Bleb Analysis and Short-Term Results of Biodegradable Collagen Matrix–Augmented Ahmed Glaucoma Valve Implantation: 6-Month Follow-up

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Purpose. To evaluate the short-term efficacy of a biodegradable collagen matrix (BCM) as an adjuvant for Ahmed valve implantation surgery to prevent the hypertensive phase.

Methods. This prospective study included 43 refractory glaucoma eyes, all followed for 6 months. Refractory glaucoma was defined as an IOP higher than 20 mm Hg with antiglaucoma eye drops without previous glaucoma surgery. Conventional method was performed in 21 eyes and BCM-augmented Ahmed valve implantation (BAAVI) in 22 eyes. In the BAAVI group, a 10 × 10 × 2–mm BCM was sutured on an Ahmed glaucoma valve FP7 model. Complete success was defined as an IOP of 21 mm Hg or lower (target IOP 1) or 17 mm Hg or lower (target IOP 2) without antiglaucoma medications and qualified success as an IOP of 21 mm Hg or lower with or without medications. Maximal bleb thickness was measured using anterior segment optical coherence tomography images.

Results. The preoperative IOPs and numbers of preoperative antiglaucoma medications were similar for both groups. Complete target IOP 1 success rates were 38.1% and 86.4%, complete target IOP 2 success rates were 19.0% and 59.1%, and qualified success rates were 52.4% and 90.9% in the conventional and BAAVI groups, respectively ($P < 0.05$). The hypertensive phase rate was lower in the BAAVI group (4.5% vs. 47.6%, $P = 0.002$). Maximal bleb thickness was increased in the BAAVI group on postoperative days 30 and 180 ($P < 0.05$).

Conclusions. Success rates were higher in the BAAVI group than in the conventional group with the change of bleb morphology. Furthermore, use of BCM significantly decreased the need for antiglaucoma medications for at least 6 months postoperatively.

Keywords: glaucoma, Ahmed glaucoma valve, biodegradable collagen matrix, hypertensive phase

Glaucoma drainage device (GDD) implantation, including insertion of an Ahmed glaucoma valve (AGV; New World Medical, Inc., Rancho Cucamonga, CA, USA), is one of the most common glaucoma surgeries.[1] Previously, GDDs were mostly implanted for patients with refractory glaucoma or neovascular glaucoma.[2] More recently, GDD implantation surgery has become widely performed, even for patients with primary open-angle glaucoma or secondary glaucoma, because of its lower postoperative complication rate than trabeculectomy with mitomycin-C (MMC) use.[3] However, the major shortcoming of Ahmed valve surgery is the prominent postoperative IOP elevation during a hypertensive phase, which typically occurs from 1 to 3 months postoperatively.[4–8]

To avoid this hypertensive phase, adjuvants might be needed. Many surgeons use MMC to enhance and maintain the filtration effect, although antimetabolite-augmented trabeculectomy can cause an increased frequency of wound leaks, hypotony, thin avascular blebs, and late infection.[9,10] In recent years, a biodegradable collagen matrix (BCM) has been introduced for trabeculectomy surgery to replace MMC.[11,12] Ologen (Aeon Astron Corporation, Taipei, Taiwan) is a biodegradable collagen implant that can last for 6 months under the conjunctival tissue. This collagen matrix can inhibit contraction of wound during the early stages.[13] We postulate that it may enhance the hypotensive effect in other types of glaucoma surgery, including Ahmed valve implantation.

The aim of this study was to compare the clinical efficacy and safety, primarily in the early postoperative period, of the BCM-augmented Ahmed valve implantation (BAAVI) method and the conventional method.

Methods

This prospective study was approved by the institutional review board of CHA Bundang Medical Center (Seongnam, Republic of Korea) and the design followed the tenets of the Declaration of Helsinki. A total of 43 refractory glaucoma eyes with a postoperative follow-up period of more than 6 months were included after randomization according to the table of random sampling numbers. Refractory glaucoma was defined as an IOP higher than 20 mm Hg despite maximally tolerated medical treatment. The exclusion criteria were age younger than 18

