

# Comparison between Ahmed glaucoma valve implant and Keiki Mehta body pressure glaucoma implant in neovascular glaucoma: 24-month results

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Received: 2025-01-05 Accepted: 2025-09-29

## Abstract

• **AIM:** To compare the 24-month clinical results of the Keiki Mehta body pressure (BP) glaucoma implants (KMI) versus the Ahmed glaucoma valve implants (AGVI; FP-7Model) in neovascular glaucoma (NVG).

• **METHODS:** Patients with NVG and uncontrolled intraocular pressure (IOP) exceeding 21 mm Hg despite maximum-tolerated antiglaucoma medications were included in this retrospective study and treated with either KMI, or AGVI. Preoperative and postoperative IOP (at the 1d, 1, 3, 6, 12, and 24mo), number of glaucoma medications needed, success rate, postoperative complications, and visual acuity were evaluated.

• **RESULTS:** The study enrolled 41 patients, comprising 19 (11 males) in the KMI group (mean age: 58.8±10.6y) and 22 (11 males) in the AGVI group (mean age: 60.2±16.8y). Preoperative IOP was similar between the groups ( $P=0.077$ ). Postoperative IOP at the 1<sup>st</sup> day and 1<sup>st</sup> month were lower in the KMI group compared to the AGVI group ( $P=0.003$  and  $P=0.001$ , respectively). No significant difference was found between the groups at other time points. In both groups, 1<sup>st</sup> day and 24<sup>th</sup> month values were lower than baseline values (all  $P<0.001$ ). At the end of 24mo, the number of antiglaucoma agents required, the success rate and total complications rate were similar between the groups ( $P=0.444$ ,  $P=0.843$ ,  $P=0.233$ , respectively).

• **CONCLUSION:** KMI may be an alternative to AGVI in the management of NVG. To the best of our knowledge, this study is the first to compare the results of AGVI versus KMI

for the treatment of NVG.

• **KEYWORDS:** Ahmed glaucoma valve; Keiki Mehta body pressure glaucoma implant; neovascular glaucoma

**DOI:10.18240/ijo.2026.07.11**

**Citation:** Gulmez Sevim D, Ozer F, Erkilic K, Sener H, Evereklioglu C, Unlu M. Comparison between Ahmed glaucoma valve implant and Keiki Mehta body pressure glaucoma implant in neovascular glaucoma: 24-month results. *Int J Ophthalmol* 2026;19(7):1308-1315

## INTRODUCTION

Refractory glaucoma remains difficult to control despite the development of new devices or medications. Glaucoma drainage devices (GDD) are based on the principle of creating a shunt between the anterior chamber and the episcleral surface with tube, and they are an alternative treatment methods for intraocular pressure (IOP) that cannot be controlled with medication or other surgery<sup>[1-3]</sup>.

Neovascular glaucoma (NVG) may occur as a result of ocular ischemia from various causes, such as retinal artery or vein occlusion, ocular ischemic syndrome, and diabetic retinopathy<sup>[4]</sup>. This type of glaucoma has a refractory nature, making its management extremely challenging. In addition to glaucoma treatment, the release of vascular endothelial growth factor (VEGF) from the underlying ischemic disease must be treated with panretinal photocoagulation (PRP) and anti-VEGF injections. GDDs are usually preferred to the treatment of refractory glaucoma such as NVG, but which is more effective is still under investigation<sup>[5-7]</sup>.

Although both the Ahmed glaucoma valve implant (AGVI) and the Keiki Mehta body pressure (BP) valve glaucoma implant (KMI) are categorized as valved glaucoma drainage devices, their working principles are not identical. The AGVI incorporates a unidirectional valve mechanism that restricts aqueous outflow until the IOP exceeds a defined threshold, thereby reducing the risk of early postoperative hypotony. The KMI was developed in association with Surgiwear. The device consists of a tube, a membrane valve, and a

button (15 mm×17 mm, medical-grade silicone). All parts are made of medical-grade silicone, ensuring flexibility and biocompatibility. The “peaks” on the button prevent conjunctival and Tenon’s compression, thereby promoting optimal aqueous distribution<sup>[8]</sup>. The valve mechanism is designed to open when IOP surpasses the surrounding tissue pressure, thereby facilitating controlled aqueous outflow. Unlike flow-restricting valves, the KMI employs a body pressure-regulated mechanism in which the episcleral plate and tube design dynamically modulate aqueous drainage<sup>[8-9]</sup>. The design differences between the two devices may influence early and long-term IOP control, complication profiles, and the overall surgical success. For this reason, a direct comparison of their therapeutic outcomes in NVG is clinically relevant and may guide device selection in refractory cases. However, it should be noted that the current evidence supporting the clinical use of KMI is still limited, with only a few peer-reviewed publications available to date. Thus, while this novelty represents a potential advantage, it also underscores the importance of interpreting our findings within the context of a relatively scarce evidence base. By directly comparing KMI with the well-established AGVI, this study provides not only new data on KMI but also contributes to filling an important gap in the literature. The aim of this study is to compare the 24-month clinical results and postoperative complications of the KMI with the AGVI in NVG.

