Designing, Fabricating, and Assessing the Efficacy of a BiPAP Mask-mounted Blink-based Communications System

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Abstract

Loss of voluntary muscle control associated with progressive amyotrophic lateral sclerosis is correlated with a significant decrease in the ability to communicate effectively. Some existing technologies employed aim to bridge the communication gap by utilizing a caretaker to convey thoughts and phrases, while other technologies are situationally limited and pose a large financial burden to patients. This technical project focused on the integration of an open-source blink detection algorithm with a BiPAP mask-mounted camera to develop an effective and modular communication system that will increase the autonomy of ALS patients and decrease caretaker burden. A lightweight 3D-mount was designed to securely attach to existing BiPAP masks, ensuring compatibility and ease of use for patients. The mount accommodates a camera system positioned in proximity to the patient's eye, enabling real-time monitoring of blinking patterns. The camera captures video footage, which is processed by a proprietary algorithm specifically designed to detect intentional blinks. The efficacy of the system was assessed using a series of simple blink tests that were performed on the investigators. Results from the testing phase demonstrated 20 percent effectiveness of the designed system in accurately detecting intentional blinking patterns at low frame rates, while offering promise for enhanced effectiveness in the future at higher speeds. The integrated system offers a non-invasive and user-friendly solution for ALS patients to communicate their need for assistance, enhancing their autonomy and quality of life. The scope of this project was to use readily accessible, low cost hardware to produce a proof of concept demo, with future work aiming to minimize bulkiness and field of view obstruction to enhance operational functionality of the system.

Keywords: amyotrophic lateral sclerosis, ALS, augmentative and assistive technology, assistive communications, computer vision, blink detection, eye gaze, eye tracking, communication device

Introduction

Amyotrophic lateral sclerosis (ALS), or Lou Gehrig's disease, is a debilitating, progressive, and terminal neurodegenerative disease that results in the dysfunction and death of brain and spinal motor neurons, and thus the slow destabilization and eventual loss of voluntary motor control. ALS holds an incidence of 1-2.6 cases per 100,000 annually and a prevalence of 6 per 100,000, as evaluated in 2016 (Talbott et al., 2016). Most ALS patients are diagnosed in their late fifties to early sixties, and die within three to four years of diagnosis due to pneumonia caused by consistent shallow breathing (Corcia et al., 2008). ALS is marked by uncontrollable muscle twitching (fasciculations), cramping, stiffness, slowed movement, and progressive muscle weakness (Masrori & Van Damme, 2020). This usually affects small areas, but spreads outwards as the disease develops until it occurs more or less globally. There are generally two main forms of ALS: spinal ALS, in which paralysis begins in the arms, legs, and other limbs; and bulbar ALS, in which paralysis begins in the muscles of the head and neck. Bulbar ALS is associated with faster mortality than spinal ALS, and other contributors to survival time include age at diagnosis, level of cognitive impairment, and some genetic factors (Knibb et al., 2016).

Regardless of the subtype, eventually symptoms reach the neurons controlling oral musculature (bulbar neurons), degrading one's ability to speak, eat, and swallow (Moawad, 2022). In some forms of ALS, such as bulbar ALS, this type of degradation occurs particularly quickly (Masrori & Van Damme, 2020). Clear and effective communication becomes more and more challenging until eventually it is impossible by natural means alone. This negatively impacts patient health and safety, as ALS patients can no longer communicate (or communicate well) things like needs for food and water, pain, or time-sensitive emergency information. Furthermore, speaking is the most common means by which humans form and maintain bonds. The loss of the ability to speak prohibits ALS patients from interacting with loved ones and others in the way in which they are likely most familiar – spoken language.

Communication Technologies

Augmentative and assistive communication (AAC) devices play an important role in providing ALS patients the means and agency by which to communicate again. These AAC devices can generally be categorized by technical complexity. Less technologically advanced AACs tend to be significantly less expensive than their more capable counterparts, and tend to require less setup and training. Examples of such communication vectors include alphabet boards, cardboard or plastic boards with letters and common phrases, and communication books, collections of boards containing common words and pictures (Williams, 2023).