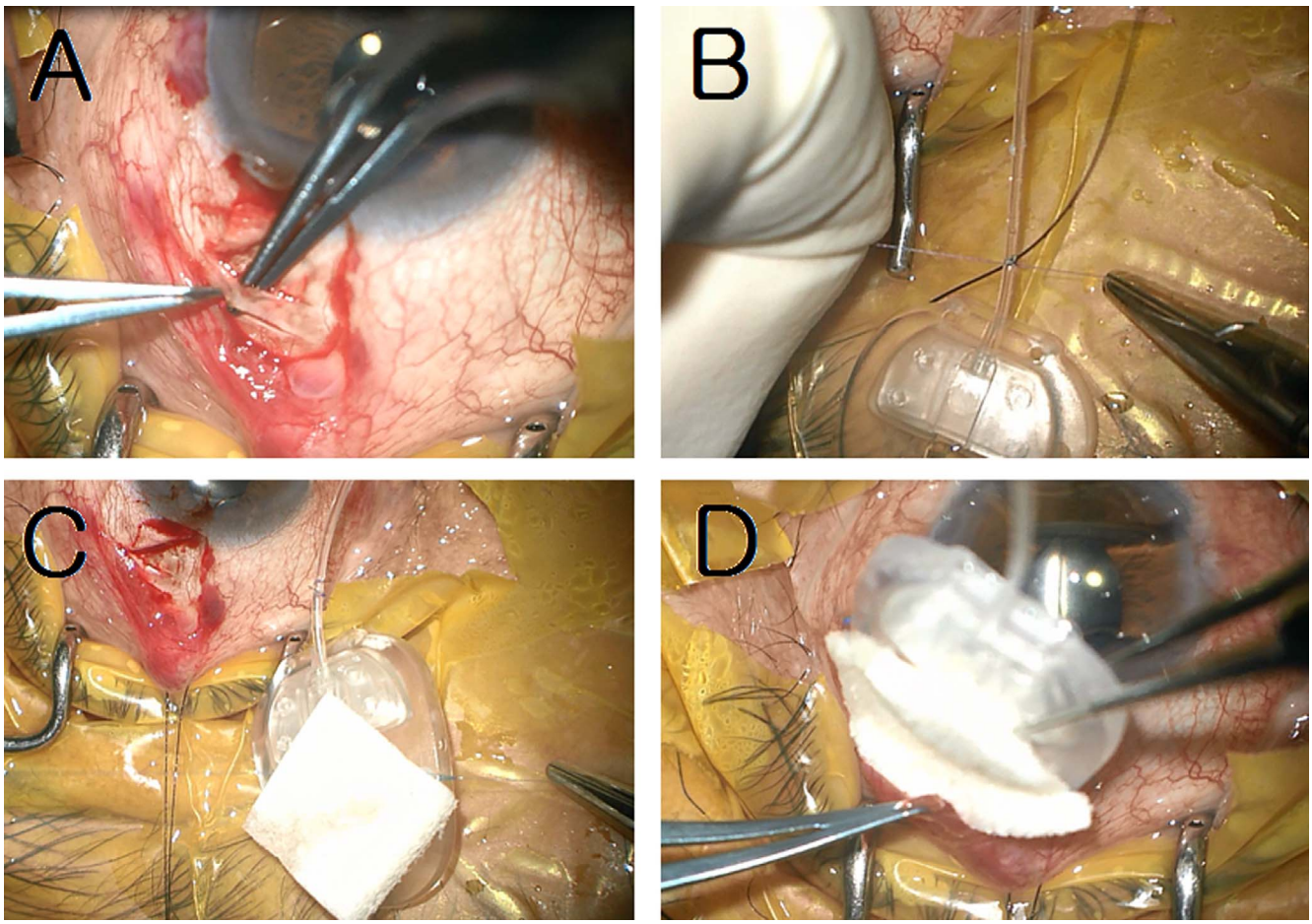

FIGURE 1. Serial intraoperative views illustrating the technique of biodegradable collagen-augmented Ahmed valve implantation. (**A**) Creation of a scleral tunnel. A 4 × 4-mm right-angled triangular covering flap and a 2-mm wide bridge flap were created. (**B**) The tube was tied with two 8-0 Vicryl sutures at its proximal portion, at 2 to 4 mm from the plate, before valve priming with balanced salt solution irrigation. (**C**) A 2 × 10 × 10-mm Ologen material was fixated over the plate portion using two 8-0 Prolene sutures. (**D**) The Ologen-covered valve was inserted into the sub-Tenon's space and fixated on the sclera using two 8-0 Prolene sutures.

years, previous history of glaucoma surgery, and postoperative complications (such as endophthalmitis or possible tube obstruction due to severe hyphema). After providing adequate explanations about the operation and obtaining written informed consent, all surgical procedures were performed by a single surgeon (SR) in 2014. Preoperatively, all subjects underwent a full ophthalmologic examination, including determination of the corrected distance visual acuity (CDVA), Goldmann applanation tonometry by a glaucoma specialist (SR), axial length (AXL) determination, and fundus examination after pupil dilation. Fundus photography and red-free photography were performed with a fundus camera (VX-10i; Kowa, Nagoya, Japan). Central corneal thickness was measured using an ultrasonic pachymeter (UP-1000; Nidek, Gamagori, Japan) and AXL was measured using an Echoscan (US-4000; Nidek). Postoperatively, anterior segment spectral domain optical coherence tomography (AS-OCT) images were obtained (described below).The endothelial cell count was determined using a Konan Specular Microscope X (NSP-9900; Konan Medical, Inc., Hyogo, Japan), pre- and postoperatively.

Surgical Procedure

After creation of a fornix-based flap of the conjunctiva and Tenon capsule in the superotemporal quadrant, a 4 × 4–mm right-angled triangular scleral flap and a continuous 2-mm-wide × 6-mm-long bridge-shaped scleral flap were constructed (Fig. 1A). To avoid an extensive hypotensive phase and overpowered tube priming, the tube was tied twice with 8-0 polyglactin sutures (Vicryl; Ethicon, Somerville, NJ, USA) in its proximal portion, between 2 mm and 4 mm from the plate (Fig. 1B). After tying the sutures, tube priming was performed with balanced salt solution irrigation. In the BAAVI group only, the plate of an AGV was covered by a 10 × 10 × 2–mm BCM, using 8-0 polypropylene sutures (Fig. 1C). The Ahmed valve was positioned in the middle of the quadrant with the anterior edge of the plate located 8 to 10 mm posterior to the limbus, and it was fixed at the sclera by two 8-0 polypropylene sutures (Fig. 1D). The tube was placed under the bridge flap, and its tip was cut to the proper length, so the tube could be inserted into and maintained adequately in the anterior chamber. A short scleral track under the triangular flap was created with a 23-gauge needle into the anterior chamber. The cut tube was inserted through this scleral track. The triangular flap was then covered and sutured using an 8-0 polyglactin suture. The conjunctiva and Tenon capsule were reapproximated to the limbal area with interrupted 8-0 polyglactin sutures.