## **PARTICIPANTS AND METHODS**

**Ethical Approval** All procedures were in accordance with the Declaration of Helsinki. The study protocol was approved by the Erciyes University Local Ethics Committee (No: 2023/170). All patients provided written informed consent before surgery. The consent process explicitly included information that the Keiki Mehta “BP Valve” glaucoma shunt is CE-marked but not FDA-approved or widely available internationally.

**Participants and Outcome Measures** This retrospective study included patients with uncontrolled NVG who were followed up and subsequently underwent glaucoma surgery with either AGVI (New World Medical, Inc., Rancho Cucamonga, CA, USA; FDA-approved and CE-marked) or KMI (manufactured by Surgiwear Ltd., Shahjahanpur, India; CE mark 1023, European Authorized Representative: Obelis s.a., Brussels, Belgium) to achieve adequate IOP control at Erciyes University between March 2018 and March 2022. A comprehensive preoperative examination was conducted for all patients at least 5d prior to the surgical procedure. A slit-lamp biomicroscopic examination was conducted, along with lens status assessment, IOP measurement (with Goldmann applanation tonometry), gonioscopy (with a Goldmann four-mirror lens), and optic disc evaluation (with a Volk 90 D lens).

Logarithm of the minimum angle of resolution (logMAR) was used for best corrected visual acuity (BCVA), with the following notations for vision worse than 20/400: finger counting=2.0, hand movements=2.3, light perception=2.6, and no light perception=2.9<sup>[10]</sup>. The medical history and surgical history of all patients were reviewed and recorded.

The diagnosis of NVG was made by glaucoma specialists (Gulmez Sevim D or Erkilic K) with the presence of at least two of the following: 1) neovascularization in the iris, 2) neovascularization in the anterior chamber angle (with total or partial closure of the angle) on gonioscopic examination, 3) refractory elevated IOP ( $\geq 21$  mm Hg), 4) ischaemic signs and neovascularisation in fundus fluorescein angiography, 5) fundoscopic features of ophthalmic disorders that may cause ischaemia, such as diabetic retinopathy, retinal vascular occlusion or ocular ischemic syndrome. One eye of each patient was included in the study. Exclusion criteria were as follows: 1) history of ocular surgery other than trabeculectomy, cataract surgery (with intraocular lens in capsule without any complications), AGVI, or KMI; 2) age less than 18y and greater than 80y; 3) glaucoma other than NVG; 4) no light perception. In addition, patients with a history of trabeculectomy surgery had a flat bleb and were not working effectively and had high IOP. Consequently, these patients were deemed to have failed trabeculectomy.

All patients were observed and evaluated prior to surgery (baseline) and on the first postoperative day. Subsequent evaluations were conducted at 1, 3, 6, 12, and 24mo postoperatively. The following data were recorded at each visit: BCVA, IOP measurement (with Goldmann applanation tonometry), the number of antiglaucoma medications added for IOP control postoperatively, antiglaucoma medication initiation timing, and any postoperative complications.