Complex technological AAC devices like eye gaze-tracking computers (for example, the Tobii Dynavox I-Series or the Eyegaze Edge) are unsurprisingly more robust than low-tech methods. They permit patients to do more than just generate speech independently – they can surf the web, send emails, video chat with others, and more. More importantly, unlike low-tech AACs, they can communicate emergent information – a need to use the bathroom, pain, hunger, etc. – without needing to use a caregiver as a “translator”. Beyond the obvious aforementioned benefits, early intervention with AAC devices has also been correlated with higher quality of life scores for both patients and caregivers when assessed with the McGill Quality of Life questionnaire (Londral et al., 2015).

Impediments to AAC Use

However, both categories of AACs have limitations that restrict their ability to be used by those with ALS. Low technology devices almost always require the use of a caretaker or secondary individual to determine the content of the communication. Information provided by the patient (a movement or sound) is used to confirm or deny a particular letter, word, or image selection. This process is prone to error, restricts ALS patients to very simplistic sentences, and, most of all, is vastly less efficient than speech or other standard forms of communication. Eye gaze devices and other high-tech AACs are significantly more accurate and faster than low-tech AACs, and do not require the recipient of the message to “translate” in stream; however, they are much, much more expensive, and operate under a strict range of parameters that can be challenging to meet in all environments and scenarios. For example, the Tobii Dynavox I-Series must be consistently oriented to the user’s face and body such that the screen and the face are parallel, and maximum tilt, pitch, and yaw of the head are all 25° (Tobii Dynavox AB, 2023). For example, patients lying down or in non-standard seating positions must have the tracker oriented directly in front of their face at all times. Furthermore, eye tracking operation is not guaranteed just because the eye or eyes of the patient are in the view of the eye tracking camera and fulfill the aforementioned orientational requirements. The head and eyes must be within the device’s tracking volume, the user must avoid sunshine on the face or the tracking camera, and the device may need to be recalibrated when transitioning from inside to outside environments. If the user’s head falls so as to no longer match the operational parameters of the device, they may no longer be able to communicate. New or temporary caregivers may also lack the knowledge to properly position and set up the device for patient use. These limitations introduce the need for an AAC device that is robust enough to allow for communication when the above parameters are challenged.

Abstract Device Design

Through consultation with our technical advisor, we determined that the best device form for an orientation-robust AAC device would be as follows: a camera mounted on a BiPAP mask positioned close to the eye. This camera would be connected to a computer, which could record and process any blinks enacted by the user. When intentional blinking occurred, the computer would notify a caregiver or family member nearby. We selected a BiPAP mask as the host platform for the system because such masks are tightly secured to the user’s head, and any camera mounted well to the mask will always have the same orientation to the user’s eye, regardless of movement. Moreover, BiPAP and other non-invasive ventilation devices have been shown to prolong survival and are commonly used by ALS patients at night and during sleep - times when other AAC devices may not function as well, or at all (Kleopa et al., 1999).

Results

Mount Design

One aim of the project was to develop a lightweight, rigid, and durable mount to house the camera system and attach the system to the Mirage Quattro BiPAP mask. Necessary measurements of both the camera and mask were taken to develop a preliminary 3D computer-aided design of the mount using Autodesk Fusion360. The initial design was iterated several times to accommodate various design criteria. The upper supporting beam of the mount was aligned at a 30º offshoot from the longitudinal plane of the face. Three cutouts were made in the upper and lower beams as well as the backplate to accommodate protrusions from the camera, lens, and adapter that created points of contact with the mount itself. Two curved connection points were also added to the upper and lower beams to support a more secure connection with the mount (Fig. 1A). Due to limited availability of high-definition, fully unwrapped 3D models of the Mirage Quattro BiPAP mask, and any BiPAP mask at all for that matter, a traditional CPAP mask model was purchased on TurboSquid. The model included both the mask and a mock user, to allow better visualization of how the mount would be oriented on the user's face and how much of the field of view would be obstructed (Fig. 1B). A full assembly of the mount, camera system, mask, and user was assembled; isometric and right-side views of the assembly are pictured in (Fig. 1C-D).