Postoperative Management

The postoperative follow-up visits were performed on days 1 and 3 and weeks 1, 2, 3, 4, 6, 8, 12, 16, 20, and 24 after the

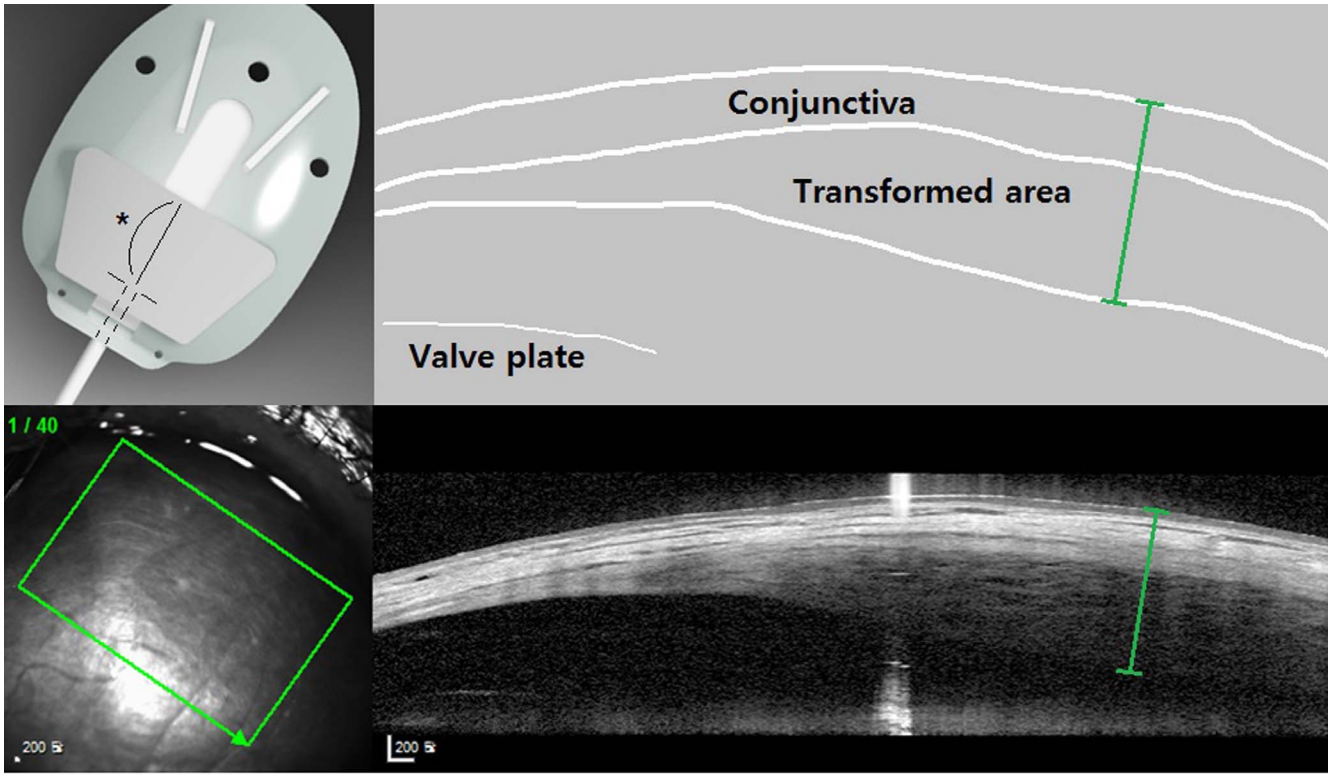

Figure 2. Schematic images and OCT images of a bleb thickness measurement. *Left column*: The *asterisk* indicates the 3.5-mm distance between the end of the tube portion and the outlet of the valve part. *Right column*: Cross-sectional image of a bleb consisting of a more hyperreflective wall and a less hyperreflective thick layer (= Ologen-transformed area). The maximum wall thickness was measured.

operation. Eye drops consisting of Vigamox (0.5% moxifloxacin hydrochloride; Alcon Laboratories, Inc., Fort Worth, TX, USA) and Pred Forte (1% prednisolone acetate; Allergan, Inc., Irvine, CA, USA) were begun on the day after surgery and continued four times per day for 1 month. Chamber formation was performed using an intracameral Unial (sodium hyaluronate; Unimed, Seoul, South Korea) injection if the early IOP (within 2 weeks postoperatively) was lower than 6 mm Hg and the peripheral anterior chamber depth was less than the half of the peripheral cornea thickness. If a hypertensive phase was confirmed (as described below), antiglaucoma eye drops were prescribed and added in this order to keep the IOP lower than 20 mm Hg: preservative-free timolol/dorzolamide fixed combination drops (Cosopt-s; Santen Pharmaceutical Co., Ltd., Osaka, Japan) twice per day, the alpha-agonist brimonidine (Alphagan; Allergan, Inc.) drops twice per day, and latanoprost drops at night (Xalatan; Pfizer, New York, NY, USA).

