mg/kg into rabbits intravenously caused patchy RPE degeneration and photoreceptor degeneration.

Injection of $NaIO_3$ at a dose of 40 mg/kg which is the most commonly used concentration for functional evaluations of retinal prostheses[24,33] caused apoptosis in the photoreceptor layer and in the INL at 1 week after the injection and apoptosis in the GCL at 3 weeks. A severe apoptosis of the GCL was noted 4 months after the injection.[33] In another study,[24] an injection of $NaIO_3$ at a dose of 40 mg/kg led to a reduction of 76% in the a-wave and of 67% in the b-wave amplitudes of the control subjects.

In contrast to $NaIO_3$, the retinal degeneration of our model was limited and uniform and large enough for a functional evaluation of a retinal prosthesis. Our model at 1 year (group 2) showed that the cell counts in the GCL were not significantly different ($P = 0.903$; Table 1). More important, we were able to elicit EEPs by STS electrode at 1 year after the irradiation (Fig. 1O). Thus, our model can be used as a retinal degenerative model for testing retinal prostheses for at least 1 year after irradiation.

A recent study[34] demonstrated that phased tissue remodeling and functional reprogramming of the neural retina may occur in degenerative diseases such as retinitis pigmentosa. However, most studies on developing a degenerative model including our model did not investigate the possibility of neural reprogramming, and more investigations are needed to confirm tissue remodeling and functional reprogramming of the neural retina in degenerative retinal models.

In conclusion, we succeeded in developing a middle-sized animal model of photoreceptor degeneration. Our model will help to determine the optimal stimulus parameter to elicit EEPs in degenerated retinas by STS electrode. In addition, these parameters may be helpful to elicit phosphenes from patients with RP. This middle-sized animal model is easy to handle and to be created, and should be helpful to evaluate not only the STS system but also other types of retinal prostheses including subretinal and epiretinal stimulations.

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CLINICAL STUDY

Prospective randomized comparison of DisCoVisc and Healon5 in phacoemulsification and intraocular lens implantation

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Abstract

Purpose To compare two ophthalmic viscosurgical devices (OVDs), DisCoVisc (viscous dispersive) and Healon5 (viscoadaptive), in terms of their overall clinical performance during phacoemulsification and intraocular lens (IOL) implantation.

Methods In 323 patients (DisCoVisc; 157, Healon5; 166), the surgeons evaluated on a three-point scale, the maintenance of anterior chamber (AC) during continuous curvilinear capsulorhexis (CCC), maintenance of AC during IOL implantation, retention during phacoemulsification, ease of injection, facilitation of CCC, transparency during surgery, and ease of removal from the eye. The time needed to completely remove OVDs after IOL implantation was measured. Masked examiners measured intraocular pressure (IOP), corneal thickness, and corneal endothelial cell count up to 90 days postoperatively.

Results DisCoVisc was assessed to be significantly better than Healon5 in maintenance of AC during CCC ($P=0.0008$, Cochran–Mantel–Haenszel test) and IOL implantation ($P=0.0055$), retention during phacoemulsification ($P=0.0009$), ease of injection ($P<0.0001$), facilitation of CCC ($P<0.0001$), transparency ($P<0.0001$), and ease of removal ($P<0.0001$). The washout time was 29.6 ± 13.4 and 36.2 ± 17.5 s in the DisCoVisc and Healon5 groups, respectively ($P=0.0002$, unpaired t-test). The mean endothelial cell loss was $1.8\pm8.7\%$ in the DisCoVisc group and $3.8\pm8.3\%$ in the Healon5 group ($P=0.0358$). There were no statistically significant between-group differences in IOP and corneal thickness.

Conclusion DisCoVisc was better retained in the eye during phacoemulsification and was easier to remove after IOL implantation. The corneal endothelial cell loss was significantly less with DisCoVisc than with Healon5. It was indicated that the whole surgical process can be efficiently covered by DisCoVisc alone.

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Keywords: ophthalmic viscosurgical device; viscoelastic material; cataract surgery; corneal endothelium

Introduction

The introduction of ophthalmic viscosurgical devices (OVDs) for use in ophthalmic surgery has had a significant effect on the practise of ophthalmology. OVDs have become indispensable tools in a variety of ophthalmic surgical procedures, especially in cataract surgery. The most important functions of OVDs during cataract surgery are maintenance of the anterior chamber (AC) and protection of the ocular tissues, in particular the corneal endothelium. During phacoemulsification, OVDs can protect the corneal endothelium by preventing the direct contact of debris-bearing turbulence and surgical instruments.

The property of a viscoelastic formulation is closely tied to its physicochemical and rheological properties.[1,2] Higher viscosity cohesive OVDs and lower viscosity dispersive

OVDs have their own unique advantages and disadvantages. High-viscosity cohesive OVDs help to maintain and preserve space as well as to displace and stabilize tissues. These materials, however, tend to easily flow out of the eye during phacoemulsification. Low-viscosity dispersive OVDs tend to remain in the eye adjacent to the corneal endothelium, providing potential protection during phacoemulsification. The disadvantage of this type of OVDs is that they poorly maintain space and are sometimes difficult to remove.

A viscoadaptive viscoelastic, Healon5, belongs to another class of OVDs.[3–5] Its distinguishing characteristic is that the rheological behaviour changes under varying conditions of turbulence. It exerts an effect as a very viscous, cohesive viscoelastic agent at low flow rate and as a pseudodispersive viscoelastic agent at higher flow rate. A previous clinical study showed that the viscoadaptive OVD (Healon5) was superior to the cohesive OVD (Healon) in retention during phacoemulsification, AC maintenance during anterior capsulotomy, and facilitation of intraocular lens (IOL) implantation.[6] On the other hand, injection and removal of the viscoadaptive OVD were judged to be more difficult than the cohesive OVD.[6]

Recently, a new class of OVD, DisCoVisc, has been developed and introduced in the market.[7] DisCoVisc is a viscoelastic solution of sodium chondroitin sulphate and sodium hyaluronate, having a viscosity of 75 000 ± 35 000 milliPascal-seconds (mPas) at a shear rate of 1/s and 25 °C. Each millilitre of DisCoVisc contains not more than 40 mg sodium chondroitin sulphate and 17 mg sodium hyaluronate. It has been claimed that DisCoVisc has an intermediate cohesive/dispersive index, facilitating both space maintenance and tissue protection. Experimental studies reported that DisCoVisc showed excellent retention during phacoemulsification.[8–10] When compared with the viscoadaptive Healon5, DisCoVisc was retained better in the chamber and was easier to remove.[9]

The clinical usefulness of DisCoVisc in cataract surgery, however, has not been reported, except for one study that compared DisCoVisc and soft-shell technique using Viscoat and Provisc.[11] We conducted the current prospective randomized clinical study to compare the performance of DisCoVisc and Healon5 regarding maintenance of the AC during continuous curvilinear capsulorhexis (CCC) and IOL implantation, retention during phacoemulsification, ease of injection, facilitation of CCC, transparency during surgery, and ease of removal from the eye. The time required to remove from the eye after IOL implantation was measured and compared. The intraocular pressure (IOP), corneal endothelial cell count, and corneal thickness were also assessed as safety-related parameters.

Materials and methods

Subjects

A multicentre randomized study was carried out to compare DisCoVisc and Healon5 during phacoemulsification and IOL implantation. Patients aged ⩾40 years with age-related cataract requiring surgery were enroled in the study. Exclusion criteria were: IOP of ⩾22 mm Hg, glaucoma in either eye, proliferative diabetic retinopathy, corneal endothelial damage (cell count of $<1500/mm^2$), history of uveitis, and congenital eye diseases.

Six surgical centres participated in the study. The patients were randomly assigned to either of the two study groups according to a computer-generated, randomized list prepared by the case registration centre (ACRONET Co., Tokyo, Japan). The randomized list was stratified for multiple institutions and implemented for each block of patients within the individual institutions. On the basis of information provided by the surgeon, the case registration centre enroled the patients, after confirming that each patient met all inclusion criteria and did not violate any of the exclusion criteria. After registration, the surgeon was advised by the case registration centre about the registration number of each patient and the OVD assigned according to the randomized list.

A total of 323 eyes of 323 patients were included, 157 for the DisCoVisc group (male/female; 54/103, 70.3 ± 8.2 years old, mean ± SD) and 166 for the Healon5 group (66/100, 70.3 ± 7.9 years old). Only one eye of each patient was included in the study.

The study protocol was approved by the institutional review board of each participating surgical centre, and the study was conducted in accordance with the Declaration of Helsinki. All patients provided informed consent in a written form before participation. The study was part of the phase III clinical trial under the Ministry of Health, Labor, and Welfare of Japan.

Surgery

The OVDs to be used were made known to the surgeons as it was difficult to maintain the blinding of the surgeons because of the different physicochemical properties of OVDs. All postoperative measurements and observations were conducted by investigators other than the surgeons, who were not informed about the allocated OVD.

