. This analysis included only white patients aged 56 to 87 years old without prior surgery. For all analyses, P values of <0.05 were considered statistically significant.

RESULTS

A total of 100 eyes from 88 patients were evaluated: 52 eyes from 45 patients in the XEN group and 48 eyes from 43 patients in the EX-PRESS group. One eye was excluded from the EX-PRESS group that had previously undergone the XEN procedure. Baseline characteristics were similar between groups with no significant difference in mean preoperative VA, IOP, and number of medications as shown in Table 1. However, the XEN group had a higher number of white patients (88.5% vs. 68.8%, P = 0.03), older mean age (77.8 ± 9.5 vs. 67.5 ± 12.7 y, P < 0.001), and women (82.7% vs. 68.8% P = 0.05).
TABLE 1. Baseline Characteristics for Eyes Undergoing XEN or EX-PRESS Placement

|                          | XEN (n = 52) | EX-PRESS (n = 48) | P     |
|--------------------------|--------------|-------------------|-------|
| **Patient demographics** |              |                   |       |
| Age (y), mean            | 77.8 ± 9.5   | 67.5 ± 12.7       | <0.001|
| Left eye                 | 26 (50.0%)   | 26 (54.2%)        | 0.64  |
| Male                     | 9 (17.3%)    | 22 (45.8%)        | —     |
| Female                   | 43 (82.7%)   | 26 (54.2%)        | 0.004 |
| Ethnicity                |              |                   |       |
| White                    | 46 (88.5%)   | 33 (68.6%)        | 0.03* |
| African American         | 0            | 5 (10.4%)         | —     |
| Hispanic                 | 1 (1.9%)     | 4 (8.3%)          | —     |
| Other                    | 5 (9.6%)     | 6 (12.5%)         | —     |
| **Preop VA**             |              |                   |       |
| Preop Logmar, Mean       | 0.258 ± 0.3  | 0.342 ± 0.57      | 0.26  |
| Range                    | 0-1.4        | -0.125 to 2.9     |       |
| Worse than 20/50         | 16 (30.8%)   | 12 (25.0%)        | 0.54  |
| **Preop IOP, mm Hg**     |              |                   |       |
| Mean                     | 21.4 ± 8.3   | 18.9 ± 7.0        | 0.13  |
| Range                    | 8.5-44       | 8.0-43            |       |
| **Preop medications**    |              |                   |       |
| Mean                     | 2.8 ± 1.2    | 3.1 ± 1.4         | 0.37  |
| Range                    | 0-6          | 0-6               |       |
| **Glaucoma type**        |              |                   |       |
| Primary open angle       | 35 (67.3%)   | 34 (70.8%)        | 0.67† |
| Pseudoxfolliation         | 7 (13.5%)    | 1 (2.1%)          |       |
| Pigmentary               | 1 (1.9%)     | 2 (4.2%)          |       |
| Chronic angle closure    | 1 (1.9%)     | 2 (4.2%)          |       |
| Normal tension           | 6 (11.5%)    | 7 (14.6%)         |       |
| Juvenile                 | 0            | 2 (4.2%)          |       |
| Secondary/steroid        | 2 (3.8%)     | 0                 |       |
| **Cup-to-disc ratio, mean** | 0.83 ± 0.13 | 0.84 ± 0.09      | 0.65  |
| (range)                  |              |                   |       |
| **Preoperative MD, mean**|              |                   |       |
| (range)                  | -12.1 ± 7.0  | -12.7 ± 8.9       | 0.75  |
| Preoperative MD, mean    | -27.26 to -30.76 | 0.11  | 1.96 |
| (range)                  |              |                   |       |
| **Disease severity, nį** |              |                   |       |
| Mild                     | 2 (3.8%)     | 0                 | —     |
| Moderate                 | 14 (26.9%)   | 11 (22.9%)        | —     |
| Severe                   | 32 (61.5%)   | 36 (75.0%)        | 0.33† |
| Indeterminate            | 4 (7.7%)     | 1 (2.1%)          |       |
| **Previous surgery**     |              |                   |       |
| Laser trabeculoplasty    | 27 (51.9%)   | 19 (39.6%)        | 0.24  |
| Endoscopic               | 12 (23.1%)   | 10 (20.8%)        | 0.80  |
| Cyclophotocoagulation    |              |                   |       |
| Nonvalved tube           | 3 (5.8%)     | 0                 |       |
| iStent                   | 9 (17.3%)    | 5 (10.4%)         | 0.32  |
| Cataract                 | 49 (94.2%)   | 34 (70.8%)        | 0.007 |
| Goniotomy                | 19 (38.5%)   | 16 (33.3%)        | 0.75  |
| Other                    | 16 (30.8%)   | 16 (33.3%)        | —     |