Table 1. Patient Demographics of the Total Population

	Conventional, $n = 21$	BAAVI, $n = 22$	P^*	Total, $n = 43$
Mean age, y	61.52 ± 14.30	62.73 ± 13.87	0.734	62.14 ± 13.93
Sex, % male	90	64	0.069	77
Preop CDVA, Snellen	0.16 ± 0.26	0.21 ± 0.28	0.113	0.18 ± 0.26
Postop CDVA, Snellen	0.23 ± 0.33	0.30 ± 0.30	0.121	0.26 ± 0.32
Preop IOP, mm Hg	34.14 ± 8.60	33.59 ± 9.64	0.761	33.86 ± 9.04
Preop ECC, cells/mm^2	2397 ± 460	2216 ± 621	0.207	2190 ± 560
Postop ECC, cells/mm^2	2319 ± 859	2297 ± 534	0.885	2302 ± 577
Cause, *n* (%)			0.314	
NVG	20 (95.2)	17 (77.3)		37 (86.0)
OAG	1 (4.8)	2 (9.1)		3 (7.0)
Secondary glaucoma	0 (0)	2 (9.1)		2 (4.7)
ACG	0 (0)	1 (4.5)		1 (2.3)
Preop antiglaucoma medications, *n*	3.10 ± 0.83	2.95 ± 0.58	0.498	3.02 ± 0.71
Postop antiglaucoma medications, *n*	1.29 ± 1.23	0.18 ± 0.59	0.001	0.72 ± 1.10

Data are shown as mean ± SD except where otherwise indicated. ACG, angle closure glaucoma; ECC, endothelial cell count; NVG, neovascular glaucoma; OAG, open-angle glaucoma; Postop, postoperative; Preop, preoperative.

* Mann-Whitney test and χ^2 test with Fisher exact test (between conventional and BAAVI groups).

Table 2. Comparison of Success Rate (%) Between the Two Groups

	Conventional	BAAVI	P*
Complete success			
Target IOP 1 (≤21 mm Hg)	38.1	86.4	0.002
Target IOP 2 (≤17 mm Hg)	19	59.1	0.012
Qualified success	52.4	90.9	0.007

* χ^2 test (between conventional and BAAVI groups).

Outcome Measures

The primary surgical outcomes were the postoperative IOP level and the number of antiglaucoma medications used. Complete success was defined as an IOP equal to or less than the target IOP without any antiglaucoma medications and an IOP reduction of 20% or more from baseline. Two target IOP levels for complete success were considered: IOP of 21 mm Hg or lower (target IOP 1) or 17 mm Hg or lower (target IOP 2). Qualified success was defined as an IOP of 21 mm Hg or lower with or without antiglaucoma medication use. All IOPs during the 6-month postoperative period were used to determine whether the above definitions were met. A hypertensive phase was defined as an IOP increase during two consecutive visits separated by 2 weeks to higher than 21 mm Hg, within 1 to 3 months after surgery. If the patient exhibited one IOP increase to higher than 21 mm Hg, he or she was reevaluated 2 weeks later to determine whether the criteria for a hypertensive phase was met.

Anterior Segment OCT Assessment

Postoperative blebs were imaged using a Spectralis OCT (Heidelberg Engineering GmbH, Heidelberg, Germany) on postoperative days 1, 30, and 180. Images with a quality score higher than 25 were included in the final qualitative analysis. After establishing a constant and minimal degree of room illumination, patients were asked to fixate their eyes at an infranasal position. Automatic real-time of eight frames and 41 sections with a 139-μm interval were used for imaging the cross-section of the bleb. To compare the same plane of the scan section for each examination, the highly experienced examiner matched the patients' eye position according to their large conjunctival vessels. To analyze the same position in which aqueous humor flows out, the maximum bleb thickness was measured only at a point 3.5-mm from the end point of the tube in the coronal OCT scan on postoperative day 30 and 180 (Fig. 2).

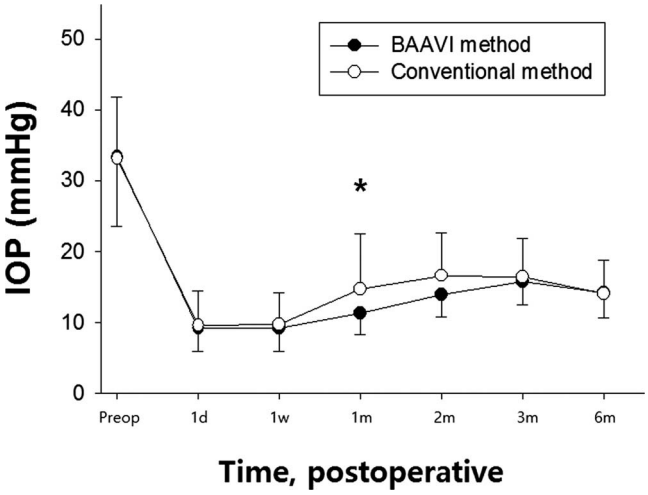

Figure 3. Mean IOP changes during the follow-up period in the conventional method group and BAAVI method group. The IOP at 1 month postoperatively was significantly lower in the BAAVI group than in the conventional group. *$P < 0.05$ between groups.

