Comparison of outcomes between Aurolab aqueous drainage implant placed in the superotemporal versus inferonasal quadrant

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ABSTRACT

Aim To determine the outcomes of Aurolab aqueous drainage implant (AADI) placed in the superotemporal versus the inferonasal quadrant in adult eyes with refractory glaucoma.

Methods This was a retrospective study of eyes that had AADI placement and completed a minimum of 2-year follow-up. The choice of the quadrant was at the surgeon's discretion and mainly depended on the amount of scarring and conjunctival mobility. The cumulative failure rate of the AADI was defined as intraocular pressure (IOP) >21 mm Hg or not reduced by 20% below baseline on two consecutive follow-up visits after 3 months, IOP ≤5 mm Hg on two consecutive follow-up visits after 3 months, reoperation for glaucoma or a complication, or loss of light perception vision.

Results We included 84 eyes with AADI in the inferonasal quadrant versus 69 eyes in the superotemporal quadrant. A significant drop in IOP was seen in both groups (18.4±10.4 mm Hg in the inferonasal group vs 17.7±11.1 mm Hg in the superotemporal group; p=0.63) at 3-month follow-up and this was maintained until last follow-up. Best-corrected visual acuity, IOP, number of IOP-lowering medications and complications were similar between the two groups at all time points. The cumulative success rate at 2-year follow-up without IOP-lowering medications was 57.1% (47.1%–68.1%) in the inferonasal group and 50.7% (39.8%–63.1%) in the superotemporal group (p=0.47).

Conclusions Inferonasal AADI placement appears to be an equally safe and effective surgical option compared with superotemporal AADI placement and may be helpful in certain clinical situations.

INTRODUCTION

Management of refractory glaucoma is challenging and may require multiple surgeries to control intraocular pressure (IOP) and salvage vision.[1] Conventional trabeculectomy with mitomycin C is usually the first surgery of choice in eyes with primary glaucoma, while aqueous shunts are directly reserved for eyes known to have a high risk of failure of trabeculectomy.[2] The utilisation of aqueous shunts has increased steadily in recent years, and many glaucoma surgeons are currently recommending these devices in eyes without prior incisional ocular surgery at low risk of filtration failure.[3] Although the Baerveldt glaucoma implant and the Ahmed glaucoma valve are the most widely used shunts with well-documented long-terms outcomes,[4] lower-cost devices such as the Aurolab aqueous drainage implant (AADI) have been recently introduced and have shown to have good efficacy and safety in a variety of conditions.[5–9]

The quadrant selected for aqueous shunt implantation is an important consideration in surgical planning. The two most preferred locations of shunt placement are the superotemporal quadrant and the inferonasal quadrant. The superotemporal quadrant is usually preferred for placement of single-plate implants due to ease of surgical exposure for placement of the end plate. However, certain clinical situations may require aqueous shunt implantation in a different quadrant. The inferonasal shunt placement is a popular alternative site. Limited studies have shown equivalent IOP-lowering with aqueous shunt placement in superior and inferior quadrants.[10–12] Similarly, different sizes of conjunctival forniceal recess may produce different rates of tube exposure, retraction and plate exposure in different quadrants.[11] Additionally, the risk of optic nerve impingement by the end plate[13] and postoperative diplopia are potentially different between superotemporal and inferonasal aqueous shunt placement.[14]

The AADI, a new non-valved aqueous shunt, has been shown to have good IOP-lowering effect at 4-year follow-up in adult eyes with refractory glaucoma.[5] However, its efficacy and safety have not been characterised when placed in the superotemporal versus inferonasal quadrants. In this retrospective study, we evaluate surgical outcomes with the AADI placed in different quadrants in a cohort of adult eyes with refractory glaucoma.

METHODS

Case records of all adult patients who underwent AADI surgery between January 2012 and December 2015 were identified from a computerised database using a standardised International Classification of Diseases, Ninth Revision coding, and data of those patients with a minimum of 2-year follow-up were included in the analysis.