Six surgeons at six surgical centres performed phacoemulsification and foldable IOL implantation. IOLs used were hydrophobic acrylic foldable three-piece IOLs (MA60BM; Alcon, Fort Worth, TX, USA) or single-piece IOLs (SA60AT; Alcon). Same products were used

within each surgical centre. After IOL implantation, DisCoVisc was removed using the irrigation/aspiration (I/A) tip without any special washout techniques, whereas Healon5 was washed out using the behind-the-lens technique or Rock'n Roll technique.[12,13]

Data collection

The surgeons subjectively assessed the clinical performance (efficacy) of DisCoVisc and Healon5 during surgery based on seven criteria: maintenance of the AC during CCC, maintenance of the AC during IOL implantation, retention during phacoemulsification, ease of injection, facilitation of CCC, transparency during surgery, and ease of removal from the eye. The surgeons evaluated each OVD on a three-point rating scale (1 = good, 2 = average, and 3 = poor).

The time needed to completely remove the OVDs from the chamber with the I/A tip was recorded.

The IOP was measured using the Goldmann applanation tonometer preoperatively and at 5 and 24 h, and 7, 30, and 90 days postoperatively. The specular microscopy was performed preoperatively and 90 days after surgery. Corneal thickness was measured with an ultrasound pachymeter preoperatively and at 24 h, and 7, 30, and 90 days after surgery.

Statistical analysis

The time course of changes in numerical parameters was analysed using analysis of variance. Inter-group difference in numerical data was analysed with the unpaired *t*-test. The surgeons' assessment scores of clinical performance of OVDs and the incidence of adverse effects, inducing IOP elevation, were analysed using the Cochran–Mantel–Haenszel test. Corneal endothelial count before and 90 days after surgery was compared with the paired *t*-test. A *P*-value of <0.05 was considered significant.

A prestudy power calculation based on the data of the International Organization for Standardization (ISO) 15798:2001(E) Annex D indicated that a sample size of 135 eyes in each group would be sufficient to examine the inter-group difference in incidence of IOP elevation over 30 mm Hg using a significance level of 10% (α) and a power of 80% ($1-\beta$). The calculation based on ISO 16671:2003(E) Annex F revealed that the lower limit of 95% confidence intervals will exceed -7.5% (non-inferiority margin) with a power of 80% ($1-\beta$) in a sample size of 135.

Results

Among the subjects enroled, 6 patients (3 in the DisCoVisc and 3 in the Healon5 groups) were excluded from the analysis because of intraoperative complication (1 in DisCoVisc), use of another IOL (1 in DisCoVisc and 1 in Healon5) or OVD (1 in Healon5), or lost to follow-up (1 in DisCoVisc and 1 in Healon5). Thus, the data in a total of 317 eyes (154 in DisCoVisc and 163 in Healon5) were analysed. The number of eyes evaluated at each predetermined examination point is shown in Table 1.

Intraoperative performance of DisCoVisc and Healon5 was evaluated by the surgeons (Table 2). DisCoVisc was assessed to be significantly better than Healon5 in terms of maintenance of the AC during CCC ($P=0.0008$), maintenance of the AC during IOL implantation ($P=0.0055$), retention during phacoemulsification ($P=0.0009$), ease of injection ($P<0.0001$), facilitation of CCC ($P<0.0001$), transparency during surgery ($P<0.0001$), and ease of removal from the eye ($P<0.0001$).

The time needed to completely remove the OVDs from the chamber with the I/A tip was 29.6 ± 13.4 and 36.2 ± 17.5 s in the DisCoVisc and Healon5 groups, respectively. There was a significant difference between the two groups ($P=0.0002$).

Safety-related parameters were evaluated by the investigators other than the surgeons. The time course of changes in IOP is shown in Figure 1. In both groups, IOP reached the peak at 5 h after surgery, followed by gradual decreases to the preoperative level by 7 days postoperatively. There was no significant inter-group difference in IOP at any examination points. At 5 h postoperatively, IOP above 30 mm Hg was observed in 11 eyes (7.2%) of the DisCoVisc group and 12 eyes (7.4%) of the Healon5 group. The incidence did not differ significantly ($P=0.954$). The IOP quickly returned to the normal level in all cases.

The mean corneal endothelial cell loss at 90 days postoperatively was $1.8 \pm 8.7\%$ in the DisCoVisc group and $3.8 \pm 8.3\%$ in the Healon5 group. There was a significant difference between the groups ($P=0.0358$).

Table 1 The number (percentage) of eyes assessed at each predetermined point

	Preop	*5 h*	*24 h*	*7 days*	*30 days*	*90 days*
DisCoVisc group	154 (100%)	154 (100%)	146 (94.8%)	154 (100%)	151 (98.1%)	152 (98.7%)
Healon5 group	163 (100%)	163 (100%)	155 (95.1%)	163 (100%)	163 (100%)	161 (98.8%)

Table 2 Results of surgeons' assessment

	DisCoVisc			*Healon5*			
	Good	*Average*	*Poor*	*Good*	*Average*	*Poor*	
Maintenance of AC during CCC	130	24	0	112	48	3	$*P=0.0008$
Maintenance of AC during IOL implantation	126	28	0	112	47	4	$*P=0.0055$
Retention during phacoemulsification	90	64	0	68	86	9	$*P=0.0009$
Ease of injection	141	12	1	80	108	5	$*P<0.0001$
Facilitation of CCC	82	72	0	15	110	38	$*P<0.0001$
Transparency during surgery	138	16	0	65	96	2	$*P<0.0001$
Ease of removal	80	72	2	7	133	23	$*P<0.0001$

Abbreviations: AC, anterior chamber; CCC, continuous curvilinear capsulorhexis; IOL, intraocular lens.
*Significantly different between groups (Cochran–Mantel–Haenszel test).

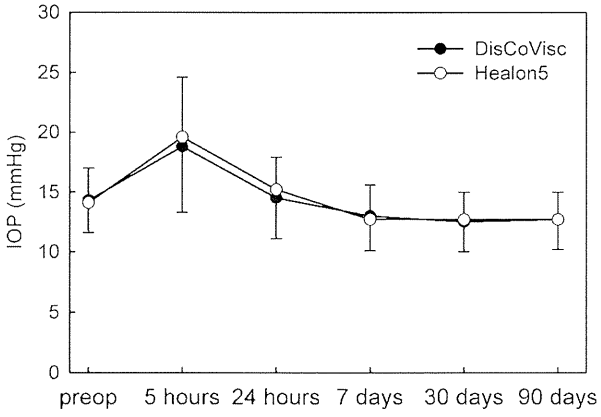

Figure 1 The time course of changes in intraocular pressure. There was no significant inter-group difference at any examination points. Mean ± SD.

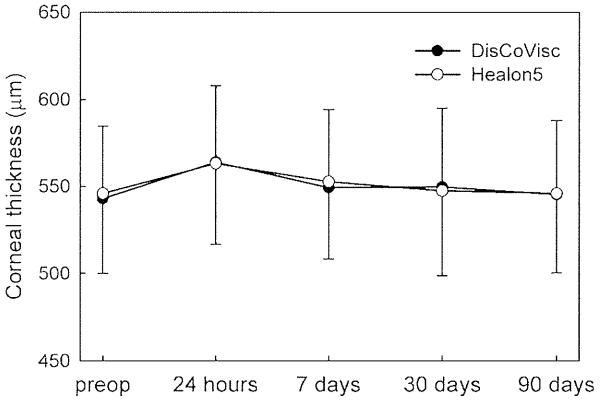

Figure 2 The time course of changes in corneal thickness. There was no significant inter-group difference on any examination occasions. Mean ± SD.

The time course of changes in corneal thickness is shown in Figure 2. The thickness reached its peak at 24 h after surgery, and returned to the preoperative level by 7 days after surgery. There was no significant inter-group difference on any examination occasions.

There were no intraoperative complications related to OVDs, including thermal burn of the wound. Besides IOP elevation as mentioned above, there was one case of transient mild corneal oedema (0.6%) and macular oedema (0.6%) in the Healon5 group, but no other postoperative complications were encountered. There was no significant inter-group difference in the incidence of postoperative complications. No patients in either group lost best corrected visual acuity by one line or more compared with the preoperative level.

Discussion

DisCoVisc is a viscous-dispersive OVD, having the properties of both cohesive and dispersive OVDs.[7] A previous experimental study showed that the retention and removal properties of DisCoVisc fell between cohesive Provisc and dispersive Viscoat, and DisCoVisc was retained in the AC during phacoemulsification better than Healon5, whereas removal of DisCoVisc with the I/A tip was easier than Healon5.[9] We obtained similar results in the current clinical study. DisCoVisc was rated better than Healon5 in terms of maintenance of the AC during CCC and IOL implantation as well as retention during phacoemulsification. These results seem to reflect the more dispersive property of DisCoVisc, against the pseudodispersive nature of Healon5. On the other hand, removal time of OVDs with the I/A tip was significantly shorter with DisCoVisc than with Healon5. The surgeons' subjective assessment also indicated that DisCoVisc is significantly easier to remove than Healon5 after IOL implantation. Clinically, it is known that Healon5 is difficult to be washed out at the end of surgery because of the presence of an IOL. Healon5 is often trapped behind the IOL,[2] especially so with the acrylic foldable IOL.[14] The viscoadaptive OVDs are so rigid to permit scrolling around obstacles in the eye

(IOLs), resulting in interrupted contact with the aspiration port.[2] The OVD fragment behind the IOL is exposed to too little turbulent flow to move towards the aspiration port, unless the I/A tip is placed behind the IOL or a special technique is used. DisCoVisc is not so rigid and has sufficient cohesion to stay together in the presence of aspiration and is supple enough to bend around obstacles. The behind-the-lens technique or Rock'n Roll technique is not necessary for the washout of DisCoVisc.