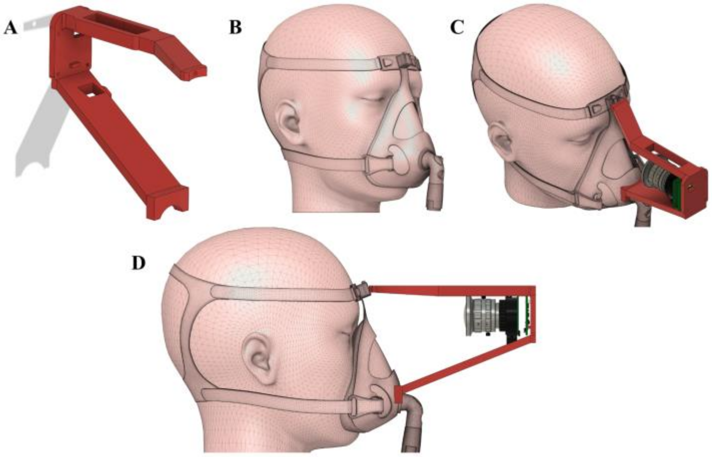

Fig. 1. Designing and modeling mount with model user. **(**A**)** Final mount design; isometric view. **(**B**)** TurboSquid CPAP mask model with user utilized for visualizations. **(**C**)** Full mount assembly of mount, camera, mask, and user; isometric view. **(**D**)** Full mount assembly; right-side view.

Static stress testing was performed using a Fusion360 simulation in which 300 grams (approximately 3 Newtons) were loaded in a downward direction from the backplate of the board; the results of the test are pictured in Figure 2. 300 grams was designated as the maximum allowed weight during camera selection, and although the total weight of the system came in at only 61 grams, additional weight was added to account for excess mounting materials that might be used. The results of the test, which indicated a minimum safety factor of 15.0, demonstrated no structural points of weakness throughout the design. One additional test was run using 5000 grams (approximately 50 Newtons) as the added load. This test did identify one small point of weakness, however the results were excluded from this report due to the unreasonable weight 5000 grams would be for a close-eye Raspberry Pi camera.

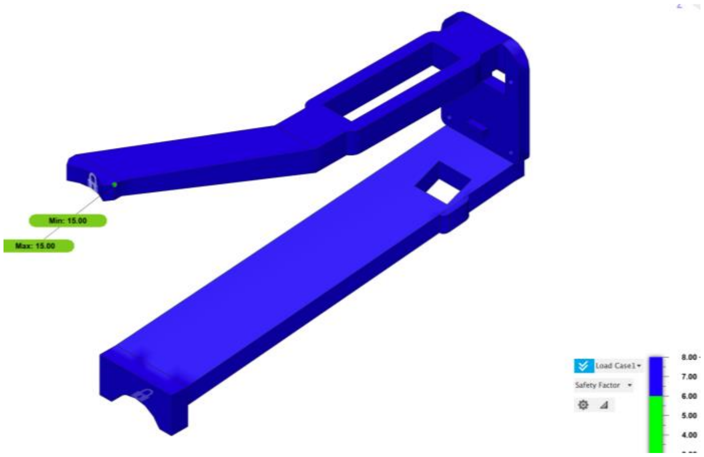

Fig. 2. Static stress testing of model to identify structural weaknesses

The mount was first printed using an SLA resin, which offers high precision, durability, and a smooth surface finish, making it ideal for producing detailed and accurate prints that must secure tightly in different applications. The initial print was processed and sanded, however small errors in measurement made the fit less than ideal. It was determined that through manual sanding adjustments, the improper fitting of the mount to both the camera system and the BiPAP mask could be easily addressed.

Performance Testing

Two forms of testing occurred: evaluation of the hardware's ability to intake frames in tandem with the algorithm, and evaluation of the algorithm's ability to detect blinking at low and high frames per second (FPS).

