Development and Clinical Evaluation of an Eye Movement Input Device Designed to Assist Continuous Communication in Amyotrophic Lateral Sclerosis Patients

Tomoya Miyasaka\(^1\,*\)  Masanori Shoji\(^2\)  Toshiaki Tanaka\(^3\)

\(^1\)Department of Physical Therapy, Faculty of Health Sciences, Uekusa Gakuen University, Chiba 264-0007, Japan  
\(^2\)Little Snow, Sapporo, Hokkaido 065-0033, Japan  
\(^3\)Research Center for Advanced Science and Technology, University of Tokyo, Tokyo 113-0033, Japan

Received 10 May 2010; Accepted 4 Oct 2010; doi: 10.5405/jmbe.790

Abstract

We developed an eye movement input device that could continually be used by a simple input in amyotrophic lateral sclerosis (ALS) patients. The device configuration consisted of a head unit weighing 85 g with a mounted video camera, and an eye movement detector device with a circuit for detecting eye movement on a small liquid crystal monitor. The function of the developed eye movement input device was to enable, by movement of the eyes, a 1-channel contact signal output to a communication support device or computer, and ringing of a bell. Users could operate this without looking at the main unit device monitor. Operation status was confirmed by the communication support device screen or input sound, or the chiming sound of a bell. Between 2004 and 2007, the eye movement input device was clinically evaluated in 4 ALS patients. The 4 patients included 2 men and 2 women, 3 aged 50-59 and 1 aged 70-79. The period of use was as follows: 33 months in patient 1, 2 months in patient 2, 1 month in patient 3, and less than 1 week in patient 4. The clinical evaluation results and a discussion of patient 1 (woman, aged 50’s) are described in detail. The device was designed so she could input commands to a personal computer and bell output. The device assisted her communication included daily requests to a caregiver for body repositioning or suction of saliva and conversations with nearby persons. Periodically, responses to physician inquiries helped to determine caregiver and treatment planning. The present results showed that the current eye movement input device effectively assisted continuous communication in ALS patients.

Keywords: Amyotrophic lateral sclerosis (ALS), Communication, Eye movement, Input device

1. Introduction

Amyotrophic lateral sclerosis (ALS) is a disease in which motor neurons degenerate, causing progressive deterioration of voluntary motor function [1]. Its incidence is 2 to 5 cases per 100,000 people, and there is presently no effective cure. In ALS, as voluntary motor function progressively decreases [2], means of communication become limited. Guidelines by the Societas Neurologica Japonica [3] recommend that communication support, such as operation of a personal computer, be started early.

To assist communication, communication support devices that assist in the operation of bells and personal computers, and input devices, are being introduced. To efficiently operate these communication support devices, it is important that input devices meet the needs of users in terms of their voluntary motor function. In ALS patients, even if input devices that are compatible with voluntary motor function are introduced, as the disease progresses, these devices often can no longer be used [4]. Thus, changes in input devices are necessary as the motor function decreases. However, every time an input device is changed, not only does the patient have to learn how to use the new device, but their caregivers also have to learn how to install it.

In Japan, ALS patients with a confirmed diagnosis are eligible to receive communication support devices and input devices [5]. When an input device can no longer be used due to disease progression, an application can be made so that the patient can receive a new input device. However, as the time from application until receipt can be as long as 1 month, this means the patient will temporarily lose the ability to communicate via an input device during this period. Therefore, changing a communication support device can become a major hindrance to maintaining continuous communication in ALS patients.

\(*\) Corresponding author: Tomoya Miyasaka  
Tel: +81-43-239-2631  Fax: +81-43-233-9211  
E-mail: t-miyasaka@uekusa.ac.jp
To solve this problem in which communication is impaired when ALS patients change input devices, researchers have been evaluating input devices that can continually be operated regardless of disease stage. Input methods have focused on eye movements, in which voluntary motor function remains intact for a long time [6]. While input devices utilizing eye movement and gaze have been previously available, none have been completely suitable for use in ALS patients. For example, remote video cameras that detect eye movements [7] while recording cannot detect effectively when lifting the eyelids is difficult. In the case of devices that detect eye movement using electrooculograms [8], it is necessary to attach electrodes to the same positions on the face, which can cause skin ulcers if used long-term. When the speed of eye movement declines, detection becomes difficult. For input devices using gaze [9], it is necessary to ensure that the monitor showing the target is always placed within the patient’s field of vision, and that the position of the monitor is altered as the angle of the head changes due to changes in the body position.