We found that corneal endothelial cell loss was significantly less in the DisCoVisc group than in the Healon5 group, most likely because of better retention of DisCoVisc than Healon5 during phacoemulsification. On the other hand, there was no inter-group difference in the mean corneal thickness after surgery. This was probably because this study was conducted in patients with simple age-related cataract without any other ocular and systemic complications. Our study population did not include those cases with small pupil, very shallow chamber, compromised endothelial cell function, corneal disorder, and blood-aqueous barrier dysfunction. It seems that the viscous-dispersive nature of DisCoVisc would be more beneficial in these difficult cases, in which clinically measurable differences in the surgical outcomes might be anticipated. Another prospective randomized study will be needed to prove this postulate.

In this study, it was found that DisCoVisc showed significantly better performance than Healon5 in terms of ease of injection and removal. Ease of injection is because of the lower viscosity of this product. Ease of removal is an important issue. If the OVD is not removed completely, IOP can increase postoperatively. In this study, the surgeons rated DisCoVisc favourably regarding the ease of removal against Healon5. This was partly because the behind-the-lens technique or Rock'n Roll technique was compulsory for the removal of Healon5 in this study, whereas no special technique was required for DisCoVisc. Another reason is that removal time was significantly longer in the Healon5 group than in the DisCoVisc group. This was primarily because it takes longer to aspirate a more viscous mass, of similar volume, through similar-sized aperture, and with similar vacuum force, compared with a less viscous mass. These factors seem to have contributed to the different scores for these OVDs. The postoperative IOP, however, did not differ significantly between groups, indicating that both OVDs were effectively and successfully washed out.

DisCoVisc was also assessed to be superior to Healon5 regarding transparency during surgery and facilitation of CCC. Transparency during surgery may be related to the appearance of interface between the aqueous humour and the OVD. Because Healon5 tends to be aspirated gradually during phacoemulsification, such interface may develop during surgery, which can somewhat interfere visibility within the eye. Meanwhile, when the AC is filled with OVD, there is no interface between the aqueous humour and the OVD, and the clarity of the AC is preserved. This will be the case of DisCoVisc, which is retained in the eye for a longer period of time during phacoemulsification than Healon5.[9] The facilitation of CCC seems to be related to the viscosity of OVDs. Healon5 is thicker and heavier, leading to the surgeons' review that CCC was more difficult to control when the chamber is filled with this agent.

This study has several limitations. First, only routine cataract cases were included in the subjects. In practise, the number of complicated cases has been increasing, at least not decreasing. Evaluation of OVDs in these tough cases will be important. Second, we only compared DisCoVisc and Healon5. In the market, there are many other OVDs with different properties. Comparison of DisCoVisc with other products will be interesting. Third, although all postoperative measurements were conducted by masked examiners, the surgeons were not masked to the type of OVDs. Because the physicochemical properties of DisCoVisc and Healon5 are so different, it was difficult to maintain the blinding of the surgeons.

This study clearly showed the advantageous features of DisCoVisc in cataract surgery; that is, greater retention in the eye during phacoemulsification and easier removal from the eye after IOL implantation. The former has been known as the characteristic of low-viscosity dispersive OVD, and the latter has been recognized as the feature of high-viscosity cohesive agents. Greater retention in the eye during phacoemulsification resulted in less damage to the corneal endothelial cells. The viscous-dispersive nature of DisCoVisc made it possible to combine these two different traits into one viscoelastic substance. Thus, the whole process of cataract surgery can be efficiently covered by one OVD, which can be of merit in ophthalmic practise both economically and medically.

Summary

What was known before

- DisCoVisc is a new class of ophthalmic viscosurgical devices, the clinical characteristics of which have not been well known.

What this study adds

- Compared with Healon5, DisCoVisc was better retained in the eye during phacoemulsification and was easier to remove after IOL implantation. The corneal endothelial cell loss was significantly less with DisCoVisc than with Healon5.

Conflict of interest

The authors declare no conflict of interest.

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Repeatability and reproducibility of anterior ocular biometric measurements with 2-dimensional and 3-dimensional optical coherence tomography

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PURPOSE: To evaluate the repeatability and reproducibility of central corneal thickness (CCT), anterior chamber depth (ACD), and anterior chamber width (ACW) measurements using 3-dimensional (3-D) corneal and anterior segment optical coherence tomography (CAS-OCT) and 2-dimensional (2-D) anterior segment OCT (AS-OCT).

SETTING: Department of Ophthalmology, Institute of Clinical Medicine, University of Tsukuba, Ibaraki, Japan.

DESIGN: Nonrandomized clinical trial.

METHODS: The CCT, ACD, and ACW were measured in normal eyes using a prototype 3-D swept-source CAS-OCT device and a 2-D time-domain AS-OCT device (Visante). The coefficient of repeatability and reproducibility and the intraclass correlation coefficient (ICC) were calculated to evaluate the repeatability and reproducibility of the measurements.

RESULTS: Eighty-five eyes (85 subjects) were evaluated. The mean CCT measurement was 557.5 μm ± 40.5 (SD) with CAS-OCT and 556.4 ± 39.4 μm with AS-OCT; the mean ACD measurement, 3.13 ± 0.40 mm and 3.16 ± 0.39 mm, respectively; and the mean ACW, 11.80 ± 0.47 mm and 11.79 ± 0.49 mm, respectively. There was no statistically significant difference in CCT or ACW measurements between the 2 devices ($P>.05$, Wilcoxon signed rank test). Although the ACD measurements were significantly different ($P<.0001$), the difference was small (0.03 mm). Significant linear correlations were found between the measurements of the 2 devices ($P<.0001$). The ICC was greater than 0.99 for CAS-OCT and greater than 0.96 for AS-OCT.

CONCLUSION: Corneal and anterior segment OCT and AS-OCT provided comparable and well-correlated anterior ocular biometric measurements, with sufficient repeatability and reproducibility.

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Although 2-dimensional (2-D) imaging is often used for image analysis in ophthalmology, 3-dimensional (3-D) imaging technology is emerging as a way to achieve more detailed assessment and better visualization of ocular structures. Three-dimensional corneal and anterior segment optical coherence tomography (CAS-OCT) was developed on the basis of swept-source OCT technology, which is a form of Fourier-domain OCT.[1,2] Fourier-domain OCT has higher sensitivity and measurement speed than 2-D time-domain OCT.[3]

A 2-D time-domain anterior segment-OCT (AS-OCT) system (Visante, Carl Zeiss Meditec) is commercially available; the system has a light source with a 1310 nm wavelength and is reported to yield highly repeatable and reproducible anterior segment measurements.[4–6] However, because of the measurement speed, 3-D images of the ocular tissue cannot be obtained. The measurement speed of swept-source CAS-OCT is more than 10 times that of 2-D time-domain OCT; furthermore, swept-source CAS-OCT provides robust protection against sample motion and thus can yield 3-D images of ocular structures.[1,7]

Arbitrary cross-sectional images of the eye's anterior segment can be obtained with 3-D CAS-OCT;

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thus, theoretic biometric measurements of any site can be performed in arbitrary directions.[8] The repeatability and reproducibility of anterior ocular biometric measurements obtained using 3-D OCT and 2-D AS-OCT devices have not been compared; therefore, in the current study, we evaluated such measurements.

SUBJECTS AND METHODS

This study evaluated normal eyes with no ocular abnormalities except refractive error. Only the right eye of each participant was studied. The study was performed in accordance with the tenets of the Declaration of Helsinki, and all participants provided written informed consent.

Biometry Measurements

All measurements were recorded between 11:00 AM and 3:00 PM without pupil dilation. The examination room was illuminated at 6.0 ± 1.5 lux, with the illumination measured with a light meter (LM-8000, Fuso). Two experienced ophthalmologists (S.F., K.K.) sequentially obtained measurements by 3-D CAS-OCT and by AS-OCT under the same lighting conditions.

The study used the Visante 2-D AS-OCT device and a prototype 3-D CAS-OCT device built by the Computational Optics Group, University of Tsukuba and Tomey Corp.[1] The prototype is based on swept-source OCT technology, which is a derivative of Fourier-domain OCT and has the same high sensitivity and rapid measurement speed.[2,9] Swept-source OCT uses a fast-wavelength scanning-laser source and a balanced photodetector for spectrally resolved interferometric detection, which is a fundamental mechanism of Fourier-domain OCT. Standard spectral-domain OCT uses a broadband light source and a high-speed spectrometer. The light source used in the prototype 3-D CAS-OCT device has a −3 dB wavelength scanning range, which is equivalent to the −3 dB bandwidth of spectral-domain OCT (110 nm), and a center wavelength of 1.3 μm. This wavelength is longer than that of retinal spectral-domain OCT and has higher penetration into the highly scattered tissues of the anterior eye. The prototype CAS-OCT system provides 3-D visualization of the anatomic structures of the anterior segment, such as the cornea, anterior chamber, scleral spur, angle recess, and filtering bleb.[10–12] The measurement speed is 20 000 A-lines/s. The device measures tissue with a maximum width of 16.0 mm × 16.0 mm and a maximum depth of 6.0 mm. The mean axial resolution in 4.0 mm deep tissue is 11.0 μm. The lateral resolution of acquired images is less than 30.0 μm. The acquisition time is 3.3 seconds per volume for a resolution of 256 voxels × 256 voxels × 1024 voxels; the acquisition time of 256 A-scans per 1 cross-section image is 0.0129 second. A typical 3-D scan is divided into 256 horizontal cross-sections, each of which comprises 256 A-scans. This CAS-OCT system generates 2-D images by sectioning 3-D images in arbitrary directions (Figure 1, *A*, *B*, *C*, and *E*).