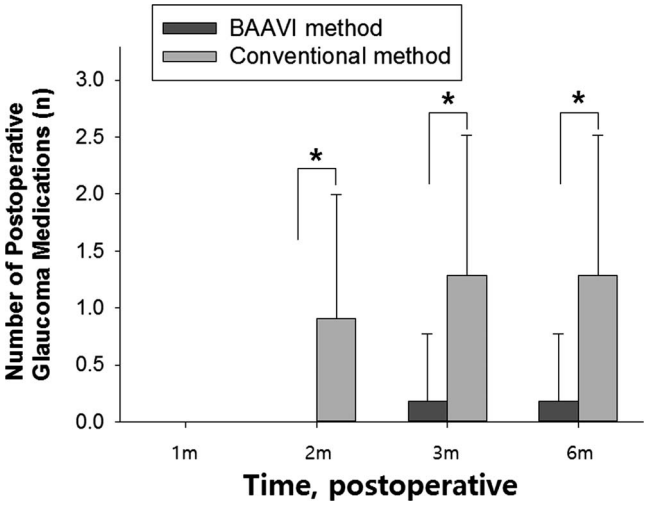

Figure 4. Comparison of the numbers of postoperative antiglaucoma medications between the conventional method group and the BAAVI method group. During the whole period from 2 to 6 months postoperatively, the BAAVI group needed a significantly lower number of medications than the conventional group. *$P < 0.05$ between groups.

Statistical Analyses

Statistical analyses were performed using the SPSS software (version 21.0; SPSS, Inc., Chicago, IL, USA). χ^2 (or Fisher's exact), and Mann-Whitney *U* tests were used to compare demographic characteristics; *P* values less than 0.05 were defined as being statistically significant. Based on an initial pilot study of the first six cases, a minimal number of 18 subjects were deemed necessary to detect a 4-mm Hg difference in IOP values with a 90% statistical power in the setting of a 4-mm Hg SD.

Results

Clinical Data Comparison

The Ahmed valve implantation was performed in 43 eyes of 40 patients who were followed for at least 6 months. The

Table 3. Postoperative Complications and Rate of Occurrence of a Hypertensive Phase

	Conventional, n = 21	BAAVI, n = 22	P*	Total, n = 43
Early hypotony	3 (14.3)	4 (18.2)	>0.999	7 (16.3)
Hyphema	2 (9.5)	2 (9.5)	>0.999	4 (9.3)
Choroidal effusion	1 (5.0)	1 (4.5)	>0.999	2 (4.8)
Tube exposure	0	0	N/A	0
Endophthalmitis	0	0	N/A	0
Wound leak	0	0	N/A	0
Hypertensive phase	10 (47.6)	1 (4.5)	0.002	11 (25.6)

Data are shown as number of cases (%). N/A, not applicable.
* χ^2 test with Fisher's exact test (between conventional and BAAVI groups).