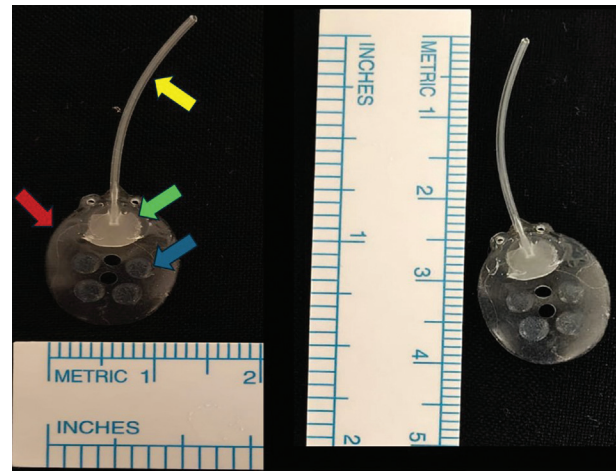
**Pre- and Postoperative Management** In the preoperative period, the PRP treatment was completed as much as possible, targeting the entire peripheral retina in all patients. In addition, intravitreal anti-VEGF injection was injected into patients with rubeosis iridis within 3d prior to the KMI and AGVI surgery. Preoperative IOP was managed with maximally tolerated topical antiglaucoma medications, and intravenous mannitol was administered in cases with uncontrolled IOP. All antiglaucoma medications were discontinued on the first postoperative day. A standardized regimen of topical corticosteroids (dexamethasone 0.1% every 2h, tapered over 6–8wk), topical antibiotics (moxifloxacin 0.5% four times daily for 2wk), and cycloplegic drops (cyclopentolate hydrochloride 1% twice daily for 2wk) was prescribed for all patients. In cases where postoperative IOP exceeded 21 mm Hg, antiglaucoma medications were reintroduced and adjusted according to IOP control. Adjunctive treatments, such as

completion PRP or repeated anti-VEGF injections, were performed postoperatively when required, based on clinical findings. In addition, mitomycin-C (MMC) was applied in 3 patients in the KMI group and 3 patients in the AGVI group as an adjunctive intraoperative measure. No other antifibrotic agents (such as 5-fluorouracil) were used.

**Surgical Technique of the Ahmed Glaucoma Valve Implantation** Both KMI and AGVI (FP-7Model) were performed by two experienced glaucoma surgeons (Gulmez Sevim D or Erkilic K) under general or local anesthesia. Although all surgeries were conducted with both surgeons present to ensure consistency, the primary surgeon varied between Gulmez Sevim D and Erkilic K.

The superior temporal bulbar conjunctiva and Tenon's capsule were opened from the fornix. The rectus muscles were identified. The tube was irrigated with a balanced salt solution and checked for openness and the valve mechanism. The episcleral plate (polypropylene body of implant) was fixed to the sclera 8-10 mm posterior to the corneoscleral limbus with a 9/0 non-absorbable nylon suture (Ethibond) through the holes on the plate. For tube insertion, the anterior chamber was entered parallel to the iris plane 1-2 mm posterior to the corneoscleral limbus using a 23-gauge (G) blade. The end of the tube was cut 2-3 mm and inserted into the anterior chamber by passing it through the scleral tunnel with straight forceps. Its opening was angled upward into the anterior chamber. The tenon and conjunctiva were sutured to the limbus with 8/0 absorbable (Vicryl) sutures, and all eyes received subconjunctival injections of steroids and antibiotics.

**Surgical Technique of the Keiki Mehta Implantation** The valve was primed by injecting saline through a 27-G needle into the tube, then the air bubble in the tube was expelled, and the patency of the shunt was checked by flushing the tube. The superior temporal bulbar conjunctiva and Tenon's capsule were opened from the fornix. A pocket was created under the conjunctiva and Tenon's capsule, and a curved blunt spatula was used to further clarify the pocket. An episcleral plate was inserted into the pocket created under the conjunctiva and tenon. The plate was sutured to the sclera through its holes using 9/0 non-absorbable nylon suture (Ethibond). Two deep cuts were made into the sclera with a graduated micrometer knife to bury the tube, and then a 23-G blade was used to create the passage through the sclera into the anterior chamber. The tube was trimmed 2-3 mm with the bevel up. The tube was pushed through the intrascleral tunnel and the end of the tube was observed in the anterior chamber. The conjunctiva and tenon were sutured to the limbus with 8/0 absorbable (Vicryl) sutures. All eyes received subconjunctival injections of steroids and antibiotics. The structural components of the Keiki Mehta BP valve are illustrated in Figure 1.



**Figure 1 Keiki Mehta body pressure (BP) valve implant** The device is composed of a silicone tube (yellow arrow) measuring 25 mm in length, connected to an oval episcleral plate (red arrow). The oval plate measures 12 mm (width)×15 mm (length) and houses the valve system (green arrow). Four circular elevations ("buttons" blue arrow) on the plate prevent conjunctival compression and promote bleb formation. The implant is manufactured entirely from medical-grade silicone.