* P value compares Caucasian versus other race/ethnic groups combined.
† P value compares 2 groups of POAG, PXF, pigmentary, normal tension to CAGC, juvenile, secondary/steroid.
‡ P value compares severe glaucoma with combined mild/moderate cases.
§ Indeterminate and unspecified glaucoma are not included in the statistical testing.
∥ P value compared severe glaucoma with both moderate/mild combined.
* Eyes may have had > 1 prior surgery.
** IOP indicates intraocular pressure; MD, mean deviation; VA, visual acuity.

Previous surgery are not included in the statistical testing.

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vs. 54.2%, P = 0.004]. Glaucoma type and severity were similar between study groups. Aside from a greater frequency of eyes with previous cataract surgery in the XEN group (94.2% vs. 70.8%, P = 0.007), there were no significant differences in previous ophthalmologic procedures performed. One patient in the XEN group had a combined surgery with cataract extraction. All other implants were standalone procedures.

The unadjusted Kaplan-Meier survival curves for IOP thresholds of 6 to 12, 6 to 15, 6 to 18, and 6 to 21 mm Hg are shown in Figures 1 and 2 with corresponding scattergrams at 1 year in Figure 3. Complete success at 1 year comparing the XEN with EX-PRESS groups was 10.9% vs. 48.9% for 6 to 12 mm Hg, 15.6% vs. 55.6% for 6 to 15 mm Hg, 17.8% vs. 55.6% for 6 to 18 mm Hg, and 17.8% vs. 55.6% for the 6 to 21 mm Hg threshold, respectively. Qualified success comparing XEN with EX-PRESS was 30.2% vs. 62.2% for 6 to 12 mm Hg, 65.8% vs. 73.3% for 6 to 15 mm Hg, 75.0% vs. 79.6% for 6 to 18 mm Hg, and 77.5% vs. 81.8% for the 6 to 21 mm Hg threshold, respectively. Both crude and adjusted HRs of failure in the XEN group were compared with the EX-PRESS group as shown in Table 2. Failure because of persistent hypotony occurred more frequently in the EX-PRESS group (1 vs. 4). Failure because of reoperation was higher in the XEN group (9 vs. 4). Adjusted HR for the XEN compared with EX-PRESS surgeries was significantly elevated with all thresholds for complete success, but only the 6 to 12 mm Hg threshold for qualified success. The sensitivity analysis that included the 67 white patients aged 56 to 87 years with no prior surgery had similar mean ages across the 2 surgery groups (XEN: 76.9, Ex-press: 72.4 y) and resulted in similar HRs and statistical findings for complete and qualified success (Supplemental Table 1, Supplemental Digital Content 1, http://links.lww.com/IJG/A535). For comparison with the tube versus trabeculectomy studies, an additional criterion was evaluated with failure defined as IOP of > 21 mm Hg or reduced < 20% from baseline, IOP of ≤ 5 mm Hg, reoperation for glaucoma, or loss of light perception vision at least 3 months after surgery. Using this definition, qualified success (allowing for medications) was 35% in the XEN group and 59% in the EX-PRESS group (HR, 2.45 [0.51-11.9]; P = 0.265). Complete success was 14% for XEN and 46% for EX-PRESS (HR, 4.56 [1.29-16.2]; P = 0.019).