Therefore, researchers have developed an eye movement input device that can continually be used by a simple switch input [10]. The specifications of the device take into consideration the needs of ALS patients, in terms of changes in physical function, daily activities, and communication. In the current study, this recently developed model was clinically evaluated in 4 ALS patients. This paper presents information on the development of this eye movement input device along with clinical evaluation results. We discuss the functionality of this eye movement input device, which was developed based on these results, and how effectively ALS patients can maintain continuous communication when using this eye movement input device.

2. Materials and methods

2.1 Design of the eye movement input device

The device configuration consisted of a head unit weighing a total of 85 g with a mounted video camera, and an eye movement detector with a detection circuit for eye movement on a small liquid crystal monitor (see Fig. 1). Two photosensors that detect eye movement were installed on the monitor screen. The parts of the device cost was about 45,000 JPY.

Eye movement was recorded using a small video camera mounted on the head unit (see Fig. 2). The camera was positioned over the cheek so the field of view was not obstructed. Imaging was possible when the eyelids were naturally opened ≥ 50%. The head unit permitted operation of the eye movement input device at any head and neck angle. That operation was possible in a supine position, left or position [11], seated position, or when seated in a wheelchair and moving.

The principle of eye movement detection was based on the limbus tracking method [12]. The eye movement detection circuit was comprised of two photosensors for eye movement detection and compensation (see Figs. 3, 4) and a differential circuit [13] (see Fig. 5). The differential circuit was to amplify the difference between the PDsmp input signals of the detection photosensor and the PDref input signals of the compensation photosensor. When the detection photosensor detected a brighter moving image than the compensation photosensor, the differential circuit outputted a signal to the communication support device or computer, and an electric bell. Regarding the eye movement detection method, the eye moved in a range of 5-30% in abduction or supra-abduction (oblique superior), as shown in Fig. 6. In order to reduce potential eye strain, video imaging of the eye movement was performed using only natural light.

![Figure 1. Configuration of the eye movement input device.](image1.png)

![Figure 2. Head unit of the eye movement input device.](image2.png)

![Figure 3. Photo IC (left 1), photosensor (left 2) and output characteristics (right).](image3.png)
Among factors that could cause malfunction, sensor output changes due to overall illumination changes of the eye movement image were offset by the differential circuit (see Fig. 5). With this differential circuit, malfunction due to illumination changes, including the required range of illumination in the living space, did not occur. In addition, this could be used immediately after turning on the power (see Table 1).

Table 1. Measures against malfunctions.

<table>
<thead>
<tr>
<th>Differential circuit</th>
<th>With multilayer optical filter</th>
<th>Without multilayer optical filter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Output [mV] when 13-w fluorescent lamp is on</td>
<td>0.9</td>
<td>241.0</td>
</tr>
<tr>
<td>13-w fluorescent lamp light malfunction with penetration</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Ambient illumination [Lx]</td>
<td>15-50000</td>
<td>500-20000</td>
</tr>
<tr>
<td>After turning on power, stabilization time [min]</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

2.2 Function and specifications of eye movement input device

The function of the developed eye movement input device was to enable, by movement of the eyes, a 1-channel contact signal output to a communication support device or computer, and ringing of a bell (see Fig. 7). Users could operate this without looking at the main unit device monitor. Operation status was confirmed by the communication support device screen or input sound, or the chiming sound of a bell.

With respect to the developed input device, we confirmed that the communication support devices “Den No Shin” (Hitachi) and “Let’s Chat” (Funcom), and the input assistance software for physically handicapped persons “Operate Navi Ex ver 2.0” (NEC), could be operated together with the bell operation. The eye movement input device was installed as in Fig. 8. Installation by a healthy person in 1 to 3 minutes has been confirmed.

Figure 4. Function of optical filters.

Figure 5. Eye movement detection circuit of the device.

Figure 6. Eye movement detection method.