**Criteria of Surgical Success** The patients were classified as having achieved a complete success, qualified success, or failure at the 6-month and 24-month postoperative follow-up. Surgical success was defined by final IOP, need for glaucoma medication, light perception status, and additional glaucoma surgery intervention. The presence of these three conditions was defined as complete success: 1)  $6 < \text{IOP} < 21$  mm Hg, 2) no need for glaucoma medication, 3) no loss of light perception. The presence of these three conditions was defined as qualified success: 1)  $6 < \text{IOP} < 21$  mm Hg, 2) need for glaucoma medication, 3) no loss of light perception. Failure was defined by these three criteria: 1)  $\text{IOP} \geq 21$  mm Hg despite use of glaucoma medications or persistent hypotony ( $\leq 5$  mm Hg) or no reduction of less than 20% from baseline at two consecutive follow-up visits, 2) additional glaucoma surgery intervention, 3) loss of light perception.

**Statistical Analysis** SPSS version 22 (IBM, Chicago, USA) was utilized to conduct statistical analysis. A linear mixed effects model was used to compare continuous parameters longitudinally and cross sectionally. A power analysis was performed using the G\*Power software (version 3.1) with *F* tests for ANOVA with repeated measures (within-between interaction). The power analysis indicated an effect size (*f*) of 0.25, an  $\alpha$  error probability of 0.05, a correlation among repeated measures of 0.5, and a nonsphericity correction ( $\epsilon$ ) of 1. With a total sample size of 41, two groups (AGVI and KMI), and seven measurements (baseline, postoperative 1d, 1, 3, 6, 12, and 24mo), the calculated noncentrality parameter ( $\lambda$ ) was 35.88, the critical *F* value was 2.14, and the degrees of freedom for the numerator and denominator were 6 and 234,

respectively. The achieved power ( $1-\beta$  error probability) was 0.998, demonstrating that the study design was sufficiently powered to detect significant differences.

For normally distributed data, a Student *t*-test was performed, while a Pearson Chi-square test was used for nominal-ordinal data. Descriptive nominal data were presented as percentages. Mean±standard deviation was calculated for continuous data. The cumulative probability of surgical success was analyzed using the Kaplan-Meier method, with the calculated success rate being compared using the log-rank test. Statistically significant results were determined by *P*-values less than 0.05.

## RESULTS

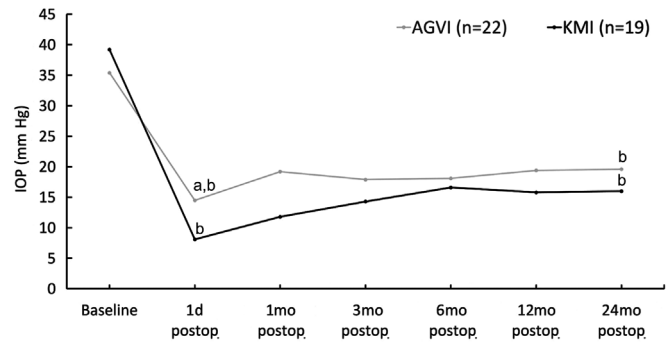
A total of 41 eyes of 41 patients were enrolled in the study, 19 patients (19 eyes) in the KMI group and 22 patients (22 eyes) in the AGVI group. Demographic characteristics, number of previous cataract or trabeculectomy surgeries, and etiology of NVG are shown in Table 1.

The preoperative and follow-up IOP values are shown in Figure 2. Postoperative IOP on the first postoperative day was lower in the KMI group (AGVI 14.5±8.7 mm Hg, KMI 8.1±1.5 mm Hg, *P*=0.003). In addition, IOP at the 1mo was also lower in the KMI group (KMI 11.8±3.8 mm Hg, AGVI 19.2±8.5 mm Hg, *P*=0.001). When comparing IOP between the different time points within both groups, significant differences were identified between the baseline and the first postoperative day, as well as between the baseline and the 24<sup>th</sup> postoperative month (KMI: baseline, 39.2±8.4, 1d, 8.1±1.5, 24mo, 16±5.8; both *P*<0.001; AGVI: baseline, 35.4±7.2, 1d, 14.5±8.7, 24mo, 19.6±9.2; both *P*<0.001). The comparison at other time points was similar within both groups.

