Evaluation of Visual Function and Prognosis for Patients with Proliferative Diabetic Retinopathy with the Low Vision Evaluator

HIROSHI KUNIKATA, YOICHI NAKAGAWA and MAKOTO TAMAI

Department of Ophthalmology and Visual Science, Tohoku University Graduate School of Medicine, Sendai, Japan

KUNIKATA, H., NAKAGAWA, Y. and TAMAI, M. Evaluation of Visual Function and Prognosis for Patients with Proliferative Diabetic Retinopathy with the Low Vision Evaluator. Tohoku J. Exp. Med., 2004, 204 (3), 229-236 — Proliferative diabetic retinopathy (PDR) is a leading cause of visual loss in adults in industrialized countries. PDR patients with light perception (LP) or hand movement (HM) acuity due to severe vitreous hemorrhage require vitreous surgery. The purpose of this study was to determine whether the visual acuity of PDR patients with LP or HM can be graded into finer steps with the Low Vision Evaluator (LoVE). In addition, we determined whether the LoVE results are correlated with the amplitude of the electroretinogram (ERG), the presence of retinal detachment (RD), or postoperative visual prognosis. The LoVE instrument is a subjective device that measures the thresholds for light stimulus and is equipped with a pair of goggles with white light-emitting diodes as the stimulus. We measured the LoVE thresholds of 19 PDR patients, whose fundi could not be observed due to vitreous hemorrhage and whose visual acuity was LP or HM. The 13 patients with HM vision had LoVE thresholds that ranged from 25.0 and 40.0 dB, and the 6 patients with LP vision had LoVE thresholds that ranged from 20.0 and 40.0 dB. The LoVE thresholds of 9 patients with RD were significantly lower than those of 10 patients without RD (p < 0.001). The LoVE thresholds were correlated with the amplitude of the a- and b-waves of the ERG and the postoperative best-corrected visual acuity (BCVA) (a-wave: r = 0.70, p < 0.001; b-wave: r = 0.71, p < 0.001; postoperative BCVA: r = 0.46, p < 0.05). These results indicate that the LoVE is capable of grading the visual function of PDR patients with conventional LP and HM vision into finer steps. Thus, the LoVE is an invaluable device in predicting the postoperative visual acuity of patients with vitreous hemorrhage. ——— proliferative diabetic retinopathy; Low Vision Evaluator; light perception; hand movement; visual acuity
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Address for reprints: Hiroshi Kunikata, M.D., Department of Ophthalmology and Visual Science, Tohoku University Graduate School of Medicine, 1-1 Seiryo-machi, Aoba-ku, Sendai 980-8574, Japan.
e-mail: kunikata@oph.med.tohoku.ac.jp
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Diabetic retinopathy is a common complication of diabetic mellitus and is a leading cause of visual loss in adults in industrialized countries. If the glycemic control is poor, the retinopathy can easily progress to proliferative diabetic retinopathy (PDR) that causes neovascularization, and leads to vitreous hemorrhage and tractional retinal detachment. These complications require vitreous surgery.

The vision of patients with PDR is usually severely reduced to hand movement (HM) or light perception (LP) vision (Duke-Elder 1962). And, because vitreous hemorrhage is often present in these eyes, preoperative ophthalmoscopic assessment of the retina is difficult, and the potential visual acuity that can be achieved by vitrectomy cannot be judged. Thus, electroretinogram (ERG) and B-scan ultrasonography (B-scan) are used to obtain information on the potential benefit of vitreous surgery. However, the equipment necessary to perform these tests is expensive, and a special room with a technician is required. Furthermore, these instruments are large and not easily portable.

To overcome these disadvantages, we have developed a relatively simple instrument, called the Low Vision Evaluator (LoVE), that can be used to quantify the visual function (Tamai et al. 1999, 2004; Yamada et al. 2000; Kunikata et al. 2001, 2005; Akiyama et al. 2002; Takahashi et al. 2003). The LoVE has been used to assess the very low visual function of patients with retinitis pigmentosa and with glaucoma (Tamai et al. 1999, 2004; Yamada et al. 2000; Akiyama et al. 2002; Takahashi et al. 2003). The testing procedures are simple, and reliable measurements can be obtained for children 4-years-old and older (Kunikata et al. 2005). In addition to its use as an evaluator of visual function in eyes with retinal diseases, we think that it can be used to quantify changes in visual function following new therapeutic procedures for patients with low vision (Verin et al. 1986; Vingolo et al. 1998-99; Horiguchi et al. 1994; Fex et al. 1996; Abe et al. 1999, 2000; Pasantes-Morales et al. 2002).

At present, a correlation of the results of LoVE thresholds to the values obtained from other tests of retinal function, such as the ERG, has not been determined. The purpose of this study was to determine whether patients with PDR with HM and LP vision can be graded into finer steps, and to determine whether the LoVE thresholds are correlated with the ERG amplitudes, the findings of B-scan, and especially the postoperative visual acuity.