The 2-D AS-OCT system also has a central wavelength of 1.3 μm. With the system's standard software, the lateral resolution of acquired images is 60 μm and the axial resolution, 18 μm. The system produces anterior segment images up to 6.0 mm in depth and 16.0 mm in width. The acquisition time of 256 A-scans per 1 cross-section image is 0.125 second. On the AS-OCT images, the corneal vertex reflection is visualized as a vertical flare extending from the strong anterior corneal apex reflection.

The subjects were instructed to look at an internal fixation target during scanning with CAS-OCT and AS-OCT. On the horizontal cross-sectional slice with the corneal vertex reflection, the anterior chamber width (ACW) was measured as the distance from angle to angle (ATA) (Figure 1, *C*). On the same cross-sectional slice, a line was drawn from the ATA with a perpendicular projection that extended forward from the median point through the cornea. Central corneal thickness (CCT) and anterior chamber depth (ACD) were measured along this perpendicular line (Figure 1, *C*).[13] With the 2-D AS-OCT system, the CCT is usually measured with the dedicated cornea mode (high resolution cornea 10.0 mm wide and 3.0 mm deep); however, this mode cannot detect the angle or measure in a manner similar to that of the CAS-OCT device. The built-in caliper tool of the AS-OCT system was thus used to measure the CCT, ACD, and ACW on the horizontal cross-sectional slice with the corneal vertex reflection in anterior segment mode (Figure 1, *D*).

Statistical Analysis

Statistical analysis was performed using StatView software (version 5.0, SAS Institute, Inc.). The CCT, ACD, and ACW measurements were evaluated using Bland-Altman plots, 95% limits of agreement (LoA) (mean difference 1.96), and the Pearson correlation coefficient (r).[14] The repeatability and reproducibility coefficients and intraclass correlation coefficients (ICCs) for the measurements were assessed. The definitions of the coefficients of repeatability and reproducibility were based on those adopted by the British Standards Institution and other groups.[5,8,15,16] In brief, the coefficient of repeatability was defined as 2 standard deviations (SDs) of the differences between the measurements obtained for the same subjects obtained in a different session by the same observer. The coefficient of reproducibility was defined as 2 SDs of the differences between the measurements obtained for the same subject obtained at the same visit by different observers. The coefficients of variation were calculated from 5 consecutive CAS-OCT and AS-OCT scans by the same observer. The results of all association tests were considered statistically significant when the P value was less than 0.05.

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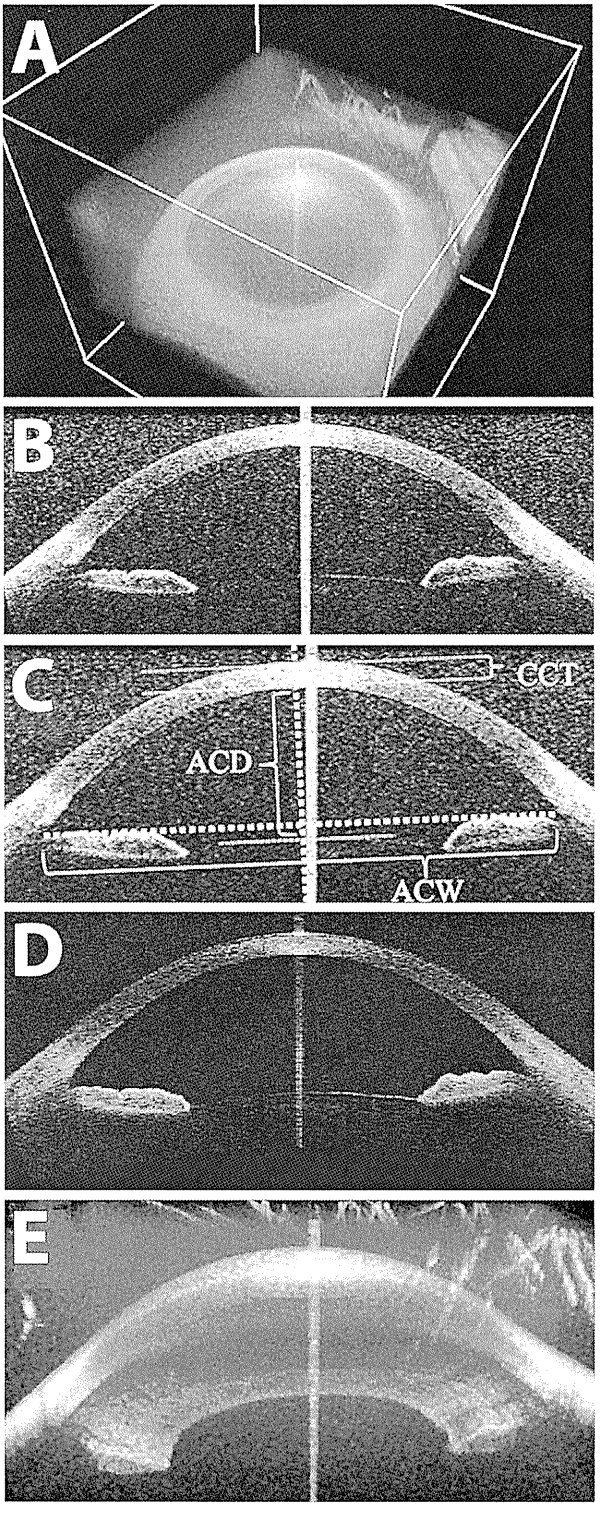

Figure 1. *A*: The 3-D image of the anterior segment obtained by CAS-OCT. *B*: Two-dimensional cross-sectional image created from the 3-D image obtained with CAS-OCT. *C*: For ACW measurement, a line is drawn from the ATA with a perpendicular projection that extended forward from the median point through the cornea. The CCT and ACD are measured along the perpendicular line. *D*: Two-dimensional cross-sectional image obtained with AS-OCT. *E*: Gonioscopic view of the anterior segment obtained with CAS-OCT (ACD = anterior chamber depth; ACW = anterior chamber width; CCT = central corneal thickness).

RESULTS

The study evaluated 85 eyes of 85 participants. The mean age of the 58 men and 27 women was 39.1 years ± 22.6 (SD) (range 22 to 89 years). The mean refractive error was −3.0 ± 2.1 diopters (D) (range −7.5 to 0.5 D).

Comparison of Measurements

Table 1 shows the mean CCT, ACD, and ACW measurements. There was no statistically significant difference in the CCT and ACW measurements between CAS-OCT and AS-OCT ($P = .128$ and $P = .608$, respectively; Wilcoxon signed rank test). Although there was a statistically significant difference in ACD measurements between the 2 devices ($P < .0001$), the difference was small (0.03 mm). There was a significant linear correlation between the CCT ($r = 0.981$, $P < .0001$), ACD ($r = 0.986$, $P < .0001$), and ACW ($r = 0.986$, $P < .0001$) measurements obtained by CAS-OCT and by AS-OCT (Figures 2 to 4).

Figures 5 to 7 show the Bland-Altman plots of the mean difference between the CCT, ACD, and ACW measurements. The 95% LoA for the CCT, ACD, and ACW measurements obtained by the 2 techniques were −12.0 to 10.1 μm, −0.07 to 0.12 mm, and −0.40 to 0.38 mm, respectively.

Repeatability and Reproducibility

Table 2 shows the repeatability and reproducibility of the CCT, ACD, and ACW measurements by CAS-OCT and AS-OCT. The repeatability and reproducibility were excellent with both devices. The ICCs for the CCT, ACD, and ACW measurements obtained using the CAS-OCT system were between 0.990 and 0.999, and these values tended to be slightly higher than those obtained using the AS-OCT system (ICC = 0.960 to 0.999).

DISCUSSION

In the current study, we compared 3-D CAS-OCT and 2-D AS-OCT systems for anterior segment biometric measurements of the eye and tested the repeatability

Table 1. Mean CCT, ACD, and ACW measurements.