The method of direct detection of brightness of the eye movement image by the photosensors installed on the screen was a simplification of an optical system and a detection circuit. With only one photo IC (integrated circuit) installed on the monitor screen, penetration of ambient light into the photo IC, or overall illumination changed of the eye movement image, could easily cause a malfunction. Therefore, the eye movement detection circuit was a combination of 2 photosensors, consisting of a photo IC and optical filter, and a differential circuit to prevent the occurrence of malfunction. Among factors that could cause malfunction, the penetration of ambient light into the photo IC was blocked by 3 types of optical filters in a multilayer configuration (see Fig. 4A). With the optical filters attached, when a 13-w fluorescent lamp was turned on in front of the main device, the lighting from any position did not cause malfunction (see Table 1).
3. Clinical evaluation

Between 2004 and 2007, the eye movement input device was clinically evaluated in 4 ALS patients. The clinical evaluation was planned based on the Declaration of Helsinki and it was conducted with the approval of Sapporo Medical University [10]. Details of the evaluation were explained and informed consent was obtained from all the patients.

The test period was 1 month, but this period could be extended by patient request. The method of evaluation was observation by the researchers, who visited the patients at home. In addition, an interview was conducted with the patients, their families, and visiting nurses.

3.1 Clinical evaluation summary

The 4 patients included 2 men and 2 women, 3 aged 50-59 and 1 aged 70-79. The ALSFRS-R [14] score for functional evaluation of ALS was 0 in 3 patients and 18 in 1 patient. Three patients had normal voluntary motor function of the eyes and eyelids, and 1 had involuntary movement of the eyelids and face (see Table 2).

### Table 2. Basic attribute of the patients.

<table>
<thead>
<tr>
<th>Patient</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>M/F</td>
<td>F</td>
<td>M</td>
<td>F</td>
<td>M</td>
</tr>
<tr>
<td>Age</td>
<td>50’s</td>
<td>50’s</td>
<td>50’s</td>
<td>70’s</td>
</tr>
<tr>
<td>ALSFRS-R</td>
<td>18</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Motor function of the eye/eyelids</td>
<td>Normal</td>
<td>Normal</td>
<td>Involuntary</td>
<td>Normal</td>
</tr>
</tbody>
</table>

In 2 patients, the eye movement input device was used to ring a bell, while there was a combined use of a communication device and bell, which included a personal computer, in the other 2 patients. Prior to the new input devices, a push-button switch was used by 2 patients, a cell telephone push button by 1 patient, and a touch switch by 1 patient.

The period of use was as follows: 33 months in patient 1, 2 months in patient 2, 1 month in patient 3, and less than 1 week in patient 4. Patient 2 used the device as a bell. He had developed a pulmonary complication, so his duration of the device use was shortened to 2 months. Patient 3 had involuntary movements of eyelids and some facial muscles. It was hard for her to operate the device because she was not able to hold her eyelid open. Patient 4 was a senior citizen: he had no desire to use the device continuously.

The clinical evaluation results and a discussion of patient 1 are described in detail in the following section (see Tables 3 and 4).

### Table 3. Results of the clinical evaluations.

<table>
<thead>
<tr>
<th>Patient</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose of use</td>
<td>Bell</td>
<td>Personal</td>
<td>Bell</td>
<td>Bell</td>
</tr>
<tr>
<td>Computer</td>
<td>Device</td>
<td>Device</td>
<td>Device</td>
<td>Device</td>
</tr>
<tr>
<td>Prior to the new input devices</td>
<td>Cell phone</td>
<td>Push button</td>
<td>Push button</td>
<td>Touch switch</td>
</tr>
<tr>
<td>Period of use</td>
<td>33 months</td>
<td>2 months</td>
<td>1 month</td>
<td>1 week</td>
</tr>
</tbody>
</table>

### Table 4. Usage of the input devices.

<table>
<thead>
<tr>
<th>Usage time</th>
<th>Installation</th>
<th>2 months and later</th>
</tr>
</thead>
<tbody>
<tr>
<td>Push-button switch</td>
<td>20 min/day</td>
<td>Use became difficult</td>
</tr>
<tr>
<td>Eye movement input device</td>
<td>5 min/day</td>
<td>5 hours/day</td>
</tr>
<tr>
<td>Eye movement input device</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Learning time of operation</td>
<td>1 day</td>
<td></td>
</tr>
<tr>
<td>procedure for patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Learning time of installation</td>
<td>10 days</td>
<td>30 days</td>
</tr>
<tr>
<td>procedure for caregivers</td>
<td>(daughter)</td>
<td>(mother)</td>
</tr>
<tr>
<td>Installation time for caregivers</td>
<td>1 min.</td>
<td>10 min.</td>
</tr>
<tr>
<td>caregivers</td>
<td>(daughter)</td>
<td>(mother)</td>
</tr>
</tbody>
</table>

*After changing to a soft flexible wire and 7 inch monitor, installation time for mother shortened to 3 min.