Non-blink performance testing

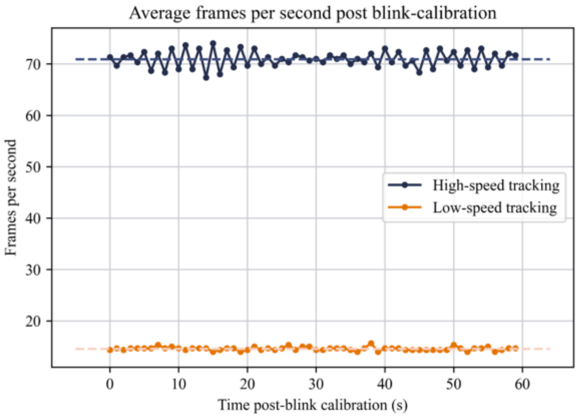

Fig. 3. Frames per second analysis in low- and high-speed eye tracking modes.

We desired to benchmark the ability of the algorithm to intake frames. At the beginning of the startup sequence of each algorithm instance is a blink calibration period lasting around twenty seconds. Because the algorithm is calibrating for blinking and actively processing data, frame rate (reported by the algorithm once per second) was only recorded until after calibration was completed. One trial consisted of frame rate being recorded for a period of sixty seconds. Trials were conducted three times in both high and low tracking modes. On a standard consumer laptop (Dell XPS 9320; 13th Gen Intel® Core™ i7-1360P, 2.2 Mhz, 12 Cores; 32 GB RAM; integrated graphics), the algorithm was able to output an average of 70.933 FPS in high-FPS tracking mode and 14.572 FPS in low-FPS tracking mode (Fig. 3). Though the low-speed tracking mode averaged at less than half of our target FPS, high-speed tracking achieved over double target FPS.

Initial blink performance testing

Testing was performed under heavy illumination, and with the camera held significantly closer to the eye than the mount design, so as to reduce the chance of erroneous pupil detection. Initially, testing occurred at both high and low FPS, but recurrent errors in high-FPS tracking mode (as detailed in the Discussion section) prevented any blinks from being detected at high speed. This forced testing to occur only in low-FPS mode. Five trials were conducted, in which ten blinks were administered to the system over 30–60s. Blink detection (true positive) was recorded, as was missed blink detection (false negative) and erroneous blink detection (false positive). As is visible in the confusion matrix in Table 1, the algorithm performed poorly at detecting blinks at low FPS. 20% of all blinks were captured and properly detected by the algorithm, while 80% were missed. The three false positives that did occur were a result of a dark object (like the tester’s hair) moving into the frame.

Table 1
Confusion matrix of low-FPS blink detection testing.

	Actual Positive	Actual Negative
Predicted Positive	4, 2, 2, 0, 2 = 10 (20%)	1, 1, 1 = 3
Predicted Negative	6, 8, 8, 10, 8 = 40 (80%)	N/A

Discussion

Difficulties in acquiring camera hardware and submitting a full human subject testing protocol to the IRB-SBS, as well as unforeseen processing difficulties, caused significant delays in the timeline for system development, and ultimately limited the groups abilities to adequately address overall shortcomings in the systems ability to detect blinks as well as differentiate intentional from unintentional blinking.

Efficacy Evaluation in Human Subjects

We intended that a full-scale human subject testing protocol would be submitted to the Institutional Review Board for Health Sciences Research (IRB-HSR). Accordingly, a significant amount of work was completed towards accomplishing this goal, including protocol design, recruitment materials development, and consultation with the IRB-HSR office. Ultimately, however, the protocol was taken down another path. The complexity of the IRB-HSR, due to potential risks posed to participants by traditional pharmaceuticals or more invasive medical devices, caused the approval process to become increasingly unrealistic. Furthermore, discussion with the technical advisor, Dr. Alec Bateman, highlighted the fact that though the system could be used in ALS patients, the system itself was not inherently a medical device, but rather a communication input method. The technology has potential applications to practically anyone wearing a front-face mask, such as fighter pilots. Consequently, it was decided that it was more fitting to pursue approval for human subject testing through the Institutional Review Board for Social and Behavioral Sciences (IRB-SBS), which deals with non-health sciences human subject research.