	Mean ± SD		
Method	CCT (μm)	ACD (mm)	ACW (mm)
3-D CAS-OCT	557.5 ± 40.5	3.13 ± 0.40	11.80 ± 0.47
2-D AS-OCT	556.4 ± 39.4	3.16 ± 0.39	11.79 ± 0.49

ACD = anterior chamber depth; ACW = anterior chamber width; AS-OCT = anterior segment optical coherence tomography; CAS-OCT = corneal and anterior segment optical coherence tomography; CCT = central corneal thickness

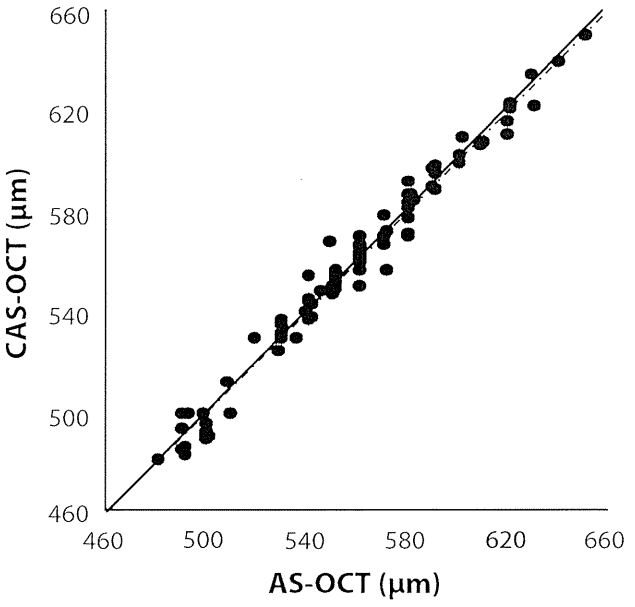

Figure 2. Correlation of CCT measurements between CAS-OCT and AS-OCT. The best-fit line ($y = -10.338 + 1.02x$) and the line of equivalence ($y = x$) are represented by the solid line and the dotted line, respectively (AS-OCT = anterior segment optical coherence tomography; CAS-OCT = corneal and anterior segment optical coherence tomography).

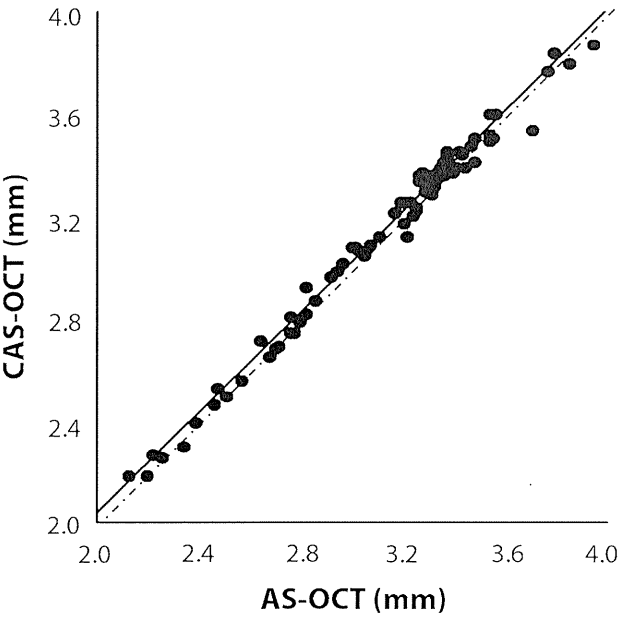

Figure 3. Correlation of ACD measurements between CAS-OCT and AS-OCT. The best-fit line ($y = 0.076 + 0.984x$) and the line of equivalence ($y = x$) are represented by the solid line and the dotted line, respectively (AS-OCT = anterior segment optical coherence tomography; CAS-OCT = corneal and anterior segment optical coherence tomography).

and reproducibility of the measurements. The CCT and ACW measurements with the 2 systems did not significantly differ; however, the ACD measurements did, although the difference was small (0.03 mm). Furthermore, the Pearson correlation test and Bland-Altman plots showed significant correlation and similarity between the 2 devices. We cannot give a definitive reason for why the only significant difference between the 2 systems was in the ACD measurements. Sometimes, the surface of the lens could not be detected on OCT images as clearly as the cornea and angle. In addition,

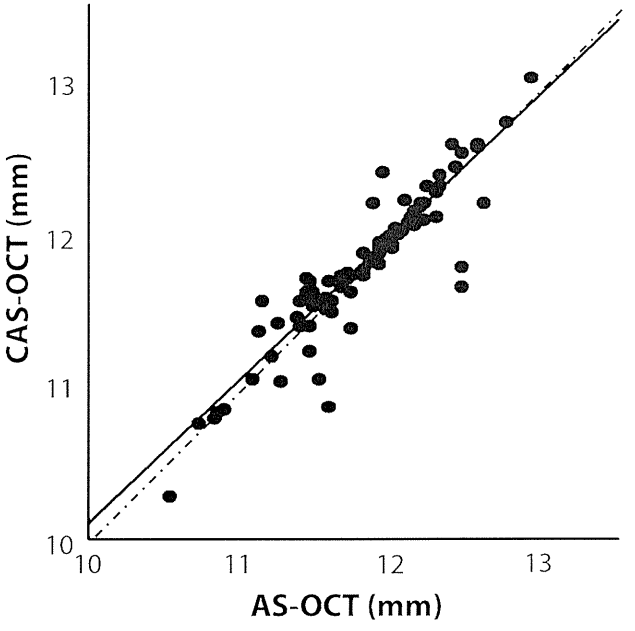

Figure 4. Correlation of ACW measurements between CAS-OCT and AS-OCT. The best-fit line ($y = 0.724 + 0.938x$) and the line of equivalence ($y = x$) are represented by the solid line and the dotted line, respectively (AS-OCT = anterior segment optical coherence tomography; CAS-OCT = corneal and anterior segment optical coherence tomography).

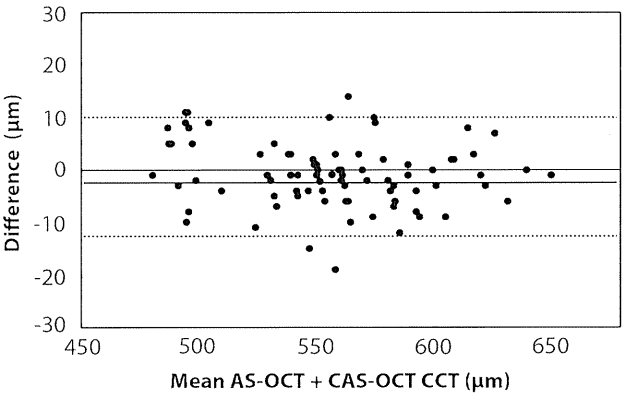

Figure 5. Bland-Altman plots of the difference from the mean in the CCT determined using CAS-OCT and AS-OCT. The mean and SD (1.96) are indicated (AS-OCT = anterior segment optical coherence tomography; CAS-OCT = corneal and anterior segment optical coherence tomography; CCT = central corneal thickness).

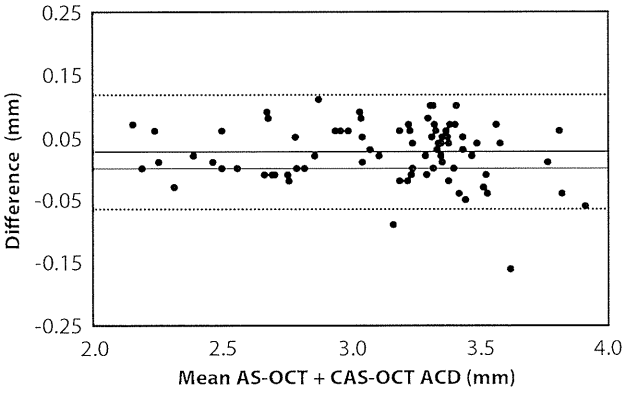

Figure 6. Bland-Altman plots of the difference from the mean in the ACD determined using CAS-OCT and AS-OCT. The mean and SD (1.96) are indicated (ACD = anterior chamber depth; AS-OCT = anterior segment optical coherence tomography; CAS-OCT = corneal and anterior segment optical coherence tomography; CCT = central corneal thickness).

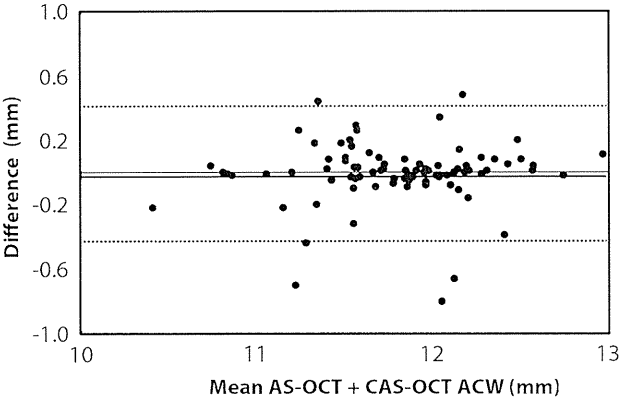

Figure 7. Bland-Altman plots of the difference from the mean in the ACW determined using CAS-OCT and AS-OCT. The mean and SD (1.96) are indicated (ACD = anterior chamber width; AS-OCT = anterior segment optical coherence tomography; CAS-OCT = corneal and anterior segment optical coherence tomography; CCT = central corneal thickness).

the difference in the depth-discrimination mechanisms of 2-D AS-OCT and 3-D CAS-OCT might account for this. Because 2D-CAS OCT is based on time-domain OCT technology, the axial motion of the sample during measurement affects the axial elongation or shortening of the OCT image more significantly. Because this effects only axial distance, it may not affect the ACW. Furthermore, the CCT is significantly smaller than the ACD; thus, the effect may not be significant. This might explain why the only AS-OCT and CAS-OCT measurements that were significantly different were those of the ACD.