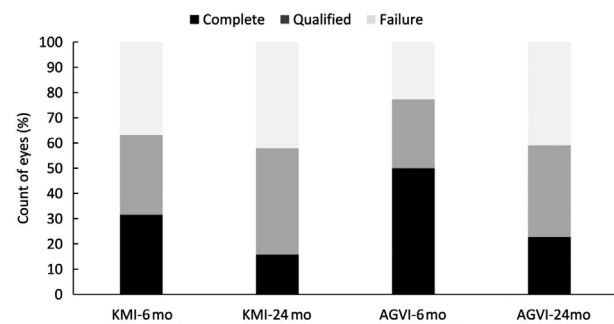
Comparing baseline and 24mo, the KMI group required less antiglaucoma medication at 24mo, whereas the AGVI group required similar amounts (from 3.8±0.8 to 3.18±1.6 in AGVI, *P*=0.104; from 3.7±0.9 to 2.79±1.5 in KMI, *P*=0.038). BCVA was similar between groups at all time points and did not change over time within either group (Table 2).

The success rates were similar between the groups at 6mo (in KMI group, the number of complete success eyes=6, qualified success eyes=7, failure eyes=6; in AGVI group, the number of complete success eyes=11, qualified success eyes=5, failure eyes=6, *P*=0.451) and at 24mo (in KMI group, the number of complete success eyes=3, qualified success eyes=8, failure eyes=8; in AGVI group, the number of complete success eyes=5, qualified success eyes=8, failure eyes=8, *P*=0.843), shown in Figure 3.

Figure 4 illustrates the Kaplan-Meier survival curves for the cumulative success (qualified success and total success) rate. At the conclusion of the 24mo, the probability of cumulative success was 57.9% in the KMI group, while it was 59.1% in the AGVI group. The log-rank test indicated that there was



**Figure 2 Change in IOP over time** KMI: Keiki Mehta body pressure valve glaucoma implants; AGVI: Ahmed glaucoma valve implants; IOP: Intraocular pressure. <sup>a</sup>*P*<0.05 vs KMI, <sup>b</sup>*P*<0.05 vs Baseline.



**Figure 3 Percentages of the success rates** KMI: Keiki Mehta body pressure valve glaucoma implants (*n*=19); AGVI: Ahmed glaucoma valve implants (*n*=22).

**Table 1 Demographic characteristics and previous surgery of the patients**

Parameters	KMI ( <i>n</i> =19)	AGVI ( <i>n</i> =22)	<i>P</i>
Age (y)	58.8±10.6	60.2±16.8	0.774
Gender (M/F)	11/8	11/11	0.756
Cataract surgery	12 (63.2%)	13 (59.1%)	0.790
Trabeculectomy surgery	4 (21.1%)	4 (18.2%)	0.817
Etiology of NVG	-	-	0.615
Central retinal vein occlusion	5	9	-
Diabetic retinopathy	12	11	-
Uveitis	2	2	-

KMI: Keiki Mehta body pressure valve glaucoma implants; AGVI: Ahmed glaucoma valve implants; NVG: Neovascular glaucoma.

no statistically significant difference between the two groups (*P*=0.936 and  $\chi^2=0.0064$ ).

Figure 5 illustrates the postoperative complications that were observed, and there was no difference between the groups (*P*=0.233). The choroidal effusion occurred in 4 patients (21%) in the KMI and 2 patients (9%) in the AGVI. The choroidal effusions were of a low grade and located in the periphery of retina. The choroidal effusion regressed when IOP was normalized, and no suprachoroidal hemorrhage occurred after surgery. The most serious complication was bullous keratopathy [in 1 patient (5%) of the KMI group] and endophthalmitis [in 1 patient (4%) of the AGVI group]. This patient with endophthalmitis received intravitreal antibiotic therapy.

**Table 2 Comparison of preoperative and 24-month outcomes in terms of BCVA and number glaucoma agents**

Follow-up	Number of glaucoma medications			BCVA (logMAR)		
	AGVI (n=22)	KMI (n=19)	P	AGVI (n=22)	KMI (n=19)	P
Baseline	3.8±0.8	3.7±0.9	0.659	2.2±0.5	2±0.6	0.361
6mo	1.2±1.6	1.8±1.4	0.181	2±0.8	1.9±0.7	0.879
24mo	3.18±1.6	2.79±1.5	0.444	2.1±0.7	2.02±0.7	0.632
<i>P</i> <sub>baseline vs 6mo</sub>	<0.001	<0.001	-	0.123	0.522	-
<i>P</i> <sub>baseline vs 24mo</sub>	0.104	0.038	-	0.298	0.653	-

KMI: Keiki Mehta body pressure valve glaucoma implants; AGVI: Ahmed glaucoma valve implants; BCVA: Best-corrected visual acuity; logMAR: Logarithm of the minimum angle of resolution.