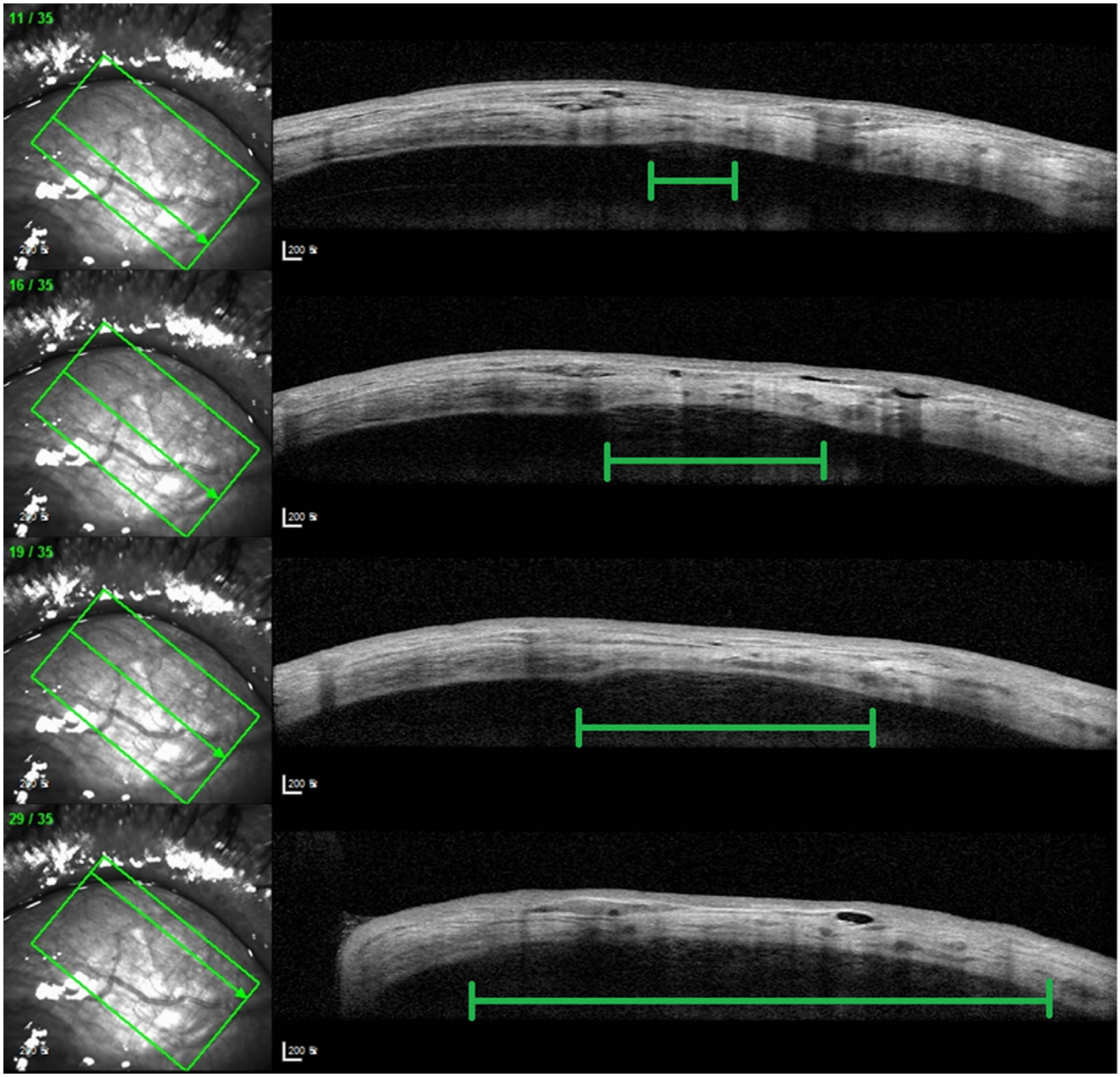

FIGURE 5. Bleb morphology assessment using AS-OCT. This is a left eye case in the biodegradable collagen-augmented Ahmed valve implantation group, in which the AS-OCT image was taken on postoperative day 1. The BCM can be distinguished under the conjunctiva and Tenon's capsule layer, with its homogeneous appearance and reflectance shadowing. We can assume that an edge of the quadrangle-shape BCM was noted in the top image. *Green lines* indicate the lateral margin of the BCM.

conventional method was performed in 21 eyes, and the BAAVI method was performed in 22 eyes. The demographic features of the population are summarized in Table 1. No significant differences were observed between the two groups with regard to age, best-corrected visual acuity, IOP, number of preoperative antiglaucoma medications, AXL, or endothelial cell count.

According to χ^2 testing, the overall success rate was significantly higher in the BAAVI group than in the conventional group (Table 2). The rates for qualified success were 52.4% and 90.9% ($P = 0.007$), complete success with target IOP 1 were 38.1% and 86.4% ($P = 0.002$), and complete success with target IOP 2 were 19.0% and 59.1% ($P = 0.012$) in the conventional AGV implantation and BAAVI groups, respectively.

Figure 3 demonstrates the IOP changes after both methods. The IOP at 1 month postoperatively was significantly lower in the BAAVI group than in the conventional group (11.1 ± 2.8 mm Hg versus 17.0 ± 8.1 mm Hg, $P = 0.027$). The postoperative IOP difference between the two groups decreased as the number of postoperative antiglaucoma medications in the conventional group increased after 1 month postoperatively (Fig. 4).

Table 3 presents details regarding the complications in both groups. The frequency of a hypertensive phase was significantly lower in the BAAVI group compared with the

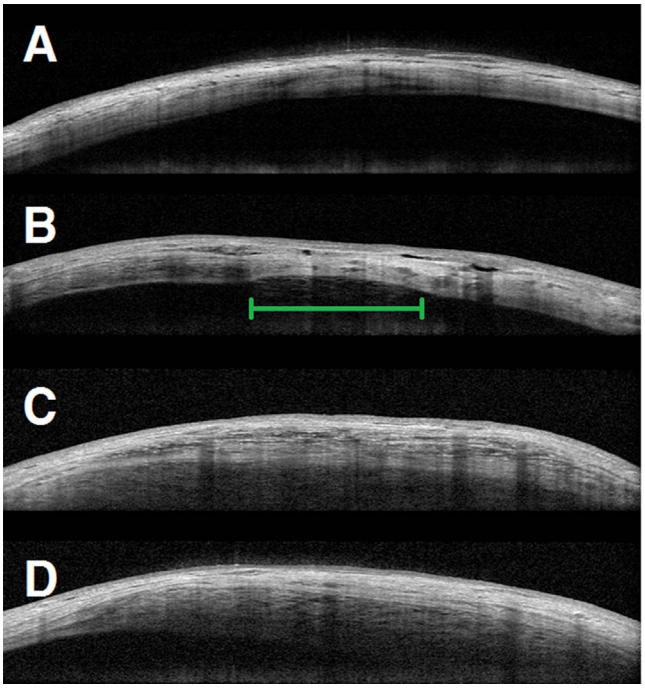

FIGURE 6. Change in bleb morphology over time. (**A**) A general case of bleb morphology in the conventional group. An upper higher-reflectance layer (conjunctiva) and a lower relatively lower reflectance layer (Tenon's capsule) were noted on postoperative day 180. (**B–D**) Representative AS-OCT images at the same cross-section location in a subject in the biodegradable collagen-augmented Ahmed valve implantation group. (**B**) On postoperative day 1, the BCM was clearly seen through the AS-OCT scan. (**C**) However, the BCM's reflectance became indistinct and the bleb thickness was increased and widened (the bleb itself started to change) on postoperative 1 month at the same cross-section location. (**D**) The inner layer, which should be Tenon's capsule, was quite thickened and showed reflectance shadowing implying tissue hydration on postoperative day 180. *Green lines* indicate the lateral margin of the BCM.

conventional group (4.5% vs. 47.6%, $P = 0.002$). Because cases with severe hyphema, which could substantially affect tube flow, were excluded, early hypotony was the most common complication in both groups resulting in chamber formation 2 weeks postoperatively.