The number and type of postoperative procedures for both the XEN and EX-PRESS groups are shown in Table 3. All bleb revisions were performed because of uncontrolled IOP and scarring in all but one procedure in the EX-PRESS group, which required wound closure because of conjunctival retraction. There was no significant difference between groups for intraoperative bleb revision (11 vs. 13, P = 0.588), and while needling was more frequent after XEN compared with EX-PRESS, the difference did not reach statistical significance (15 vs. 9, respectively, P = 0.262). The majority of eyes in the EX-PRESS group, however, did undergo laser suture lysis (n = 29, 60% of eyes, 47 total procedures), increasing the number of total postoperative procedures. The number of clinic visits was found to be significantly higher in the EX-PRESS group at 3 months (median 8.0 [range, 4 to 16] vs. 5.0 [2 to 13], Wilcoxon rank sum; P < 0.0001) and 1 year postoperatively (median 14 (range, 8 to 30) vs. 10 (range, 4 to 21), P = 0.0003).

The mean IOP and number of glaucoma medications over the course of follow-up is shown in Figure 4A and B. Mean IOP was reduced in the XEN group from 21.4 ± 1.2 mm Hg at baseline to 13.0 ± 0.6 mm Hg (P < 0.0001) at 1 year with a decrease in the median number of medications from 2.8 ± 0.2 to 1.5 ± 0.2 (P = 0.002). In the EX-PRESS group, mean IOP was reduced from 18.9 ± 1.1 to 11.5 ± 0.8 mm Hg (P < 0.0001) at 1 year with a decrease in mean medications from 3.1 ± 0.2 to 0.5 ± 0.2 (P < 0.0001). There was no significant difference in

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FIGURE 1. Kaplan-Meier survival curves for complete success at various IOP thresholds for the XEN and EX-PRESS groups: (A) 6 to 12 mm Hg, (B) 6 to 15 mm Hg, (C) 6 to 18 mm Hg, (D) 6 to 21 mm Hg. IOP indicates intraocular pressure.

FIGURE 2. Kaplan-Meier survival curves for qualified success at various IOP thresholds for the XEN and EX-PRESS groups: (A) 6 to 12 mm Hg, (B) 6 to 15 mm Hg, (C) 6 to 18 mm Hg, (D) 6 to 21 mm Hg. IOP indicates intraocular pressure.
TABLE 2. Crude and Adjusted Hazard Ratios for Failure Using Variable Intraocular Pressure Guidelines in XEN Relative to EX-PRESS Eyes

| Intraocular Pressure (mm Hg) | Crude | Adjusted* | P      |
|------------------------------|-------|-----------|--------|
| Complete success             |       |           |        |
| 6-12                         | 3.52  | (1.84-6.73) | 0.0001 | 4.73  | (1.97-11.3) | 0.0005 |
| 6-15                         | 3.37  | (1.75-6.46) | 0.0003 | 4.08  | (1.78-9.40) | 0.0009 |
| 6-18                         | 3.15  | (1.65-6.00) | 0.0005 | 3.94  | (1.73-9.00) | 0.001  |
| 6-21                         | 3.15  | (1.65-6.00) | 0.0005 | 3.94  | (1.73-9.00) | 0.001  |
| Qualified success            |       |           |        |
| 6-12                         | 2.40  | (1.25-4.62) | 0.008  | 2.94  | (1.21-7.14) | 0.017  |
| 6-15                         | 1.23  | (0.52-2.90) | 0.641  | 1.49  | (0.48-4.58) | 0.488  |
| 6-18                         | 1.14  | (0.43-3.00) | 0.794  | 1.61  | (0.40-6.38) | 0.501  |
| 6-21                         | 1.13  | (0.42-3.00) | 0.809  | 1.87  | (0.41-8.44) | 0.418  |

*Adjusted for age, gender, and White race.

FIGURE 3. Scattergram demonstrating relationship of preoperative IOP and postoperative IOP at 1 year with and without medications for the (A) XEN and (B) EX-PRESS shunts. IOP indicates intraocular pressure.
and choroidal effusions likely contributed to fewer clinic visits. The increase in clinic visits after EX-PRESS is also reflected in the need for more postoperative procedures in that group; however, it should be noted this difference is largely because of laser suture lysis, as there was no significant difference in the rate of needling or bleb revision between the 2 groups.