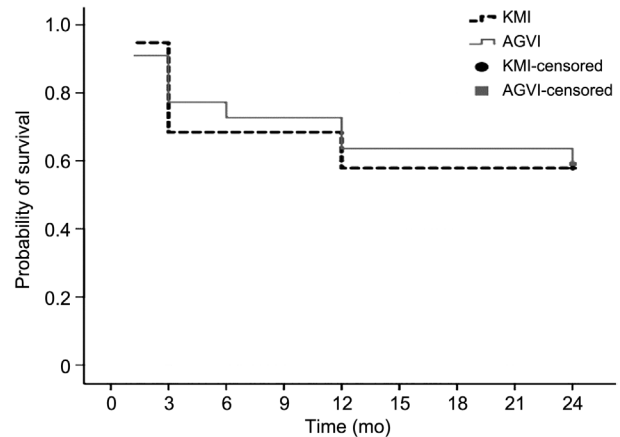
Conjunctival complications such as melting or erosion were not observed in any patient. In addition, the occurrence of surgical-related cataracts was not observed in both groups.

The timing of starting anti-glaucoma medication was similar between the groups (*P*=0.868). Most patients in both groups were started on antiglaucoma medication in the first month (4 patients in KMI group and 5 patients in AGVI group; Figure 6).

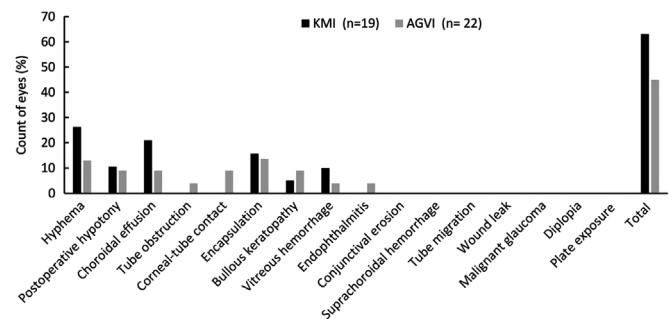
**DISCUSSION**

The management of NVG is still difficult and alternative treatment methods are still under investigation. GDDs are one of the effective surgical methods and research continues to determine which of the GDD is more effective in the NVG. The current study aimed to shed light on this issue by demonstrating the effects of different GDD procedures, such as AGVI and KMI, on NVG management.

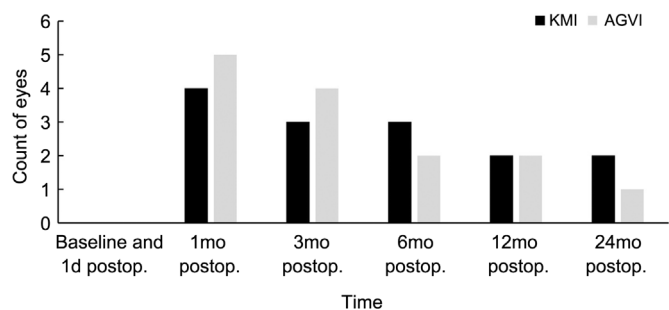
In our study, the KMI group showed significantly greater IOP reduction than the AGVI group on postoperative 1d, and at 1mo, although this difference was not sustained at later follow-up visits. This early advantage may be related to differences in valve design. The BP-controlled mechanism of the KMI may allow more rapid initial aqueous humor outflow, whereas the unidirectional valve of the AGVI is designed to restrict flow until a certain pressure threshold is reached, thereby reducing the risk of early hypotony. Clinically, this transient but marked reduction in IOP with the KMI may be particularly beneficial in patients with NVG, where acute IOP control is important for preserving residual vision and reducing the risk of ischemic complications. While the KMI group showed an increasing IOP trend between postoperative 1d and 6mo, the AGVI group showed an increasing IOP trend between postoperative 1d and 1mo, as well as 3mo and 24mo. These increased IOP trends may be due to a mechanism similar to the transient hypertensive phase described in the previous studies<sup>[11-13]</sup>. Although no universally accepted grading system for GDD-related complications exists, in line with prior studies and consensus reports, complications in our cohort were grouped for descriptive purposes according to their clinical impact: self-limiting events (such as hyphema or transient choroidal effusion) were considered mild, complications of moderate clinical significance (such as encapsulation



**Figure 4 Kaplan-Meier survival curve analysis indicating the cumulative probability of success following surgery in both groups** Log-rank test showed no significant difference in survival between groups (*P*=0.936). KMI: Keiki Mehta body pressure valve glaucoma implants (*n*=19); AGVI: Ahmed glaucoma valve implants (*n*=22).