Anterior Segment OCT Assessment

Inner bleb assessment using AS-OCT scans exhibited diverse outcomes. Usually the BCM reflectance was well maintained until 1 to 2 months postoperatively, possibly preventing shrinkage of the bleb. After that period, the bleb wall thickness was increased, transparency was decreased, and margins were blurred (implying tissue hydration) (Fig. 5). We call this the "transition period," as the whole bleb morphology was changing. The BCM reflectance and its variation over time can be clearly seen if we compare this with the bleb image of the conventional group (Fig. 6). In most cases, distinguishing the BCM demarcation was not difficult; however, even when we scanned the exact same section line, the inner bleb properties clearly changed over time. Although the bleb wall changed in the vast number of cases, in one case, the bleb images did not change except for a well-layered inner surface with relatively low reflectance (Fig. 7A). In two other cases, the BCM layer seemed to be covered not only on top but also underneath by a fine fibrotic layer (Fig. 7B); in these cases, the IOPs tended to be higher than in the other cases (17 and 21 mm Hg). Table 4 shows that the maximum bleb thickness was thicker in the BAAVI group than in the conventional group up to the 6-month follow-up evaluation ($P < 0.005$).

TABLE 4. Comparison of Maximum Bleb Thickness Measured by AS-OCT on Postoperative Days 30 and 180

	Conventional	BAAVI	P*
Maximum bleb thickness, μm			
On postoperative day 30	798.4 ± 88.6	935.5 ± 121.8	0.02
On postoperative day 180	760.2 ± 95.4	940.9 ± 184.7	0.03

Data are shown as mean ± SD.
* Mann-Whitney *U* test (between conventional and BAAVI groups).

DISCUSSION

This study assessed the early surgical outcomes of our novel method for managing refractory glaucoma. Early surgical success after GDD implantation is mainly dependent on the relationship between encapsulation formation and bleb size.[6,14] Although many innovative designs for GDDs aimed to reduce outflow resistance, rates of a postoperative hypertensive phase have varied from 18% to 40%, depending on each study's definition of success and the GDD design.[15–17]

Theoretically, sufficient bleb volume is the key to surgical success in Ahmed valve surgery, and to maintain sufficient volume, several factors might be regulated. First, the bleb wall thickness could be important. Although the number of studies regarding bleb analysis after tube surgery is limited because of technical issues, Jung et al.[18] recently reported in their retrospective study that the maximum bleb wall thickness was significantly thinner after successful Ahmed valve implantation. They speculated that a thinner bleb allows better aqueous permeability, resulting in better IOP control. However, these authors noted that the wall thickness can change over time, which means that in future studies, they should compare the AS-OCT parameters between the successful group and failed group over the same time course. To determine the validity of the possible hypothesis about "a big balloon with a thin wall," further studies with a prospective design are necessary.

Another aspect related to maintaining adequate bleb volume is the bleb intrawall properties, which may be more important than bleb wall thickness. Unlike during trabeculectomy, bleb intrawall properties generally do not concern surgeons during tube surgery because there is little that can be done to manipulate them and because dense fibrous changes in the bleb wall might cause relative homogeneity and high reflectivity, preventing better AS-OCT bleb analysis.[19–21] However, we can presume from many trabeculectomy bleb studies that bleb properties during tube surgery are also important for postoperative IOP control. In the current study, AS-OCT images at the same postoperative time period demonstrated that the bleb wall during Ahmed valve surgery was thickened and less transparent in the BAAVI group than in the conventional group.

Furthermore, the timing of aqueous humor inflow to the intrableb space is crucial for sufficient bleb volume. Recently, one group described the importance of early beta-blocker eye drop use after Ahmed valve implantation to prevent early inflow of aqueous humor into the bleb.[14] They speculated that inflammatory cytokines, such as tissue growth factor β, can promote excessive fibrovascular proliferation inside the bleb wall, eventually resulting in surgical failure.