**Materials and Methods**

**LoVE**

The LoVE (TOMEY, Nagoya) is made up of a pair of goggles with light emitting diodes (LED: NSPW310AS, NICHIA CORPORATION, Anan city, Tokushima), a control box to regulate the intensity, duration, and sequence of the LED stimuli, a printer for permanent records, and a handheld grip with an on-off button (Tamai et al. 1999, 2004; Yamada et al. 2000; Kunikata et al. 2001, 2005; Akiyama et al. 2002; Takahashi et al. 2003).

The goggle for each eye has 16 white LEDs set at equal distances along the margins of a dome, and the emitted light is reflected by a concave mirror of the dome and reaches a large range of retina transpupillarily (Tamai et al. 2004; Kunikata et al. 2005).

**Patient selection**

There were 19 patients with PDR (13 men and 6 women), and their mean ± standard deviation age was 54.2 ± 12.7 years (range, 32 to 80 years). Their visual acuity was LP and HM, and their fundus could not be observed due to vitreous hemorrhage (Table 1). The vision was tested for the ability to detect hand movements or light perception as described in the Endophthalmitis Vitrectomy Study (Endophthalmitis Vitrectomy Study Group 1995). The patients were being followed in the clinic of the Tohoku University Hospital.

After the purpose of the examination was explained to the patients, an informed consent was
obtained from all. The experiments were performed to conform to the tenets of the Declaration of Helsinki.

**Examination procedures**

The stimulus duration was fixed at 0.2 seconds (S) in this fixed duration mode of LoVE, and the intensity was changed from 0.1 cd/m² (C) to 10 C in 8 equal steps, i.e., from 0.02 CS (40 dB) to 2 CS (20 dB) in 2.5 dB steps.

Each eye was independently stimulated three times maximally at each stimulus magnitude, and if a patient responded correctly to 2 of the 3 trials to the same stimulus, he was scored as having detected that stimulus. All stimuli were preceded by a “beep” sound 0.3 S before the stimulus to alert the patient. In addition, 6 sound tests were presented without a light stimulus as catch trials. The false positive responses to catch trials and any responses prior to the light stimulus were treated as error scores. The error scores were used to assess the reliability of the subject. An examination with more than one error was treated as unreliable.

In one set of examination, each eye was randomly stimulated 27 times, and a total of 60 times including the 6 catch trials for the two eyes maximally (Tamai et al. 1999, 2004; Yamada et al. 2000; Kunikata et al. 2001, 2004, 2005; Akiyama et al. 2002; Takahashi et al. 2003). The results of LoVE with the fixed duration procedure are presented as LoVE thresholds (dB). To shorten the examination time, a skip strategy was programmed into the test (Tamai et al. 2004). The results of the test were automatically printed from the control box at the completion of the examination documenting the patient’s responses. All examinations of LoVE were performed in a regular examination office without pupillary dilation and dark-adaptation.

The conventional visual acuity was determined before the LoVE tests. After the LoVE test, B-scan was performed on all patients to determine whether retinal detachments (RD) were present. When a RD including the posterior pole was clearly present by B-scan, the patient was classified as RD positive. After the B-scan test, ERGs were recorded under standardized conditions that conformed to the International Society for Clinical Electrophysiology of Vision standards (Marmor et al. 1989; Marmor and Zrenner 1999). Bright flash ERGs were elicited by a single bright white flash after 30 minutes of dark-adaptation. All patients underwent standard three-port pars plana vitrectomy with removal of the posterior hyaloid and proliferative membrane if one existed. The preoperative data recorded included patients’ demographics, visual acuity, LoVE thresholds, the amplitude of the a- and b-waves of the ERG, and B-scan findings. The postoperative best-corrected visual acuities (BCVA) were measured by certified optometrists.

**RESULTS**

Nineteen eyes in 19 patients met the inclusion criteria (Table 1). The mean postoperative follow-up period was 8.6 ± 12.6 months (n = 19, range, 0.5 to 37 months).

**Distribution of LoVE Thresholds**

The LoVE thresholds for the 13 PDR patients with HM acuity ranged from 25 to 40 dB, and the LoVE thresholds for the 6 PDR patients with LP vision ranged from 20 to 40 dB (Table 1, Fig. 1). The mean LoVE thresholds for the PDR patients with HM vision (34.6 ± 5.85 dB) were better than those with LP vision (30.4 ± 8.28 dB) but the difference was not significant (p = 0.22; Mann-Whitney’s U-test). The mean a-wave amplitude was 151.6 ± 100.7 μV (n = 19, range, 30 to 410 μV), and the mean b-wave amplitude was 224.2 ± 149.7 μV (n = 19, range, 40 to 570 μV; Table 1). Both the mean a-wave amplitude (r = 0.70, p < 0.001) and the mean b-wave amplitude (r = 0.71, p < 0.001) of the ERGs were significantly correlated with the LoVE thresholds (Pearson’s correlation coefficient; Fig. 2).
TABLE 1. Demographic Data and Results of Patients with Proliferative Diabetic Retinopathy (PDR)

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Age (yrs)</th>
<th>Sex</th>
<th>Eye</th>
<th>Visual Acuity</th>
<th>LoVE threshold (dB)</th>
<th>ERG a-wave (μV)</th>
<th>ERG b-wave (μV)</th>
<th>B-scan RD</th>
<th>Postope BCVA</th>
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<td>F</td>
<td>OS</td>
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LoVE, Low Vision Evaluator; ERG, Electoretinogram; B-scan, B-scan Ultrasonography; RD, Retinal Detachment; Postope BCVA, Postoperative Best-Corrected Visual Acuities; OD, Oculus Dexter; OS, oculus Sinister; LP, Light Perception; HM, Hand Movement.