Demographic data were extracted from the medical records, including age and gender. Baseline ocular characteristics were also recorded, which included best-corrected visual acuity (BCVA), type

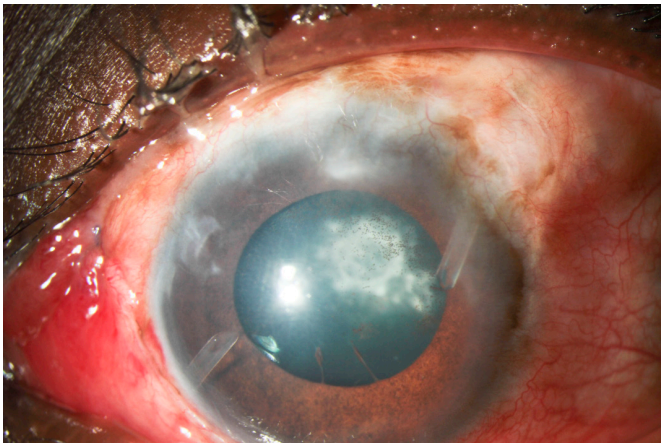

Figure 1 Inferonasal Aurolab aqueous drainage implant placement in an eye with a failed tube in the superotemporal quadrant.

of glaucoma, IOP, number of IOP-lowering medications, previous ocular surgery, automated visual field parameters including mean deviation and pattern standard deviation, and the date of AADI surgery. Intraoperative parameters recorded were the quadrant in which the AADI plate was placed and any complications noted during surgery. The choice of the quadrant was at the surgeon's discretion and mainly depended on the amount of scarring and conjunctival mobility. The IOP, number of IOP-lowering medications, BCVA, complications and reoperations were recorded on day 1, and at months 1, 3, 6, 9, 12, 18 and 24, and at last follow-up.

The surgical technique has been described in detail elsewhere.[5] In summary, after fashioning a fornix-based conjunctival flap, the superior and lateral recti muscles (for superotemporal implantation) or the inferior and medial recti muscles (for inferonasal implantation) were sequentially isolated, and the end plate of the AADI was placed beneath the adjacent muscle bellies and secured to the sclera 9–10 mm posterior to the limbus using two interrupted 9–0 nylon sutures (Aurolab, Madurai, India) through the fixation holes. After ligating the tube with 6–0 polyglactin sutures (Braided Coated Polyglactin 910 Violet; Ethicon, Johnson & Johnson India) at the tube–plate junction, the tube was trimmed to an appropriate length and introduced into the anterior chamber via a 23-gauge needle track initiated 2.5 mm posterior to the limbus. The tube was then secured to the sclera using interrupted 9–0 nylon. A piece of donor cornea or sclera was then secured over the tube entry site and the conjunctiva was reapproximated to the limbus with 8–0 polyglactin sutures (Aurolab) (figure 1).

Postoperatively topical antibiotics were prescribed four times daily for 4 weeks, topical steroid drops for 12 weeks in tapering dose and topical cycloplegic eye-drops once at night for 8 weeks.

Primary outcome measure

Failure was defined as IOP >21 mm Hg or not reduced by at least 20% below baseline on two consecutive follow-up visits after 3 months, IOP ≤5 mm Hg on two consecutive follow-up visits after 3 months, reoperation for glaucoma or a complication, or loss of light perception vision. Eyes that had not failed by the above criteria and were not receiving IOP-lowering medications were considered complete success, and those using IOP-lowering medications were qualified success. Reoperation for glaucoma or a complication was defined as additional surgery requiring a return to the operating room, including cyclodestruction surgery. Complications leading to loss of more than two lines on Snellen visual acuity on two consecutive visits were classified as vision-threatening.

Statistical analysis

All continuous variables were described as mean with SD or median with IQR, and group-wise comparisons were made between continuous variables using the Student's t-test or Wilcoxon rank-sum test for non-parametric variables. Categorical variables were described as proportions (n, %), and χ^2 test or Fisher's exact test was used to analyse group differences across categorical variables. Visual acuity was converted to logarithm of minimum angle of resolution for statistical analysis. The comparison of IOP between pre-AADI and post-AADI at different time intervals was carried out using one-way analysis of variance with Bonferroni adjustments.

Survival analysis was performed using failure of AADI as the censoring variable, and Kaplan-Meier curves were plotted to depict cumulative survival rates of superotemporal versus inferonasal AADI placement at various time points. Time to failure was defined either as the time from surgical treatment to the first of the two consecutive follow-up visits after 3 months in which the patient had persistent hypotony or uncontrolled IOP, or as the time from surgical treatment to repeat surgery for glaucoma. Differences in survival rates between the two implantation quadrants were determined using log-rank test. The probability of failure between the quadrants was also assessed using multivariable Cox proportional hazards models and displayed using HR with 95% CI. Covariates for the multivariable analysis were those which had $p<0.1$ in univariate analysis and were felt to influence the outcomes. Data were entered into Microsoft Excel and analysed using STATA (V.12.1, I/C) statistical analysis software package, and $p<0.05$ was considered statistically significant.