3.2 Basic information and needs

Patient 1 was a woman in her 50s with onset of ALS in 2003. At an early stage, she developed bulbar paralysis, and chewing and speech became difficult. At work, she used a personal computer. She did not want to use a mechanical ventilation device. The patient was cared for at home. Family caregivers included a woman in her 70s (mother) (main caregiver) and a girl in her teens (daughter). The input device was used to ensure that the patient could maintain continuous communication with her children and other family members.

3.3 Device configuration

The patient received a communication support device and input device, as shown in Fig. 9. For input to the communication device, “Operate Navi” was used. The device contained a single 1-channel contact switch. A 17-inch monitor was placed 0.8 m in front of this patient. Since the patient could perform left wrist flexion at the time of the initial device application, a push-button switch was provided for the input device. The eye
movement input device was installed in the patient’s room at the same time as the supplied device components.

![Diagram of communication support system](image)

**Figure 9. Communication support system for clinical evaluation.**

### 4. Results

Evaluation parameters included the period of device use, purpose of use, body function and position during use, means and method of input, method and type of communication, and ambient illumination. Figure 10 shows the evaluation results.

<table>
<thead>
<tr>
<th>Communication support device</th>
<th>months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction period</td>
<td>0 2 4 6 8 10 12 24 30 33 36 48</td>
</tr>
<tr>
<td>Period during use</td>
<td>Sitting</td>
</tr>
<tr>
<td>voluntary motor function was retained</td>
<td>Head/shoulders</td>
</tr>
<tr>
<td>Position during use</td>
<td>Upper extremities</td>
</tr>
<tr>
<td>Input method</td>
<td>Push-button switch</td>
</tr>
<tr>
<td>Purpose of use</td>
<td>Eye movement input device</td>
</tr>
<tr>
<td>Type of communication</td>
<td>Call a familiar person</td>
</tr>
<tr>
<td>Ambient illumination [Lx]</td>
<td>150-1500</td>
</tr>
</tbody>
</table>

**Figure 10. Results of the clinical evaluation.**

The period of use was 33 months, beginning in January 2005 and ending in September 2007, when the patient died. After the first 6 months, use of the device was suspended for 2 months because the patient was hospitalized for a laryngectomy to prevent aspiration. After 28 months, respiration gradually became more impaired, making difficult active use of the device. The device was designed so the patient could input commands to a personal computer and bell output.

Based on the ALSFRS-R presented at the time of installation, the patient was barely able to walk with assistance and hold a pen. However, after the initial 2 months, overall daily movements became even more difficult. While voluntary motor functions, which included hand and finger movements, were possible during the initial 2 months, upper limb movement became difficult at 7 months. Eyelid and eye movements were normal throughout the test period.

After positioning the patient to allow device use, swallowing was difficult. In addition, when placed in a sleeping position, saliva easily entered the trachea. Therefore, the patient had to sit up at all times (see Fig. 11(a)). At 3 months, independent support of the head became difficult, and a neck brace was applied (see Fig. 11(b)). At 5 months, independent support of the trunk became difficult (see Fig. 11(c)). After surgery was performed, a semi-Fowler’s position with the head of the bed raised was used (see Fig. 11(d)).

![Images of clinical positions](image)

**Figure 11. Positions when using the system.**

| (a) | (b) | (c) | (d) |
| Time of introduction | After 3 months | After 5 months | After 8 months |

Table 4 describes use of the input devices. Due to a decrease in the voluntary motor function of the hands and fingers, the push-button switch became difficult to use after 2 months. On the other hand, usage time of the eye movement input device, after the caregivers learned how to install it, increased to about 5 hours a day after 2 months. The patient used this every day without complaining of eye fatigue.

The method of operation, as shown in Fig. 12, involved back-and-forth movement of the left eye from a mid position to supra-abduction. The angle of eye movement was about 15 degrees, it was defined as the line of sight between mid position and supra-abduction. The eye movement of supra-abduction was defined when the patient looked at a target that was obliquely upward – positioned with respect to of the 17-inch monitor at the installation of the input device. The target was removed in use of the eye movement input device.