Fig. 1. Distribution of LoVE thresholds in eyes with LP and HM vision. [], LP; ■, HM.

Fig. 2. Correlation of LoVE thresholds to ERGs. The LoVE thresholds are correlated with amplitude of a- and b-wave of ERG (a-wave: closed circle (●), r = 0.70, p < 0.001; b-wave: open circle (○), r = 0.71, p < 0.001).
Correlation of LoVE Thresholds to B-scan Ultrasonographic Findings

The mean LoVE threshold for the 9 patients with RD detected by B-scan ultrasonography was 27.5 ± 5.2 dB which was significantly lower than that of the 10 patients without RD, 38.5 ± 2.1 dB (p < 0.001; Mann-Whitney’s U-test; Fig. 3).

Correlation of Preoperative LoVE Thresholds to Postoperative Visual Acuities

All 19 eyes with vitreous hemorrhage underwent pars plana vitrectomy, and the mean postoperative BCVA was 0.19 ± 0.22 (n = 19, range, 0.001 to 0.8; Table 1). This included one eye that had HM vision postoperatively (Patient 15), and the visual acuity was designated as 0.001 vision for the calculation. In addition, the preoperative LoVE thresholds were correlated with the postoperative BCVA (r = 0.46, p < 0.05, Pearson’s correlation coefficient; Fig. 4).

Reliability

In all 19 patients, the error responses were 0, except for Patient 17 with 1 error score.
CASE REPORTS

Patient 1. The patient was a 55-year-old man with PDR and LP vision in his right eye (Table 1, Patient 1). His LoVE threshold was 37.5 dB. Error score was 0. B-scan showed dense vitreous hemorrhage but no retinal detachment (Fig. 5A, Upper). His a- and b-wave amplitudes were 150 and 210 μV, respectively (Fig. 5A, Lower). His postoperative BCVA was 0.3.

Patient 2. The patient was a 68-year-old man with PDR and LP vision in his right eye (Table 1, Patient 2). His LoVE threshold was 27.5 dB. Error score was 0. B-scan showed vitreous hemorrhage and a large retinal detachment including the posterior pole (Fig. 5B, Upper). His a- and b-wave amplitudes were 50 and 50 μV, respectively (Fig. 5B, Lower). His postoperative BCVA was 0.1.

DISCUSSION

ERG and B-scan are most commonly used to obtain information on the potential retinal function when the fundus cannot be seen because of vitreous hemorrhages or other ocular opacities (Fuller et al. 1975; Abrams and Knighton 1982). These examinations are helpful for PDR patients in determining the preoperative prognosis for improved vision (Blankenship 1982; Algvere et al. 1985; Thompson et al. 1987; Summanen 1990).

Our results showed that the LoVE thresholds for the 19 PDR patients with the HM and LP vision ranged from 20 to 40 dB or eight steps. The correlation between ERG values and LoVE

![Fig. 5. B-scan ultrasonography images of two cases.](image-url)

A. Patient 1. The patient was a 55-year-old man with PDR and LP vision in the right eye. His LoVE threshold was 37.5 dB. B-scan showed dense vitreous hemorrhage and no retinal detachment (Upper). His a- and b-wave amplitudes were 150 and 210 μV, respectively (Lower).

B. Patient 2. The patient was a 68 year-old man with PDR and LP vision in the right eye. His LoVE threshold was 27.5 dB. B-scan showed vitreous hemorrhage and retinal detachment (Upper). His a- and b-wave amplitudes were 50 and 50 μV, respectively (Lower).
thresholds was significant with an r-value of about 0.7. The LoVE thresholds were also correlated with the ultrasonographic findings and especially, with the postoperative BCVA. Because an examination with more than one error score was considered to be unreliable, we conclude that the reliability of the LoVE thresholds for these PDR patients was very high. Cases 1 and 2 had the same visual acuity of LP but had different LoVE thresholds. Their ERG and B-scan findings were better correlated to the LoVE thresholds.

These findings suggest that preoperative LoVE thresholds provide information that is correlated with potential retinal function related to the postoperative BCVA. Because the LoVE thresholds can be quantified and the reliability were high, it will now be possible to use the LoVE thresholds to determine the retinal function and preoperative prognosis for improved vision of patients with HM and LP vision due to vitreous hemorrhage.

The limitations of this study include the small number of patients. However, in this subgroup of patients, LoVE thresholds were able to predict the postoperative visual function just as the ERGs. Further study of correlating the results of this test with the visual acuity of the patients after successful surgery will be needed in the future.

Because the detection of the stimulus is based on the minimum visible and not the minimum separable, this device is considered to be especially valuable to test patients with LP or HM vision.

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References


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