RESULTS

A total of 153 eyes of 153 patients with a minimum of 2-year follow-up were included in the analysis, including 84 (55%) eyes with AADI placement in the inferonasal quadrant and 69 (45%) in the superotemporal quadrant. A comparison of baseline characteristics of the two groups is shown in table 1. No significant differences were noted in any demographic or ocular features between the two groups.

The median preoperative IOP was 32 mm Hg (IQR=28–42 mm Hg) and ranged from 16 to 58 mm Hg, with a median of 3 IOP-lowering medications (IQR=3–4 medicines). The IOP reduced by 37% (median=20 mm Hg, IQR=14–30 mm Hg) at 1-month follow-up and by 50% at 1 year (median=16 mm Hg, IQR=12–22 mm Hg) ($p<0.001$ for both time points). The mean IOP values at different time points in the two groups are shown in table 2, and the median values are depicted in figure 2. There was a slightly greater drop in IOP in the inferonasal group in the initial postoperative period, but this was not statistically significant after 3 months. There were no significant differences in the visual acuity and number of IOP-lowering medications in both groups (table 2). The IOP-lowering medications had reduced from 3.19±0.7 in the preoperative period to 1.53±0.9 at 2-year follow-up.

Surgical complications encountered in the inferonasal versus superotemporal groups are shown in table 3. Transient choroidal detachment was the most common complication occurring in 13 eyes (8.5%). There were no significant differences in the complication rates between the two groups. Tube-related complications

Table 1 Baseline characteristics

	INQ AADI (n=84)	STQ AADI (n=69)	P value
Age, mean±SD	44.7±18.2	46.1±16.3	0.63
Gender, male, n (%)	62 (74)	53 (77)	0.67
LogMAR VA	0.57±0.52	0.51±0.54	0.25
IOP (mm Hg)	37.1±10.2	34.1±9.7	0.43
Number of IOP-lowering medications, mean±SD	3.1±0.8	3.3±0.6	0.36
MD, mean±SD	−20.86±8.1	−20.71±7.8	0.86
PSD, mean±SD	9.59±4.1	8.70±3.2	0.28
Lens status, n (%)			0.63
Phakic	57 (68)	51 (74)	
Pseudophakic	19 (23)	14 (20)	
Aphakic	8 (9)	4 (6)	
Type of glaucoma, n (%)			0.09
POAG	16 (19)	21 (30)	
PACG	4 (5)	9 (13)	
SOAG	39 (46)	30 (43)	
SACG	10 (12)	4 (6)	
JOAG	9 (11)	3 (4)	
Congenital/developmental	6 (7)	2 (3)	
Prior trabeculectomy, n (%)	53 (63)	37 (54)	0.55
Monocular status, n (%)	9 (11)	10 (14)	0.48

AADI, Aurolab aqueous drainage implant; INQ, inferonasal quadrant; IOP, intraocular pressure; JOAG, juvenile open-angle glaucoma; logMAR VA, logarithm of the minimum angle of resolution visual acuity; MD, mean deviation; PACG, primary angle-closure glaucoma; POAG, primary open-angle glaucoma; PSD, pattern standard deviation; SACG, secondary angle-closure glaucoma; SOAG, secondary open-angle glaucoma; STQ, superotemporal quadrant.

were seen in four eyes in each group, with tube occlusion by iris tissue or vitreous being the most frequent complication. Tube exposure, tube retraction, plate exposure and plate migration were seen in one eye each.

Tube ligation, tube trimming and choroidal drainage were reoperations in the early postoperative period, while cataract surgery and pars plana vitrectomy were the most common procedures performed in the late postoperative period. There was no difference in the rate of reoperations between the inferonasal versus superotemporal groups (table 4).

The cumulative probability of failure using Kaplan-Meier survival analysis was 8.5% (95% CI 5.1% to 14.2%) at 1 year, 13.1% (95% CI 8.6% to 19.5%) at 18 months and 23.5% (95% CI 17.6% to 31.1%) at 2 years. There were no differences in the cumulative rates for both complete and qualified success rates between the two groups (p=0.27, log-rank) (table 5). Cumulative success rates with failure definition of IOP >18 mm Hg or below 30% reduction from baseline are shown in online supplementary table 1, and failure definition of IOP >15 mm Hg or below 40% reduction from baseline is shown in online supplementary table 2. A comparison of the cumulative qualified success rates between the two groups at various time points is shown using a Kaplan-Meier survival curve in figure 3.