Several studies of the Visante AS-OCT system[17–19] found that the CCT and ACD values obtained with the device were similar to those obtained with optical and ultrasound (US) devices. We previously reported that the CCT and ACD measurements with the CAS-OCT system had a good correlation with those of optical and US devices.[8] In a study by Li et al.,[17] the mean CCT measured using US pachymetry, scanning-slit topography, and the AS-OCT system was 553.5 ± 30.26 μm, 553.22 ± 25.47 μm, and 538.79 ± 26.22 μm, respectively. Piñero et al.[18] report mean CCT values of 528.00 ± 20.93 μm with the AS-OCT system and 527.78 ± 22.54 μm with high-frequency US scanning; both techniques had good repeatability and reproducibility. Lavanya et al.[19] compared the ACD measurements obtained with the AS-OCT device, the IOLMaster device (Carl Zeiss Meditec), and a scanning peripheral ACD analyzer; the mean values were 3.14 ± 0.34 mm, 3.08 ± 0.36 mm, and 3.10 ± 0.44 mm, respectively.

Measuring anterior chamber dimensions is important for planning ocular surgery, such as angle-supported phakic intraocular lens (pIOL) implantation.[20,21] Formerly, the size of pIOLs was determined using the white-to-white (WTW) distance. More recently, direct ACW measurements have been used to select appropriately sized angle-supported pIOLs.[18,22–24] Using an OCT system with a central wavelength of 1310 nm, Goldsmith et al.[22] found a mean ACW of 12.53 ± 0.47 mm. Kohnen et al.[23] report a mean anterior chamber diameter (equivalent to the ACW) of 12.45 ± 0.53 mm using the AS-OCT system we used in the present study; the diameter was greater than the horizontal corneal diameter, which was determined using automated WTW measurements obtained using the IOLMaster device and Orbscan IIz topographer (Bausch & Lomb). Piñero et al.[24] report a mean ATA distance of 11.76 ± 0.52 mm using the AS-OCT system; this distance significantly differed from the WTW distance measured using corneal topography. The authors concluded that these 2 parameters are not interchangeable. Thus, direct measurement of the ACW helps in the selection of an appropriately sized anterior chamber IOL.

One advantage of the 3-D CAS-OCT device in ACW measurements is that it can record 360-degree circumferences of the anterior chamber angle (ACA); thus, the ACW can be easily measured in any direction. The ACW value varies when measured in different directions. Another advantage of 3-D CAS-OCT is that it enables noninvasive gonioscopy and shows structural abnormalities in the angle of the anterior chamber[1,11]; these data are useful in planning anterior chamber IOL implantation. In addition to OCT, US biomicroscopy has been used to measure the ACW and visualize the ACA.[25] However, US biomicroscopy requires direct contact between the probe and the eye. In addition, accurate cross-sectional imaging of the anterior chamber is difficult with the technique.

Table 2. Repeatability and reproducibility of CCT, ACD, and ACW measurements.

	CCT		ACD		ACW	
Parameter	CAS-OCT	AS-OCT	CAS-OCT	AS-OCT	CAS-OCT	AS-OCT
Repeatability						
Same day and same observer, 5 consecutive scans (n = 10)						
ICC	0.999	0.998	0.999	0.999	0.994	0.960
Coefficient of variability						
Mean	0.0019	0.0020	0.0020	0.0024	0.0024	0.0021
SD	0.0012	0.0024	0.0015	0.0011	0.0018	0.0053
Different day and same observer (n = 30)						
ICC	0.997	0.968	0.993	0.996	0.990	0.985
Coefficient of variability	5.90	20.12	0.09	0.07	0.14	0.16
Reproducibility						
Same day and different observer (n = 30)						
ICC	0.998	0.987	0.998	0.997	0.993	0.988
Coefficient of variability	5.12	12.38	0.05	0.06	0.11	0.15

ACD = anterior chamber depth; ACW = anterior chamber width; AS-OCT = anterior segment optical coherence tomography; CAS-OCT = corneal and anterior segment optical coherence tomography; CCT = central corneal thickness; ICC = intraclass correlation coefficient

In our study, the ICCs for the CCT, ACD, and ACW measurements by CAS-OCT and by AS-OCT were greater than 0.99 and 0.96, respectively. Thus, the ICC for CAS-OCT was slightly higher than that for Visante AS-OCT. The coefficients of repeatability and reproducibility tended to be better with CAS-OCT than with AS-OCT. The repeatability and reproducibility of measurements depend on consistent positioning of the eye during scanning. Both devices can monitor a subject's eye during scanning for proper positioning. In addition, CAS-OCT has an autoalignment feature; the head unit moves automatically and properly aligns the head by detecting the corneal center. Moreover, the CAS-OCT system yields 2-D images by sectioning the 3-D images in arbitrary directions, enabling rapid and easy detection of the corneal center. Previous studies[4–6,22] evaluated the repeatability and reproducibility of measurements of the anterior eye segment using OCT. Mohamed et al.[5] report that the coefficient of repeatability and reproducibility of pachymetric mapping of the Visante AS-OCT system was less than 2% in healthy individuals. Li et al.[6] found that measurements obtained with the AS-OCT system and with a slitlamp OCT system had good repeatability and reproducibility. The coefficient of variation was less than 2%, and the ICC was greater than 0.94; furthermore, the values of both OCT systems were comparable with those obtained by US pachymetry. Piñero et al.[24] found good intrasession repeatability for CCT, ACD, and ATA measurements using the AS-OCT system, with ICC values greater than 0.98.

Our study has a limitation; that is, we evaluated normal eyes only. Evaluation of diseased eyes will be the subject of future studies.

In conclusion, we evaluated the biometric measurements of the anterior eye segment by 3-D CAS-OCT and 2-D AS-OCT. The 2 techniques yielded comparable CCT, ACD, and ACW measurements with sufficient repeatability and reproducibility.

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Transconjunctival single-plane sclerocorneal incisions versus clear corneal incisions in cataract surgery

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PURPOSE: To compare a transconjunctival single-plane sclerocorneal incision with 2 tiny conjunctival cuts at both ends and a clear corneal incision (CCI) in cataract surgery.

SETTING: Department of Ophthalmology, Institute of Clinical Medicine, University of Tsukuba, Ibaraki, Japan.

METHODS: Patients having routine cataract surgery were randomly divided into 2 groups based on incision type; that is, transconjunctival single-plane sclerocorneal or CCI. The incidence of intraoperative ballooning of the conjunctiva (chemosis) and the percentage of eyes that required stromal hydration to securely close the wound in each group were recorded and compared.

RESULTS: Each group comprised 61 eyes (61 patients). No eye in the transconjunctival sclerocorneal group and 6 eyes (9.8%) in the CCI group developed intraoperative conjunctival chemosis ($P = .027$, Fisher exact probability test). Corneal stromal hydration was required in 2 eyes (3.3%) and 15 eyes (24.6%), respectively ($P = .001$).

CONCLUSION: The transconjunctival single-plane sclerocorneal incision was effective and combined the merits of CCI incisions and sclerocorneal incisions.

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Cataract surgery using a clear corneal incision (CCI) is the technique of choice for many surgeons. In a 2003 survey of members of the American Society of Cataract and Refractive Surgery, 72% of respondents said they used CCIs.[1] Clear corneal incisions are preferred mainly because of the ease of creation, absence of bleeding, and increased accessibility to the anterior chamber through the incision. Concerns exist, however, about the instability of CCIs in the early postoperative period, the lack of conjunctival coverage over the incision, and a suspected role in postoperative endophthalmitis.[2] Many surgeons still prefer a cataract incision that is covered by the conjunctiva and upper eyelid; that is, the conventional sclerocorneal incision.

To combine the merits of the CCI and the sclerocorneal incision, we developed a new technique in which a transconjunctival single-plane sclerocorneal incision is created with 2 tiny conjunctival cuts at both edges. This study compared the results of the new incision technique with those of the CCI technique.

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PATIENTS AND METHODS

Patients having routine cataract surgery were randomly divided into 2 groups based on incision type; that is, transconjunctival single-plane sclerocorneal or CCI. Patients were selected from consecutive cases in the hospital population who matched the study inclusion criteria. No eye had ocular pathology other than cataract, and no eye had a history of ocular surgery. Videokeratography (TMS-4, Tomey Corp.) and meticulous slitlamp microscopy were

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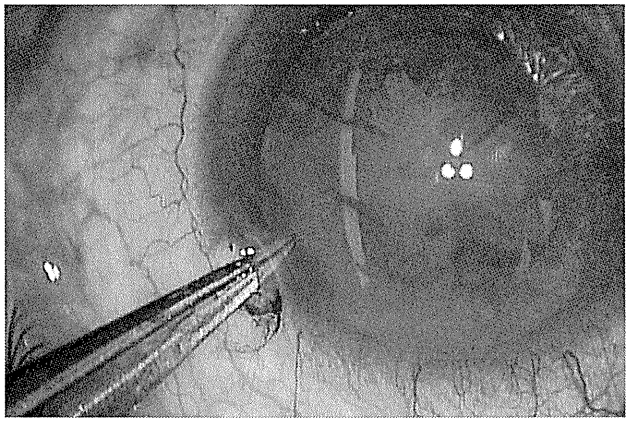

Figure 1. The globe is stabilized with a forceps, which pierces the paracentesis, moving the eye slightly downward.