A full-scale, human subject testing protocol was ultimately submitted to the IRB-SBS and is currently awaiting approval; protocol number: 6648; *Assessing Efficacy of a BiPAP Mask-Mounted Blink Detection Camera System*. The study seeks to obtain 2-30 participants ages 18 to 40 years old who are otherwise healthy with no underlying health conditions that would affect their ability to a) blink or not blink over a time period of less than or equal to six seconds, or b) wear the BiPAP mask-mounted blink detection system. The protocol asks participants to wear the blink communications system on their face, while a pre-recorded instructional track is played, directing the participant when to blink over a period of around 20-30 seconds. The system will record blinking and attempt to detect intentional blink sequences. At the same time, the sub-investigators will manually mark when participants blink. It is our hope that this study will be carried out in the upcoming year by the inheritors of this project.

Algorithm Efficacy and Blindspots

As noted in the Results section, the algorithm was not particularly efficacious at detecting blinks in the low-FPS eye tracking mode. However, there was an interesting phenomenon that occurred when eye-tracking was attempted in high-FPS mode. Once the pupil was selected and filtered, and high-FPS mode was activated, blinking would cause a pupil tracking error – an error that occurred at an estimated rate of 100%. This pupil tracking error was a type error caused by the system struggling to place the pupil when the eye was closed – when the pupil is inherently not visible. The error message returned implied that the system could not properly identify the topography of the pupil for tracking. Instead, the pupil tracking indicator would flit to other darker, shaded areas of the face: shadows, the tester's brown hair or eyebrows, etc. Curiously, when the camera was moved away from the eye during high-FPS, "blinks" were registered by the algorithm, because it could not detect the pupil at all. The system's testing JSON logs did not record these errors, meaning that we were not able to develop a more robust and quantitative understanding of how frequently this error occurred during blinking at high-FPS; however, from our experience encountering the error in testing, we cannot recall a single blink enacted at high-FPS that did not generate this error. The extreme regularity of this error occurring at high-FPS forced us to complete testing at low-FPS, as we were unable to patch this issue prior to the completion of the Capstone project. The same regularity indicates that with investigation and rectification of this error, the algorithm will be able to detect blinks at high FPS with great accuracy.

Fig. 4. Pupil identification and filtering in EyeLoop (Arvin et al., 2021). Middle (composite) image editing disclosure: non-filtered B&W overlay at 60% opacity. Right and left images resized marginally to match size of composite.

Iris color, hair color, and shadows on the face negatively impacted the ability of the algorithm to locate the pupil and detect blinking. Darker-shaded areas would interfere with the algorithm's pupil recognition, despite strong filtering and heavy facial illumination (Fig. 4). Mitigation of this issue will likely require further alteration of the algorithm in order to improve robustness, particularly in users with darker skin tones, hair color, and eye color.

Future Work

In the future, further research should be completed to enhance the general performance and usability of the system. Investigations should be completed to address the errors encountered related to high-speed pupil tracking. The parameters for pupil tracking, including the gaussian blur and binary filter added to the input images, can also be refined further to enhance the pupil tracking and thus blink detection. The camera could also be mounted closer to the eye to remove background objects and other algorithmic detriments from the field of view. Additionally, though the proprietary blink intentionality decoder was not fully completed and integrated into EyeLoop, it remains a key component of the finalized device and must be developed and integrated in the future. Miniaturization of the entire system should also seek to reduce bulkiness and view obstruction by implementing smaller camera hardware and reducing the overall size of the 3D-printed mount. Addition of IR illumination would likely make blink identification significantly more successful; however, given the safety implications of IR energy directed at the eyes, it was out of the scope of this research. Specific sequences of intentional blinks (i.e. three rapid blinks or four slow blinks, etc.) could also be implemented to signify specific needs of the patient such as if they need to go to the restroom, eat food, or drink water, helping to expand the autonomy of the patient and further reduce caretaker burden. Future studies involving ALS patients using the device in real-world settings could also provide insights into the long-term efficacy and impact of the assistive device on patient outcomes and caregiver experiences. Furthermore, collaborations with healthcare professionals, caregivers, and ALS patient advocacy groups could help expedite the acceptance of the technology into the ALS community. Overall, continued research and innovation in assistive technology for ALS and other neurodegenerative diseases holds great promise for improving the lives of patients and caregivers alike.