Cox proportional hazards showed that, after adjusting for age, type of glaucoma, preoperative IOP and quadrant of placement, prior trabeculectomy was associated with 14% higher risk of failure (HR=1.14, 95% CI 0.98 to 1.33, p=0.07). Placing the AADI in the superotemporal quadrant had a 15% higher risk of failure, but this was not statistically significant (HR=1.14, 95% CI 0.94 to 2.10, p=0.16).

Table 2 Intraocular pressure, IOP-lowering medications and visual acuity at baseline and follow-up

	INQ AADI (n=84)	STQ AADI (n=69)	P value
Baseline			
IOP	37.1±10.2	34.1±9.7	0.43
IOP-lowering medications	3.1±0.8	3.3±0.6	0.36
LogMAR VA	0.57±0.52	0.51±0.54	0.25
1 month			
IOP	21.5±11.1	24.8±11.8	0.08
IOP-lowering medications	1.9±1.03	2.1±0.9	0.23
LogMAR VA	0.74±0.5	0.67±0.6	0.18
3 months			
IOP	18.4±10.4	17.7±11.1	0.63
IOP-lowering medications	1.3±1.1	1.5±0.9	0.25
LogMAR VA	0.68±0.5	0.76±0.7	0.81
6 months			
IOP	15.4±6.6	14.9±6.1	0.74
IOP-lowering medications	1.8±1.5	1.3±1.0	0.15
LogMAR VA	0.68±0.5	0.77±0.8	0.42
12 months			
IOP	15.1±5.8	14.8±6.2	0.66
IOP-lowering medications	1.5±1.0	1.4±0.9	0.65
LogMAR VA	0.69±0.6	0.72±0.8	0.79
18 months			
IOP	14.9±6.4	14.5±6.1	0.5
IOP-lowering medications	1.4±1.0	1.2±1.0	0.17
LogMAR VA	0.71±0.7	0.87±0.9	0.27
24 months			
IOP	15.1±10.4	15.8±11.1	0.63
IOP-lowering medications	1.5±1.0	1.5±1.0	0.86
LogMAR VA	0.73±0.7	0.86±0.9	0.65

Data are presented as mean±SD.
AADI, Aurolab aqueous drainage implant; INQ, inferonasal quadrant; IOP, intraocular pressure; logMAR VA, logarithm of minimum angle of resolution visual acuity; STQ, superotemporal quadrant.

DISCUSSION

The placement of the aqueous drainage device is most frequently performed in the superotemporal quadrant due to optimum surgical exposure.[10] However, there are several ocular conditions that may preclude superotemporal shunt implantation and prompt use of another quadrant. The presence of superior

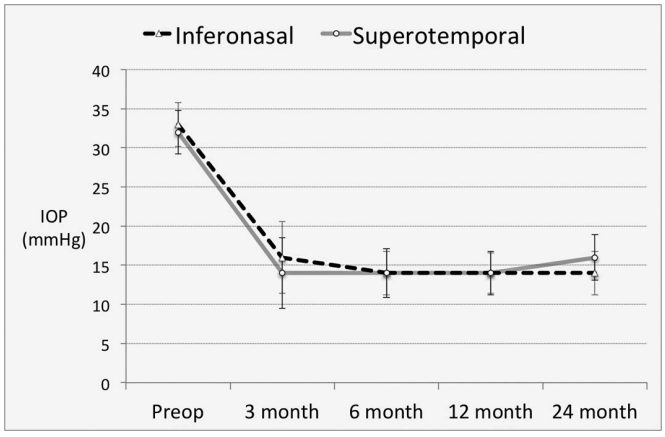

Figure 2 Graph showing intraocular pressure (IOP) at baseline and follow-up. Data are presented as mean±SD.