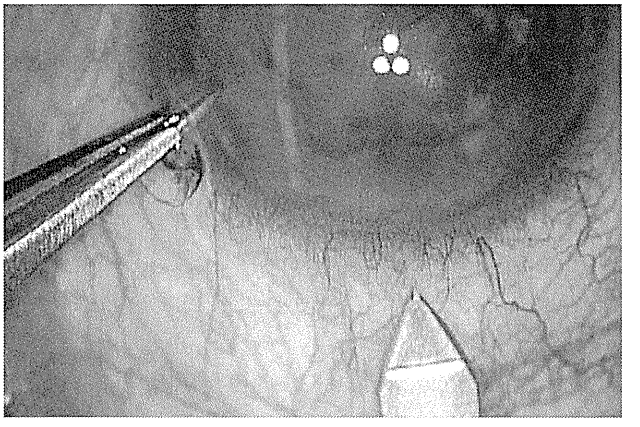

Figure 2. A single-plane incision is initiated at the conjunctiva 0.5 mm from the limbus.

performed before surgery to exclude eyes with corneal disease. The study adhered to the tenets of the Declaration of Helsinki, and all patients provided written informed consent.

Surgical Technique

Both Groups Except for the incision technique, the surgical procedures were identical in both groups. A 2.4 mm slit knife was used to create an incision in the superotemporal meridian. After a capsulorhexis was created and phacoemulsification was performed, an intraocular lens (AcrySof IQ SN60WF, Alcon, Inc.) was implanted with an injector. Then, the anterior chamber was inflated by injecting a balanced salt solution through the side-port incision. The integrity of the wound was assessed by closely checking for wound leakage and digitally gauging intraocular pressure (IOP). If necessary, corneal stromal hydration was performed.[3]

Sclerocorneal Incision The transconjunctival single-plane sclerocorneal incision was created as follows: A paracentesis was made, and the aqueous humor was replaced with an ophthalmic viscosurgical device. The globe was stabilized using the surgeon's technique of choice, which moved the eye slightly downward. In our series, the globe was fixated by piercing the forceps into the paracentesis (Figure 1). Then, with a steel slit knife, a single-plane incision was initiated at the conjunctiva 0.5 mm from the limbus (Figure 2). The knife was moved forward through the conjunctiva, sclera (Figure 3), and cornea until the horizontal liner mark on the knife surface crossed the external edge of the incision and a square wound configuration was confirmed (Figure 4). Next, the tip of the knife entered the anterior chamber through Descemet membrane. After the tip entered the chamber, the initial plane of the knife was reestablished to cut through Descemet membrane in a straight-line configuration (Figure 5). Care was taken not to direct the slit knife too inferiorly because this could jeopardize the configuration of the inner incision, changing it to a triangular form with the tunnel length shorter toward both sides of the incision (Figure 6).

After the slit knife was removed, small conjunctival incisions approximately 0.5 mm in length were made at

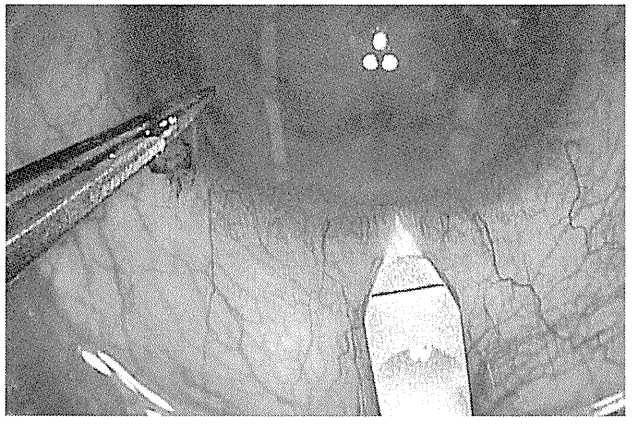

Figure 3. The knife is moved forward through the conjunctiva, the sclera, and the cornea.

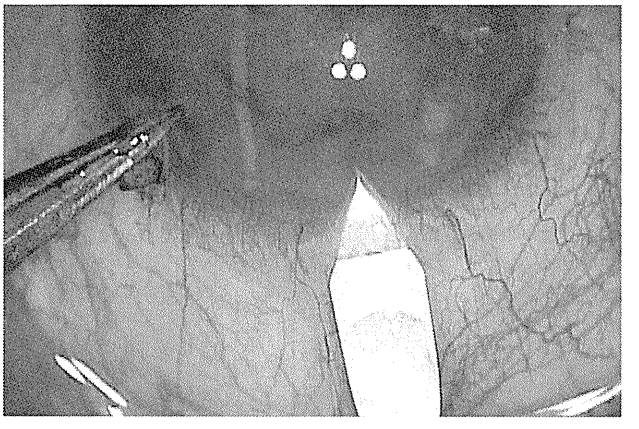

Figure 4. The knife is moved in the plane of the cornea until the horizontal liner mark on its surface crosses the external edge of the incision and a square wound configuration is confirmed. Then, the tip of the knife enters the anterior chamber and the initial plane of the knife is reestablished to cut through Descemet membrane.

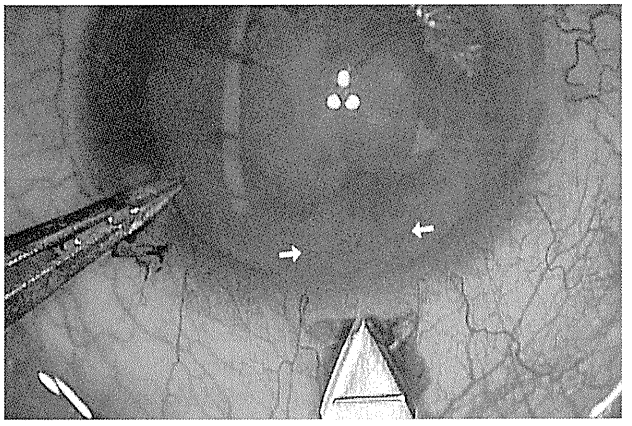

Figure 5. The inner incision is made in a straight-line configuration (*arrows*).

Figure 6. The incision has to be square with the inner portion in a straight-line configuration (*left*). If the slit knife is directed too inferiorly, the configuration of the inner incision may be jeopardized, resulting in a shorter tunnel length toward both sides of the incision (*right*).

both edges of the wound using the same slit knife (Figure 7) to prevent conjunctival chemosis during surgery. At this point, only the conjunctiva was incised without involving the underlying Tenon capsule. The incisions were extended toward the cornea instead of directed laterally or away from the cornea. The conjunctival cuts can also be made with scissors.

At the end of surgery, the anterior chamber was reformed with balanced salt solution through the paracentesis, aiming for a slightly high IOP to ensure apposition of the internal wound lips (Figure 8).

Clear Corneal Incision The CCI was made according to a previously described single-plane incision technique.[4] As in the transconjunctival single-plane sclerocorneal incision, it was confirmed that the horizontal linear mark on the knife surface crossed the external edge of the incision before the tip of the knife entered the anterior chamber and a square wound was created. After the tip entered the anterior chamber, the initial plane of the knife was reestablished to cut through Descemet membrane in a straight-line configuration.

Main Outcome Measures

The main outcome measures were the incidence of intraoperative ballooning of the conjunctiva (chemosis) and the percentage of eyes requiring stromal hydration to securely close the wound. The outcomes in the 2 groups were recorded and compared.

Statistical Analysis

The difference between groups in the incidence of intraoperative conjunctival chemosis and the percentage of eyes requiring stromal hydration was statistically assessed using

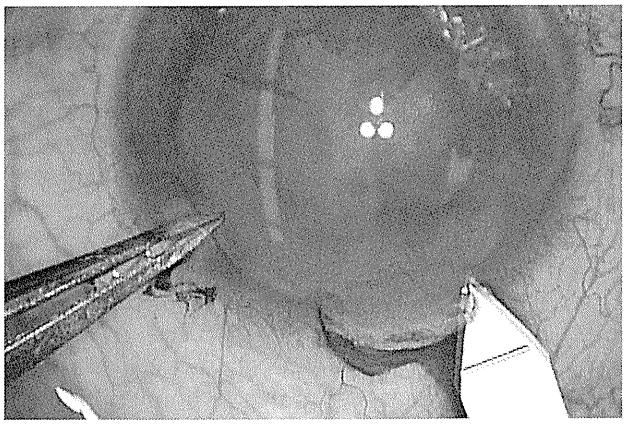

Figure 7. Small conjunctival incisions approximately 0.5 mm in length are made at both edges of the wound using the same slit knife to prevent intraoperative conjunctival chemosis. Only the conjunctiva is incised; the underlying Tenon capsule is not involved. The incisions are extended toward the cornea instead of being directed laterally.