**Figure 5 Percentages of complications in each group** KMI: Keiki Mehta body pressure valve glaucoma implants; AGVI: Ahmed glaucoma valve implants.



**Figure 6 Timing of initiation of anti-glaucoma medication in the KMI (*n*=19) and AGVI (*n*=22) groups** KMI: Keiki Mehta body pressure valve glaucoma implants; AGVI: Ahmed glaucoma valve implants.

or tube obstruction) were considered moderate, and sight-threatening events (such as bullous keratopathy, suprachoroidal hemorrhage, and endophthalmitis) were considered severe. Based on this framework, most complications in our series were mild, while severe complications were relatively rare but clinically significant. Despite both implants having valves, early postoperative hypotony was observed in 2 patients with KMI (10.5%) and 2 patients with AGVI (9%). Previous studies have reported postoperative hypotonia rates of 13% to 15% after AGVI surgery<sup>[14]</sup>. Compared to this rate, our postoperative hypotonia rates were lower in AGVI and KMI groups. Postoperative hypotonia may be caused by valve failure or decreased aqueous production<sup>[15]</sup>. In the follow-up period, hypotony was not continued in our study. Suprachoroidal hemorrhage and persistent hypotony are still feared complications in the GDD. If not treated early, these complications can lead to permanent blindness. Therefore, valved implants such as AGVI and KMI may be more advantageous in terms of persistent hypotony and associated complications. Although the number of KMI studies is not as large as the AGVI studies, some studies have supported its effectiveness in postoperative hypotony<sup>[9]</sup>. In addition, Gan *et al*<sup>[16]</sup> recently reported early postoperative hypotony in 3 out of 26 eyes (11.5%) after Baerveldt glaucoma implantation with a Supramid® ripcord stent modification in NVG patients. This rate is slightly higher than the hypotony rates observed in our KMI and AGVI groups, suggesting that valved implants may still offer an advantage over non-valved implants, even when modified with intraluminal stents. Nevertheless, direct comparative studies are needed to more definitively establish differences in hypotony risk between valved and non-valved devices. In our series, choroidal effusion was observed more frequently in the KMI group (21%) compared to the AGVI group (9%). This finding may be explained by the more pronounced IOP reduction in the early postoperative period with the KMI, where the mean IOP dropped to  $8.1 \pm 1.5$  mm Hg on the first postoperative day. Such a sudden reduction in IOP can predispose to transient choroidal effusion, particularly in eyes with neovascular glaucoma that often have compromised vascular autoregulation. Importantly, in our cohort these effusions were mild, localized to the peripheral retina, and regressed spontaneously once IOP stabilized, without leading to more serious complications such as suprachoroidal hemorrhage. Thus, while KMI implantation may be associated with a slightly higher risk of transient effusion due to its valve dynamics and early hypotensive effect, this did not adversely affect long-term outcomes in our study.

Postoperative transient hyphema was the most common complication in the current study. Choo *et al*<sup>[17]</sup> stated in their study that postoperative hyphema could lead to conjunctival

inflammation and scarring, resulting in failure. For this reason, PRP and anti-VEGFs must be administered to prevent hyphema in NVG before glaucoma surgery, even repeated injections may be necessary. This can increase the successful surgical outcome of GDD surgery<sup>[18]</sup>.

The endophthalmitis seen in our study was low-grade endophthalmitis secondary to keratitis and was not directly related to AGVI implantation. Nevertheless, endophthalmitis remains a vision-threatening complication that may require intensive antimicrobial therapy and can have long-term consequences for ocular integrity and prognosis. In particular, the use of antifibrotic agents such as MMC or 5-fluorouracil in GDD surgery may increase conjunctival thinning or leakage, thereby elevating the risk of infection and subsequent endophthalmitis<sup>[19-20]</sup>. Similarly, bullous keratopathy, which we also observed in our cohort, is a serious complication that can cause persistent pain, photophobia, and significant visual impairment. In advanced cases, keratoplasty may be required, which further increases the surgical burden in this challenging patient population. These complications underscore the importance of close postoperative surveillance and careful case selection when considering GDDs in eyes with NVG.

We did not perform endothelial cell count measurements in this study, which is a limitation. However, it is well established that uncontrolled glaucoma and NVG predispose to corneal decompensation, and factors such as tube-cornea contact or uncontrolled high IOP can further exacerbate this risk. For this reason, corneal endothelial failure remains a clinical concern, and the need for keratoplasty should be anticipated in such cases.