Table 3 Surgical complications

	INQ AADI (n=84)	STQ AADI (n=69)	P value
Tube-related complications			0.52
Tube exposure	1 (1.2)	0	
Plate exposure	0	1 (1.5)	
Tube retraction	1 (1.2)	0	
Tube occlusion (by iris/vitreous)	1 (1.2)	3. (4.3)	
Plate migration	1 (1.2)	0	
Other complications			0.43
Choroidal detachment	4 (5)	9 (13)	
Retinal detachment post-CD	1 (1.2)	0	
Corneal decompensation	3 (3.5)	2 (3)	
Previous graft failure	2 (2.4)	0	
Macular oedema	2 (2.4)	2 (3)	
Tube occlusion (by fibrin)	2 (2.4)	2 (3)	
Aqueous misdirection	0	1 (1.5)	
Severe anterior uveitis	1 (1.2)	2 (3)	
Hypotony	3 (3.5)	0	
Total number of patients with complications	22 (26)	22 (32)	0.45

Data reported as number of patients (percentage).
AADI, Aurolab aqueous drainage implant; CD, choroidal detachment; INQ, inferonasal quadrant; STQ, superotemporal quadrant.

conjunctival scarring, scleral ectasia, a large filtering bleb, corneal scarring with poor visualisation of the anterior chamber, extensive peripheral synechiae formation, or a pre-existing aqueous shunt or radial buckling element in the superotemporal quadrant are indications for shunt placement in an alternative quadrant. Additionally, eyes with intravitreal silicone oil following retinal detachment surgery would benefit from inferior placement of the shunt so that silicone oil does not exit through the tube.

There are multiple reasons why the inferonasal quadrant is the preferred second location for aqueous shunts, rather than the superonasal or inferotemporal quadrants. Superonasal shunt placement has a high incidence of diplopia, due to the presence of the superior oblique muscle in this region.[15–17] Similarly, the inferior oblique muscle insertion is located in the inferotemporal quadrant, thereby increasing the risk of diplopia when aqueous shunts are placed in this location.[16 17] Shunt implantation in the inferotemporal quadrant can cause a bulge of the lower eyelid.[16]

Table 4 Reoperations for glaucoma and complications

	INQ AADI (n=84)	STQ AADI (n=69)	P value
Tube ligation	0	1 (1.5)	0.14
Tube trimming	1 (1.2)	0	
Tube repositioning	0	1 (1.5)	
PPV±SOI	2 (2.4)	4 (6)	
Choroidal drainage	0	2 (3)	
Scleral patch graft	2 (2.4)	0	
Repeat AADI	4 (5)	0	
AADI exchange	1 (1.2)	0	
AADI explantation	0	1 (1.5)	
Iris repositioning	0	1 (1.5)	
Cataract surgery	5 (6)	5 (7)	
Repeat PK	1 (1.2)	2 (3)	
Cyclophotocoagulation	2 (2.4)	0	
Total number of reoperations	18 (21)	17 (25)	0.31

Data reported as number of patients (percentage).
AADI, Aurolab aqueous drainage implant; INQ, inferonasal quadrant; PK, penetrating keratoplasty; PPV, pars plana vitrectomy; SOI, silicone oil injection; STQ, superotemporal quadrant.

Table 5 Comparison of success at various time points between groups

At time point	INQ AADI (n=84)	STQ AADI (n=69)	P value
Complete success (absolute)*	48 (57%)	35 (51%)	0.43
Qualified success (absolute)*	67 (79%)	50 (72%)	0.29
Cumulative complete success, %			
6 months	92.8 (84.7–96.7)	91.3 (81.6–96.0)	0.47
12 months	84.5 (74.8–90.7)	82.6 (71.4–89.7)	
18 months	78.5 (68.2–85.9)	76.8 (64.9–85.1)	
24 months	57.1 (47.1–68.1)	50.7 (39.8–63.1)	
Cumulative qualified success, %			
6 months	97.6 (90.8–99.4)	95.6 (87.1–98.95)	0.27
12 months	94 (86.3–96.4)	88.4 (78.1–94.1)	
18 months	89.2 (80.4–94.3)	84.1 (73.1–90.8)	
24 months	79.7 (70.8–87.8)	72.5 (60.1–81.5)	

*Calculated at 2 years time point. Success defined as at least 20% reduction from baseline or intraocular pressure <21 mm Hg.
AADI, Aurolab Aqueous Drainage Implant; INQ, inferonasal quadrant; STQ, superotemporal quadrant.