![Diagram of eye movement input device](image)

**Figure 12. Installation of the eye movement input device for clinical evaluation.**
By setting a non-detection range of 15 deg, the range of gaze movement when looking at the 17-inch monitor was not detected. When the patient moved her eye from neutral position to supra-abduction, the eye movement input device generated contact signals to control “Operate Navi” (Fig. 13). The eye movement input device was operated without looking at the main unit monitor of the device.

The methods of communication included calling a person with a bell, slight changes in expression, use of characters on a transparent plate, and displaying short sentences of about 50 characters on the communication support device monitor. Longer sentences of ≥100 characters were input to a text editor, saved, and could be read later by another person. E-mail could also be used for contacting more distant persons. In addition, blogs could be created for contact with the public. However, at 24 months after installation, it became too difficult for this patient to input long sentences.

The device assisted her communication, including daily requests to a caregiver for body repositioning or suction of saliva and conversations with close persons. Periodically, responses to physician inquiries helped to determine caregiver and treatment planning. In addition, the patient was able to contact researchers by e-mail regarding device malfunctions or adjustments, and she was actively able to convey her own intentions about planning events such as trips. She also sought second opinions about surgery and the use of mechanical ventilation.

After 28 months of use, the patient started to complain of respiratory distress. Subsequently, the patient lost her ability to operate the communication support device. The researchers were contacted by her family, and after a discussion concerning the increasing severity of her problems, it was decided that further active support was not possible. During month 31, the patient sent a no text e-mail addressed to the researchers that contained an attached image. This was the last record of confirmed use for the researchers.

5. Discussion

We evaluated the effectiveness of the eye movement input device by comparing the eye movement input device specifications, the clinical evaluation results, and the patient’s needs.

It took 10 minutes for an older caregiver to install the eye movement input device, which prompted a complaint from the patient. Therefore, to shorten the installation time, the device was changed so that a soft flexible wire was used, which made it easier and quicker to adjust the camera position. In addition, the liquid crystal monitor screen was changed from a 4-inch to a 7-inch monitor in order to expand the range of set-up. Overall, the installation time was shortened from 10 to 3 minutes.

Operation by the patient involved back-and-forth eye movement between a mid position and supra-abduction. All movements were within the specified range of the input device. Similarly, both the positioning and range of illumination during use were within the specified range of the device. Although initially there was a problem with the set-up time required by the elderly caregiver, measures were taken that ultimately led to shortening the set-up time. Based on the above findings, the performance and specifications of the eye movement input device corresponded with the clinical evaluation results.

The input device assisted with the patient’s needs to request care from her family and have daily conversations with these family members. In addition, other important aspects of patient communication were supported, including plans for treatment and caregiving, and requests for a second opinion regarding surgery and use of mechanical ventilation.

Regarding continuous use, communication was continuously supported for about 30 months, excluding a period of hospitalization. Figure 14 shows the changes in input devices by conventional methods in this clinical evaluation.

In the reported case, voluntary function of the hands and fingers was assumed to be completely lost at 2 months, which led to an application to switch to a pressure sensor switch. At
9 months, voluntary function of the upper extremities was completely lost. This resulted in re-evaluation of the patient in an attempt to find a body part that could be used to operate an input device, for example, the voluntary muscles of facial expression or installation of an eye movement input device. Due to having to redesign the device for the patient, there was a loss of communication support for 2 to 3 months. Other than this period of time, it was assumed that the continuous communication support provided was effective for the patient.

6. Conclusions

The developed eye movement input device could be introduced irrespective of disease stage, and it was designed for continuous use. Although based on clinical evaluation in only one case, it was possible to use the device continually for about 30 months, and it met the needs of the patient. Usually, installation of an eye movement input device only occurs after disease progression. However, if this device were to be installed earlier in ALS patients, support for continuous communication could be provided. The present results showed that the current eye movement input device effectively assisted continuous communication in ALS patients.

The developed eye movement input device may also be indicated for use in patients with conditions other than in ALS, for example, in patients with quadriplegia. Moreover, in patients who can support their head, neck, and trunk, input is possible with a video camera installed at a considerable distance. The cost of the parts required for device used in the current study was 45,000 JPY. With the use of lower cost components, further devices could be produced at a much lower cost. In the future, we aim to further develop this eye movement input device, which reduces patient burden yet can be easily be installed by caregivers.

Acknowledgment

A part of this study was received a research grant from the “NOASTEC foundation” in 2004.

References