Materials and Methods

The materials used in this project sought to offer a low-cost and user-friendly technological solution to existing communication shortcomings for ALS patients.

Mask Selection Criteria

A lightweight, durable, and rigid mount was designed to house the camera hardware and subsequently secure hardware to a consumer-available BiPAP mask. Preliminary investigations were completed to identify the most common styles of BiPAP masks utilized by ALS patients to provide ventilatory support. The three most common styles were identified as nasal pillows, nasal interfaces, and full mask interfaces. Nasal pillows, which use two small cushions to seal the base of the nostrils, were eliminated from contention due to their lack of available structure around the forehead region capable of supporting a camera mount. Full mask interfaces offer the most complete air seal by encapsulating both the nose and the mouth, however they are more bulky than nasal interfaces, which offer a complete air seal around the nose without compromising the freedom of mouth functionality. A standard full interface style mask was selected as the base of choice due to its frequency of use in ALS patients and large quantity of structural points upon which a mount could be designed to rest. The Mirage Quattro full-face mask with silicon cushion, was acquired from ResMed to be used as the base of the camera system.

Algorithm Selection

Given that the team is composed of biomedical engineering students, there is a lack of computational ability and experience requisite to developing a close-eye blink detection algorithm from scratch. The Department of Computer Science was canvassed for contributors, but to no avail. Therefore, our primary means of algorithm selection was through interrogation of the literature. Because the camera was only going to have a view of a small portion of the face (and in particular, a single eye), it was important that the algorithm be able to function without a view of the user's entire face. Many blink detection algorithms track the full face first and then identify the eye, so finding the opposite was challenging. We also desired the algorithm to be open-source and to be programmed in Python for ease of implementation and customization. After a thorough literature review we identified the open-source EyeLoop algorithm as our algorithm of choice as it met all of the above criteria (Arvin et al., 2021).

Camera Hardware Criteria & Selection

There were a number of criteria for the selection of the camera hardware to be used in the computer vision components. Because a full blink is completed in around 572 ms, it is important that any camera selected would be able to perform at a high number of frames per second – at least thirty (Kwon et al., 2013). We were also concerned about data – over what protocols would frame data be communicated, over what physical medium would it be transferred, could the camera filter video or noise onboard, etc. At the beginning of the device design, we also questioned whether we should attempt to include night-vision-capable (that is, infrared) cameras and illumination; however, upon consultation with our technical advisor, it was determined that attempting to achieve blink detection in low-light conditions was beyond the scope of this particular project, despite being a design constraint in future device iterations. Because the camera would be closer to the eye than other eye tracking cameras, we also considered that we should utilize a macro lens to better capture the user's eye during tracking. From a social impact perspective, we found it important to try to use camera hardware that was inexpensive, yet still capable of meeting the above technical requirements. We used internet search engines and online stores to identify cameras that would fulfill these needs. USB spy cameras fit many of the criteria – small, macro lens, USB connective – but lacked resolution and frame rate capability necessary for our purposes. After some time, we identified the Raspberry Pi HQ (High-Quality) Camera as our camera of choice. Costing only $50.00, the HQ Camera fulfilled all of our requirements with the exception of the lens (the camera module comes without a lens) and the USB connection (Adafruit Industries, 2024). However, we were able to find a camera shield that would convert the camera's onboard CSI connection to USB while providing proper support for OS compatibility, like drivers (Amazon.com & Arducam, 2024).

Finally, the lack of lens on the camera itself meant that a lens had to be identified for our purposes. The lens needed to be able to focus on the eye at close range (8-10 cm) and needed to be able to fit to a C/CS lens mount – the mount type used by the camera. We used optic metrics and measurements, such as focal distance, focal length, and working distance to find and select the lens. The OptiTrack C/CS-mount 4.5mm F#1.6 lens was selected as the final lens for the device.

End Matter

Author Contributions and Notes

K.S.C. designed, simulated, modeled, and fitted mount, K.S.C. and B.R.M. developed IRB-SBS documentation, B.R.M. performed device testing and blink data analysis, B.R.M. wrote and tested software, K.S.C. and B.R.M. wrote the technical report.. Authors B.R.M. and K.S.C. declare no conflicts of interest.

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