To date, 3 studies have been published that compare the XEN stent with another glaucoma surgery. In 2017, Schlenker et al published a retrospective study comparing eyes treated with the XEN stent (n = 185) or trabeculectomy (n = 169) at 8 research sites over the course of 30 months of follow-up.11 In contrast to our data, the authors found no significant difference in HR for failure between groups, with failure defined as 2 consecutive visits with <6 mm Hg with vision loss or >17 mm Hg without glaucoma medications at least 1 month after surgery. However, after a post hoc power calculation, it was revealed with 80% power that there was a 15% higher risk of cumulative failure at 30 months in the XEN group. A higher total postoperative intervention rate was found in the trabeculectomy group (165 vs. 117) and a higher rate of postoperative complications in the trabeculectomy group (30 vs. 22) that is similar to our data. In contrast to our data, another study found both XEN and trabeculectomy group (30 vs. 22) that is similar to our data. In our data, the authors found no significant difference in the rate of needling or bleb revision between the 2 groups. In the aforementioned study by Schlenker et al,11 43% of eyes in the XEN group underwent needling compared with 31% in the trabeculectomy group. In contrast, Marcos Parra et al12 found needling to occur in 20% of eyes in the XEN group and only 5% of the trabeculectomy group. In our data, 27% of eyes in the XEN group underwent needling compared with 19% in the EX-PRESS group; however, this difference was not significant (P = 0.143). When bleb revisions performed in the OR are combined with clinic needling procedures, the rate approaches that of the Schlenker study at 46% for XEN and 43% for EX-PRESS. Other studies have reported similar rates of needling after XEN implantation ranging from 16% to 47%,9,10,18

Multiple studies have shown similar outcomes in patients treated with the EX-PRESS shunt or traditional trabeculectomy. Our EX-PRESS outcomes are largely comparable with these data as well. Gonzalez-Rodriguez et al19 compared EX-PRESS (n = 32) and trabeculectomy (n = 31), finding no significant difference in success rates or IOP between the 2 procedures at 3 years of follow-up. Mean IOP was reduced from 22.6 ± 2.3 mm Hg to 12.5 ± 5.1 mm Hg at 2 years in the EX-PRESS group, and medication usage was lowered from 3.5 ± 0.9 to 0.4 ± 1.0 at 1 year, similar to the decreases seen at 1 year in our data. In a prospective, randomized controlled trial, Netland et al20 found no significant difference in success rates at 2 years, IOP limiting capability, medications, or VA when

### TABLE 3. Postoperative Interventions* After XEN and EX-PRESS Placement

| Intervention       | XEN  | EX-PRESS | P    |
|--------------------|------|----------|------|
| Needling           | 15   | 9        | 0.262|
| Bleb revision      | 11   | 13       | 0.558|
| Laser suture lysis | —    | 47       | —    |
| Device removal     | 3    | 0        | —    |

*Eyes may have had >1 intervention.

### TABLE 4. Complications After XEN and EX-PRESS Placement

| Complication              | XEN          | EX-PRESS     | P    |
|---------------------------|--------------|--------------|------|
| Choroidal effusion        | 1 (1.9%)     | 9 (18.8%)    | 0.022|
| Hyphema                   | 11 (21.2%)   | 6 (12.5%)    | 0.248|
| Hypotony                  | 15 (28.9%)   | 25 (52.1%)   | 0.023|
| Persistent hypotony*      | 1 (1.9%)     | 4 (8.3%)     | 0.179|
| Wound leak                | 5 (9.6%)     | 11 (22.9%)   | 0.077|
| Device exposure           | 1 (1.9%)     | 0            | —    |
| Shallow AC requiring reformation | 1 (1.9%) | 2 (4.2%) | 0.522|
| Vision loss > 2 lines     | 6 (11.5%)    | 8 (16.7%)    | 0.452|
| Device removal            | 3 (5.7%)     | 0            | —    |
| Total                     | 41           | 65           | —    |

*Persistent hypotony was defined at >2 study visits with IOP <6 mm Hg.

AC indicates anterior chamber; IOP, intraocular pressure.