If Ologen played a role as a barrier against aqueous humor inflow and also as a water content reservoir, this means that we

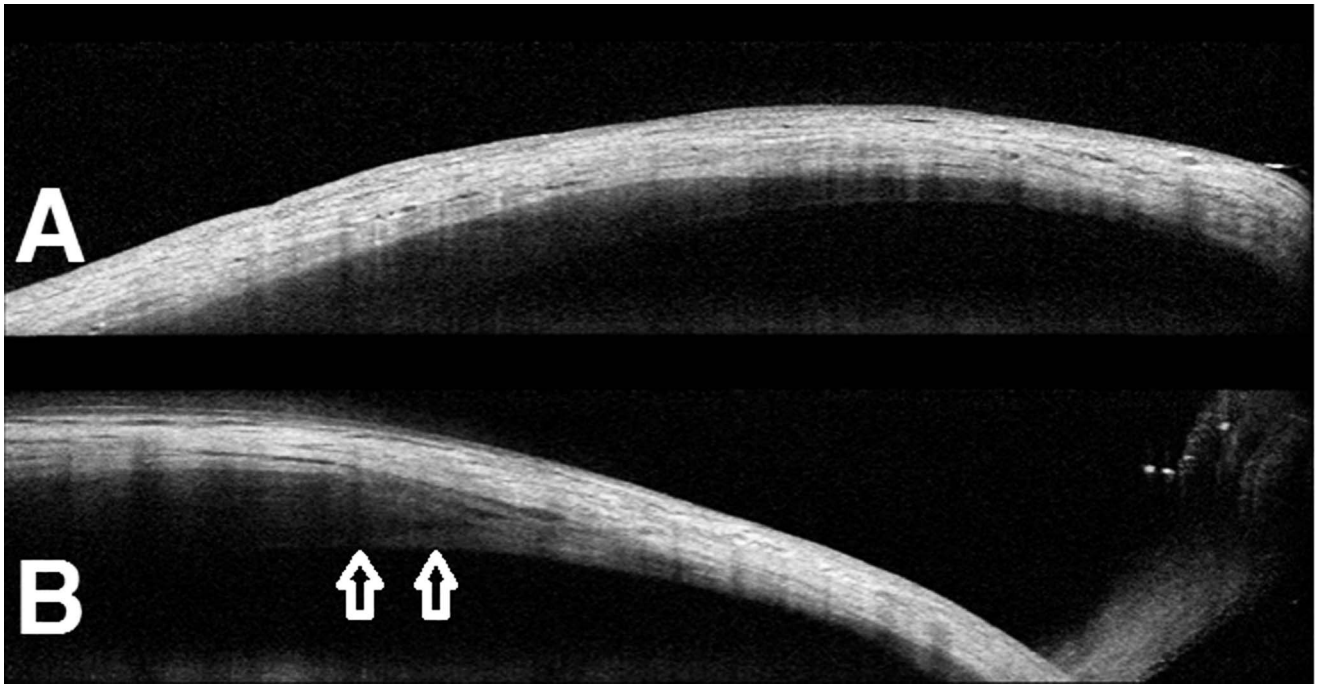

FIGURE 7. Unique features of two cases at 6 months postoperatively. (**A**) One case exhibited very low reflectance of the inner layer. (**B**) The other case showed a relatively high reflectance layer covering not only the top of the biodegradable collagen matrix layer but also underneath it, implying profound encapsulation formation.

can manipulate the bleb volume by using Ologen. Accordingly, the bleb wall properties will be the major priority in determining surgical success from now on. Interestingly, the lateral, upper, and lower margins of Ologen become blurred and even translocated over time, preventing the exact demarcation of the margin. This issue should be studied through a further histologic evaluation with an animal model.

The original design of this study was based on two essential points. One relates to the very similar time course between the hypertensive phase and Ologen's in vivo maintenance period. The hypertensive phase mostly occurs within the first 3 months after Ahmed valve implantation, and Ologen is maintained within the subconjunctival space for 3 to 6 months, according to the manufacturer. Ologen is packaged in dry form, consisting of more than 90% atelo-collagen; glycosaminoglycans compromise the remainder of the formulation. It swells after being soaked in fluids, with a three-dimensional porous structure that keeps the water content inside the structure. Ologen biodegrades under the conjunctival tissue within 6 months. Before degradation, conjunctival fibroblasts may enter its porous structure, and after biodegradation, only the subject's tissue remains in place. We speculated that these properties of Ologen would offer a larger bleb volume than the conventional method, especially in this early critical period.

The other essential aspect of our study design related to our desire to examine whether the use of Ologen could lead to less dependence on antiglaucoma medications in the postoperative period. Fibrovascular encapsulation surrounding the implant might grow into the valve portion, resulting in a hypertensive phase.[22] If Ologen prevents, or at least slows, this process, surgeons can manage their patients' postoperative IOP changes more easily and with less dependence on medications than with conventional surgical methods.

Table 4 shows the different tendency of thickness change over time in each group. In the conventional group, the maximal bleb thickness seems to decrease over time and in the BAAVI group, it seems to increase. In the conventional group, the tendency was probably due to the relationship between IOP change and encapsulation formation response. The pressure acting on the bleb wall increases with time and tissue contraction also progresses, probably resulting in the bleb wall thinning. Of course, we cannot be so sure with this small sample size. Recently, Jung et al.[23] also described that the bleb wall thickness was negatively correlated with the IOP. However, unlike our data, the mean IOP value of their subjects was decreased (from 0.51 mm and 19.3 mm Hg on postoperative 1 month to 0.64 mm and 14.9 mm Hg on postoperative 6 months). On the contrary, the thickness can be increased over time due to the change of bleb property in the BAAVI group.

In conclusion, we demonstrated that the use of a biodegradable collagen implant can prevent the hypertensive phase after Ahmed valve surgery by maintaining sufficient bleb volume and altering bleb wall properties. This BAAVI method requires additional studies to compare its long-term success rate with those after conventional Ahmed valve surgery.

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