Although there are large-scale, randomised controlled trials with long-term follow-up assessing the efficacy and safety of the Baerveldt and Ahmed implants,[4 18] there are no randomised trials evaluating differences in outcomes when aqueous shunts are placed in different quadrants. However, several authors have previously reported no differences in IOP control and success rates. Martino *et al*[10] reported no difference in IOP control in a retrospective comparison of 50 eyes with Baerveldt implantation in different quadrants (13 inferonasal and 33 superotemporal) in eyes with refractory glaucoma and a minimum of 6 months of follow-up. The cumulative success rates with IOP-lowering medications were 43.1% and 65.7% at 2 years of follow-up in the inferonasal and superotemporal groups, respectively, similar to the success rates in our study. Pakravan *et al*[11] also reported comparative outcomes of inferonasal versus superotemporal placement of the Ahmed glaucoma valve in 106 eyes (58 superotemporal and 48 inferonasal) with refractory glaucoma using a prospective study design. Although the mean follow-up was

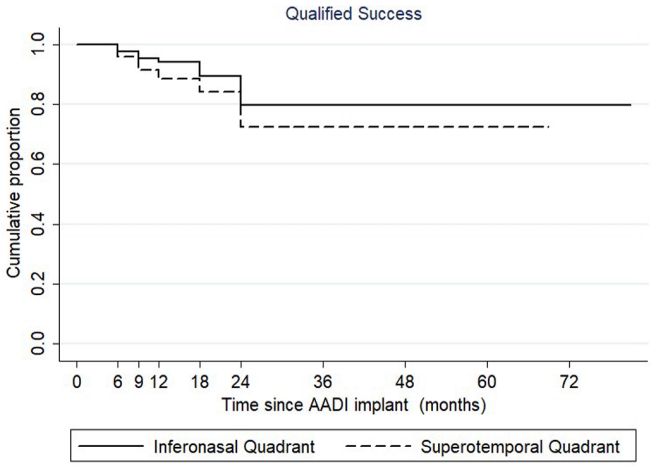

Figure 3 Kaplan-Meier plots showing the comparison of qualified success between the superotemporal and inferonasal groups. AADI, Aurolab aqueous drainage implant.

much shorter (10 months) than our study, the success rates were similar at 1 year (approximately 90% for both groups). However, the authors reported greater rates of complications in the inferior group, including implant exposure necessitating removal, cosmetically unappealing appearance and endophthalmitis. The authors attribute this to the shorter recess of the inferior fornix with lesser conjunctiva and tenon's capsule for implant coverage, leading to more tissue tension at the sutured incision and possibly increasing the rate of cheese-wired sutures and wound dehiscence. We did not notice any differences in complication rates between superotemporal and inferonasal aqueous shunt placement in our cohort. Rachmiel *et al*[12] also did not report any differences in outcomes after placing the Ahmed glaucoma valve in 83 eyes (32 superotemporal and 52 inferonasal) at 3-year follow-up. The success rates were very similar to our qualified success with similar definitions used for defining failure. In a non-comparative retrospective study, Harbick *et al*[16] reported excellent outcomes and few complications from 182 eyes that received the Baerveldt implant in the inferonasal quadrant.

Although the AADI is a relatively new glaucoma drainage device for treating refractory glaucoma based on the Baerveldt device design, it has shown excellent IOP control and success rates comparable with the Baerveldt in multiple clinical settings, including adult and paediatric eyes.[5–9 19 20] However, quadrant-wise comparisons have not been reported before. We did not observe any meaningful differences in the success or complication rates and believe that judicial selection of the surgical site by an experienced surgeon will lead to equally good outcomes, irrespective of quadrant chosen for placement.

The current study has several limitations. Patients were not randomly assigned to the quadrant of aqueous shunt implantation, and there were intrinsic patient factors that directed the surgeon in selecting the surgical site. As with all retrospective studies, data collection was variable at follow-up visits. This may have resulted in an underestimation of adverse events, as complications may be overlooked unless specific attention is directed towards their detection (eg, choroidal effusions). Postoperative interventions and the addition of IOP-lowering medications were left to the discretion of the surgeon, and no standardised protocols were used to guide postoperative management. Limited follow-up was available, particularly after 2 years. The study was conducted at one academic centre with a unique patient population, and this may affect the generalisability of the results.

In conclusion, the AADI placed in the inferonasal and superotemporal quadrants produced similar efficacy and safety results at 2-year follow-up. Although technically more challenging, the inferonasal quadrant is a viable location for aqueous shunt placement especially if the superotemporal quadrant is found to have excessive conjunctival scarring. Complication rates were not higher in the inferonasal group as feared due to the smaller conjunctival recess of the inferior conjunctiva.

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Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information and are available upon request.

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