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**FIGURE 4.** Change over time for (A) IOP and (B) number of glaucoma medications. *P < 0.05, **P < 0.01, ***P < 0.001, ****P < 0.0001. IOP indicates intraocular pressure.
comparing eyes treated with EX-PRESS (n = 59) or trabeculectomy (n = 61). A higher number of total postoperative complications were found in the trabeculectomy group, however. Another study by Good and Kahook4 that retrospectively compared EX-PRESS (n = 35) with trabeculectomy (n = 35) found a similar mean IOP at 6 months and slightly higher mean IOP in the EX-PRESS group at 1 year and final follow-up. Nonetheless, percent IOP lowering was similar between groups. In addition, a safety advantage was found in the EX-PRESS group, demonstrating fewer cases of early postoperative hypotony and hyphema and faster recovery of VA. Interestingly, the authors also reported fewer postoperative visits in the EX-PRESS group. Our study found a lower number of postoperative visits in the XEN group compared with EX-PRESS.

Our outcomes after XEN stent surgery are comparable with previous studies in the literature. In a retrospective study published in 2019 by Gabbay et al.,18 151 eyes were analyzed that underwent XEN stent surgery between 2015 and 2017. This study found an average IOP reduction from 22.1 ± 6.5 mm Hg at baseline to 15.4 ± 5.9 mm Hg at 1 year of follow-up. They also found that medication use was reduced from 2.8 ± 1.1 glaucoma medications at baseline to 0.3 ± 0.7 at 1 year. In comparison, our study found an IOP reduction on average from 21.4 ± 1.2 mm Hg at baseline to 12.6 ± 0.6 mm Hg in the XEN group. Although eyes in our study achieved a lower IOP, they were also taking more glaucoma medications (mean 1.7 ± 0.3 at 1 y). Interestingly, Gabbay and colleagues found 86% of patients to be free from failure at 1 year with success defined as a reduction in IOP >20% without additional glaucoma medications or a reduction in medications without an increase in baseline IOP. The lower failure rate compared with our data is likely due in part to these less stringent criteria for success.

Our study has several limitations that should be noted. First, the retrospective design precludes standardized enrollment criteria, uniform follow-up visit dates, and randomization that may cause bias between the 2 groups. Indeed, there were notable differences in the patient demographics between groups. Namely, patients in the XEN group were on average older, more likely to be white, and a higher proportion were female individuals compared with the EX-PRESS group. These demographic differences may have been in part because of differences in perceived efficacy or safety of each procedure among these groups. Surgeon experience and available clinical evidence have suggested a higher rate of scarring and failure with XEN because of its nature as a smaller stent.24 Therefore, patients at the highest risk of scarring and failure (men, African American, young) may have been less likely to be recommended the XEN stent.22–23 However to address this, a sensitivity analysis was performed that included only white patients aged 56 to 87 years with no prior surgery and resulted in similar HRs for failure. The fact that surgery was performed by 5 different surgeons also prevented a fully standardized surgical approach. In addition, the longer postoperative steroid regimen in the EX-PRESS group may have contributed to differing outcomes. Nonetheless, the groups were similar in terms of ocular characteristics and we were able to adjust for the different demographics to strengthen our findings. In addition, our study had a limited sample size with a significant number of patients lost to follow-up by study end (11 XEN, 4 EX-PRESS). Finally, our follow-up is limited to 1 year.

Future analysis considering longer-term data is warranted to determine the comparative durability of these procedures in the management of glaucoma. In addition, prospective, randomized trials comparing groups of more similar patient and ocular characteristics and a more diverse array of ethnicities under a larger sample size will be able to determine the impact, if any, that these variables contribute to the success of the XEN and EX-PRESS surgeries for the treatment of glaucoma.

In conclusion, both the XEN stent and EX-PRESS shunt devices are effective options for the reduction of IOP and medication use in uncontrolled glaucoma. Although mean IOP achieved at 1 year was similar, XEN-treated eyes required more medications and had a higher rate of surgical failure compared with the EX-PRESS shunt. Although the EX-PRESS shunt was capable of maintaining consistently lower IOP, it also resulted in more hypotony-related complications and required more postoperative procedures and clinic visits. Determining which patients will be best served by the XEN stent should largely be based on what goal IOP is desired, in addition to the surgeon and patient tolerance for complications and follow-up required. In the future, prospective, randomized trials of longer duration are needed to confirm these findings.

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