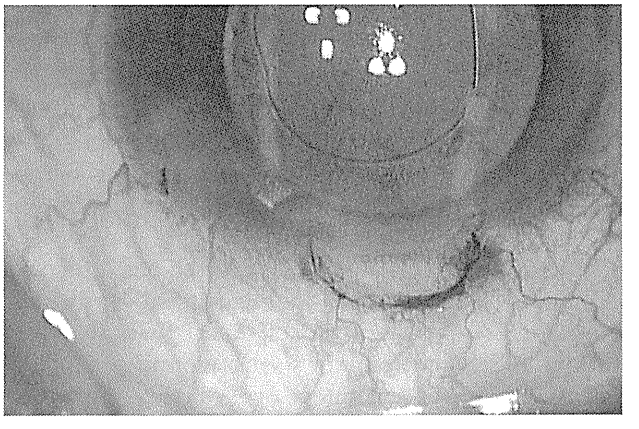

Figure 8. At the end of surgery, the anterior chamber is reformed with the goal of achieving a slightly high IOP to ensure apposition of the internal wound lips.

the Fisher exact probability test. A P value less than 0.05 was considered statistically significant.

RESULTS

The study included 122 eyes of 122 patients (51 men and 71 women); each incision group comprised 61 eyes.

There were no cases of intraoperative complications in either group. Intraoperative ballooning of the conjunctiva (chemosis) was observed in 6 eyes (9.8%) in the CCI group and no eye in the transconjunctival sclerocorneal group; the difference between groups was statistically significant ($P = .027$). Corneal stromal hydration was required to securely close the incision in 15 eyes (24.6%) in the CCI group and 2 eyes (3.3%) in the transconjunctival sclerocorneal group; the difference between groups was statistically significant ($P = .001$).

On the first postoperative day, there were no cases of ocular hypotony or wound dehiscence in either group.

DISCUSSION

Intraoperative conjunctival ballooning (chemosis) is occasionally observed during cataract surgery, especially when a CCI is used.[4] When chemosis develops, visualization of the anterior structures of the eye can be compromised. In our study, intraoperative chemosis occurred in 9.8% of eyes in the CCI group; however, no eye with a transconjunctival single-plane sclerocorneal incision had conjunctival ballooning. This result indicates that the small conjunctival incisions made at both edges of the wound effectively prevented the leaking solution from spreading under the conjunctiva. However, this does not mean that intraoperative chemosis never develops with the transconjunctival single-plane sclerocorneal incision. In our experience, moderate conjunctival chemosis has occurred in cases with advanced conjunctivochalasis in the upper conjunctiva. Still, the incidence is low and severe conjunctival ballooning around 360-degree circumferences is rarely seen.

Stromal hydration of the CCI is often performed to help seal the incision.[3,5,6] In the current study, we compared the percentage of eyes that required stromal hydration to attain secure wound sealing. A significantly lower percentage of eyes with a transconjunctival single-plane sclerocorneal incision than in the CCI group required stromal hydration. This result is not surprising because the transconjunctival single-plane incision is a form of sclerocorneal incision, and these incisions do not usually require stromal hydration.

The transconjunctival single-plane sclerocorneal incision has several other advantages. The conjunctival coverage over the wound and the presence of bleeding at the incision facilitate the wound-healing process. This feature, along with our findings, will help prevent postoperative endophthalmitis. The transconjunctival single-plane sclerocorneal technique is simpler than the conventional sclerocorneal method, which entails conjunctival preparation and scleral coagulation. Because there are few opportunities to manipulate the conjunctiva and sclera, there are fewer patient reports of pain or discomfort during surgery. Reports of postoperative discomfort and irritation are also few. Intense bleeding does not occur because of the lack of manipulation to the episcleral tissue, leading to an excellent aesthetic result.

Postoperative wound healing is rapid after surgery using the new incision technique. The apposition and healing of the conjunctival incision occur by the day after surgery, and the wound is not readily visible within a few days. There is no scar formation because coagulation or suturing of the incision is not performed. Because Tenon capsule remains almost intact and there is no conjunctival scarring, future filtering surgery can be performed without difficulty.

Although we placed the incision at the superotemporal meridian, the transscleral single-plane incision can be made superiorly or temporally. If necessary, the incision can be easily extended without inducing wound instability, which points to the flexibility of this incision technique compared with the CCI method. In addition, unlike a CCI, the transconjunctival single-plane incision resumes its shape after being stretched. The intraoperative maneuverability through the transconjunctival single-plane incision is the same as through a CCI and better than through a conventional sclerocorneal incision.

In 1996, Ernest and Neuhann[7] reported a posterior limbal incision technique, in which they placed a vertical conjunctival and scleral cut at the limbus using a crescent blade in the inverted position. The incision began at the posterior limbus to reduce ballooning of the conjunctiva. They stated that attempting to begin the incision in sclera, behind the posterior limbus, increases the risk for conjunctival ballooning. Our incision starts more posterior than their incision; therefore, we added 2 tiny conjunctival incisions at both ends of the wound to prevent conjunctival chemosis. This is the unique aspect of our technique. In 2000, Tsuneoka and Takahashi[8] reported a technique called scleral corneal 1-plane incision cataract surgery. However, conjunctival peritomy and scleral cautery for hemostasis were applied before the sclerocorneal incision was created. In 2000, Buzard and Febbraro[9] described a transconjunctival corneoscleral tunnel

"blue-line" cataract incision technique. They made a miniperitomy 1.5 to 2.0 mm behind the surgical limbus before creating a sclerocorneal tunnel incision. These 3 previous incision techniques use conjunctival peritomy and are not actually a transconjunctival single-plane incision.

The current study has several limitations. First, we tested only 2.4 mm incisions and thus the current results may not apply to other incision sizes. The percentage of eyes that required stromal hydration, however, was not extremely high. Second, detailed assessment of postoperative data, such as optical quality of the cornea, intensity of postoperative anterior chamber inflammation, and incidence of postoperative cystoid macular edema, was not performed. These will be evaluated in future studies. Third, meticulous assessment of wound integrity was not performed, as in a study by Vasavada et al.[5] in which trypan blue was used as a quantifiable ingress tracer to determine whether stromal hydration reduces ocular surface fluid ingress into the anterior chamber. Interesting results might be obtained by using such methodology.

In conclusion, we compared CCIs and transconjunctival single-plane incisions in terms of the rate of chemosis and necessity of stromal hydration. We found that the incidence of intraoperative conjunctival ballooning and the percentage of eyes that required stromal hydration were significantly lower in the transconjunctival single-plane sclerocorneal incision. We believe this is an effective incision technique that combines the advantages of the CCI and the conventional sclerocorneal incision.

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Newcastle Control Score による間欠性外斜視の評価について

Evaluation of Newcastle Control Score for assessment of intermittent exotropia

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Yoko Tsuchiya[1]・Akiko Hikoya[1]・Yoshihiro Hotta[1]・Miho Sato[1]

【要約】　目的：間欠性外斜視に対し，ニューキャッスルコントロールスコアの臨床的な有用性について評価した．

対象および方法：平成20年8月～平成21年1月に，浜松医科大学病院を受診した12歳以下の間欠性外斜視，69名に対し，医師・視能訓練士がお互いの結果を知らせずに点数をつけた．(1)医師と視能訓練士の点数の相関，(2)点数と斜視角の関係，(3)実際に行った治療方針と斜視角・合計点との関係について調査した．

結果：①検者間の点数には，相関が認められた（相関係数0.74）．②点数と斜視角には有意な相関があったが(p=0.02)，相関係数は0.29と弱いものであった．③手術適応群と経過観察群の間で，斜視角・合計点ともに，有意差を認めた．

結論：ニューキャッスルコントロールスコアは間欠性外斜視の眼位のコントロール状態を数値として評価するため，検者間で共通の基準として利用できる．また，治療方針の決定の一つとしても利用できる．

【キーワード】　ニューキャッスルコントロールスコア，間欠性外斜視，眼位，コントロール

緒言

間欠性外斜視は，外斜視と外斜位の状態をあわせもつ斜視である．眼位の状態は，屈折状態，視環境や集中力，疲労によって変化する．斜位が多く比較的良好な両眼視機能を有する[1]あいだはよいが，斜視角が増大したり，眼位のコントロール状態・両眼視機能が悪化した場合には手術が必要となる．

当院では間欠性外斜視の手術適応を，4歳以上，20⊿以上の斜視角，斜位を保ちにくい，近見立体視の悪化・不良などとしている．しかし，実際には，家族の希望が影響することが多く，斜視角が大きくても手術に至らない場合がある．

特に眼位のコントロール状態は，診察中は不良でも，「良好」と家族が判断すること[2]や，あるいは逆の場合もある．家庭での状態を把握するためには，家族から評価を聞く必要がある．斜視角は数字で表されるため，変化をみることは容易であるが，眼位のコントロール状態を記録し比較することは容易ではない．しかし，コントロール状態の変化を記録することは，治療方針を左右する．眼位のコントロール状態の評価方法には，red filter bar，occlusion foilを用いる方法[3-5]，10秒間または30秒間固視を続けている状態での眼位変化を記録する方法[6]

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