In terms of medication use, both groups demonstrated a reduction in the number of required agents compared to baseline, but statistical significance was reached only in the KMI group. However, by the 24-month follow-up, there was no significant difference between KMI and AGVI in cross-sectional comparison, indicating that neither device demonstrated a definitive superiority in reducing medication burden. While the within-group analysis highlighted a significant decrease with KMI, the between-group results suggest that both implants ultimately provided similar long-term outcomes. A decreased number of antiglaucoma medications may lead to a reduction in the wash-out effect of consecutive drops and reduce ocular surface irritation, thereby improving IOP control and patient comfort. In addition, comparison of the KMI and AGVI in the current study revealed that they exhibited comparable success rates. As NVG often requires prolonged follow-up, it should be noted that these trends and results may change over longer observation periods.

The visual acuity is usually very poor in the NVG. Even so, maintaining their current level of vision is very important for patients with NVG. Loss of light perception has a negative impact on circadian rhythm and the psychological state of patients<sup>[21-22]</sup>. Both the KMI and the AGVI seem to be successful in the protection of the current BCVA.

The present study has several limitations. First, the number of patients enrolled in the study was small (19 in the KMI group and 22 in the AGVI group), which may limit the generalizability of the results. Although our power analysis indicated that the study design was sufficiently powered to detect significant changes in IOP over time and complication rates should be interpreted with caution. Future prospective, multicenter studies with larger cohorts, longer follow-up durations are warranted to confirm and extend our findings. Second, the retrospective design of the study introduces inherent limitations, particularly in controlling for bias and confounding variables. As the study was not randomized, treatment allocation to AGVI or KMI was based on clinical judgment, which may have introduced selection bias. Additionally, variability in preoperative disease severity, prior interventions, and adjunctive treatments such as panretinal photocoagulation or anti-VEGF injections could act as confounding factors influencing postoperative outcomes. The retrospective nature also limited the standardization of follow-up intervals and postoperative management strategies across patients. Although we attempted to minimize these effects through strict inclusion criteria and consistent surgical techniques, the possibility of residual bias cannot be completely excluded. Third, although a 24-month follow-up can provide useful findings, it is essential to extend these periods in order to comprehensively assess the long-term efficacy and potential complications of surgical interventions, particularly in cases of neovascular glaucoma. Fourth, KMI was only compared to the FP-7 model of AGVI. Consequently, the outcomes may differ if the KMI is compared to other AGVI models. In addition, as device selection was based on surgeon discretion in a non-randomized design, this may have introduced variability and potential selection bias in the study outcomes. Fifth, although the KMI implant carries a CE mark, it is not FDA-approved and is not yet widely available worldwide, which may limit the generalizability of our results to broader clinical settings. Furthermore, published evidence regarding the KMI is still limited, with only a few peer-reviewed clinical reports currently available. Sixth, one of the surgical success criteria regarding IOP was defined using a lower threshold of 6 mm Hg (vs 5 mm Hg in most reports)<sup>[23]</sup>, which may limit comparability with other studies. Likewise, conversion of extremely poor vision to logMAR was applied to facilitate analysis, but should be interpreted with caution.

Finally, although we systematically described complications by clinical severity, the relatively small sample size precluded a reliable risk factor analysis for severe complications.

In conclusion, AGVI and KMI showed comparable results in terms of IOP, complication rate, success rate and number of antiglaucoma medications required, suggesting that KMI may be an alternative to AGVI in the management of NVG. To the best of our knowledge, this study is the first to compare the results of AGVI versus KMI for the treatment of NVG.

#### ACKNOWLEDGEMENTS

**Authors' Contributions:** Conceptualization: Gulmez Sevim D, Ozer F; Data curation: Ozer F; Formal analysis: Sener H; Investigation: Ozer F; Methodology: Ozer F, Gulmez Sevim D; Project administration: Ozer F, Gulmez Sevim D; Statistic Software: Sener H; Supervision: Gulmez Sevim D, Erkilic K; Validation: Gulmez Sevim D, Unlu M; Visualization: Erkilic K; Writing—original draft: Ozer F; Writing—review & editing: Gulmez Sevim D, Evereklioglu C.

**Availability of Data and Materials:** The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Conflicts of Interest:** Gulmez Sevim D, None; Ozer F, None; Erkilic K, None; Sener H, None; Evereklioglu C, None; Unlu M, None.

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