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THE MOUTH MOUSE: AN INTUITIVE BLUETOOTH CONTROLLER OF ELECTRONIC SYSTEMS FOR PERSONS WITH UPPER-LIMB IMPAIRMENT

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ABSTRACT

Manual dexterity is key to engaging one's environment and interfacing with technologies for communication and personal computing. Individuals with marginal or no dexterity are faced with obstacles and barriers limiting educational opportunity, workplace productivity, independent living and community participation. We have, developed an effective and intuitive Bluetooth tongue controller (a.k.a. "Mouth Mouse") designed to give people with severe upper limb impairment effective control of computers, smart phones and tablets. The device is inherently portable requiring no external hardware or supporting software and thus can be used virtually anywhere. Preliminary testing has shown the Mouth Mouse to be an effective computer input device. In this paper we outline key design objectives and present preliminary data demonstrating the efficacy of the Mouth Mouse as a computer input device.

Keywords: Assistive Technology, Computer Input, Tongue Control, Paralysis, Throughput

1. INTRODUCTION

Computing and communications technologies are changing the way individuals and groups interact and exchange information. The continuing growth and worldwide expansion of high bandwidth communications has led to an increased use of computers and hand-held technologies in education, the workplace, recreation and social participation. There are over 200,000 individuals in the United States living with complete or near complete paralysis due to bodily trauma or progressive neurologic diseases [1-4]. Individuals with marginal or no dexterity require assistive devices to benefit from technologies used by non-disabled persons. Customer discovery and recent research highlights features of an assistive device valued by individuals with severe upper-limb impairment [5]. These include:

- Intuitive; no complex keystrokes /commands to initiate a process or correct an error
- Non-fatiguing so it can be used for extended periods of time
- Portability so it can be used in as many places as possible
- Easy to setup for caregivers

We have developed an effective computer input device, the Mouth Mouse, designed to meet the needs and wants of people with severe upper-limb impairment. The Mouth Mouse can be thought of as a computer laptop touchpad encased in a dental retainer. Rather than sliding a finger across the touchpad, one slides the tongue across the roof of the mouth. Four force sensitive resistors laminated to a custom fit dental retainer and arranged in a diamond pattern monitor the amount of force applied by the tongue. Each sensor corresponds to a cardinal direction (N, W, E & S). The magnitude of force informs cursor speed, and applying force to two sensors simultaneously results in diagonal and curved cursor trajectories. Two additional force

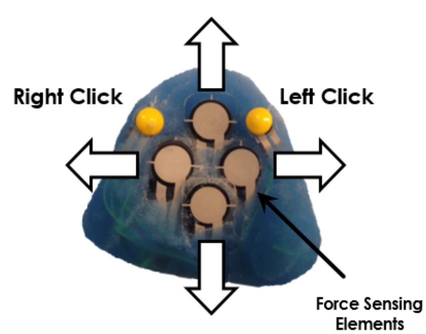

FIGURE 1: DIRECTIONAL FORCE SENSORS AND YELLOW MOUSE CLICK BUTTONS.

sensors are used for right and left mouse click buttons. Cursor direction, movement speed and mouse click commands are transmitted wirelessly using Bluetooth communication. The Mouth Mouse fully emulates a computer mouse including drag and drop functionality. Because the device is contained entirely within the mouth it is inherently portable and can be used virtually anywhere. The tongue has fine motor control and is fatigue resistant making the Mouth Mouse intuitive and easy to use for extended periods of time [6].

In this paper we outline several key considerations of our SBIR Phase I design and present preliminary data comparing the efficacy of our device to the Tongue Drive System (TDS) from Georgia Tech. The TDS has been described as state-of-the-art in lingual control and therefore this initial comparison is a powerful vehicle to compare and contrast the potential of our design. A fundamental difference between the Mouth Mouse and the TDS is our ability to generate curved and diagonal cursor trajectories and therefore we hypothesized the Mouth Mouse would be a more effective computer input device than the TDS.

2. MATERIALS AND METHODS

The Phase I project period was 6 months in duration and it was therefore decided at the outset to integrate commercially available sensors and electronics to reduce build cost and importantly design time. Several critical design considerations included: (i) choice of sensor and electronic components given the limited intra-oral space, (ii) battery selection and recharging capabilities, (iii) how to protect the sensors and components from moisture, and (iv) how to adjust or tune the sensors after assembly. The final device evolved through several iterations with each design evaluated by the PI. The PI was the sole test subject and thus IRB approval was not required.

2.1 Force Sensor and Component Selection

The Tekscan FlexiForce A301 force sensistive resistor was chosen for its small size and operational characteristics. The PI had used similar FlexiForce sensors (ie., A201) in an early prototype and therefore there was a strong expectation the A301 sensor would be an appropriate choice for the current application (Figure 2). The larger sensing area of the A301 sensor (9.5 mm diameter) made it easy to isolate an individual sensor with the tip of the tongue, and the size and proximity allowed two sensors to be contacted simultaneously to generate diagonal or curved trajectories as depicted in Figure 3. The smaller A101 sensor (3.8 mm diameter) was selected for mouse clicks given the limited palatal surface to mount the mouse click sensors (Figure 1).

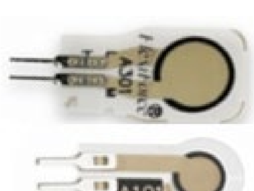

FIGURE 2: THE LARGER FLEXIFORCE A301 FORCE SENSITIVE RESISTOR WAS USED FOR CURSOR DIRECTION AND THE SMALLER A101 SENSOR FOR MOUSE CLICKS.

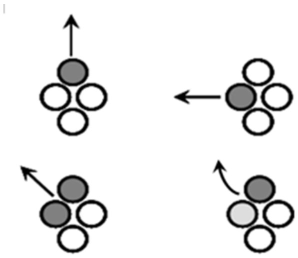

FIGURE 3: SHADED CIRCLES INDICATE TONGUE FORCE. THE DARKER THE SHADE THE GREATER THE APPLIED FORCE. THE ARROWS SHOW RESULTING CURSOR MOVEMENT.

Size, cost and power requirements were integral to the selection of electronic components. Accudyne Systems Inc. examined relevant technical materials and data specification sheets to ensure compatibility and packaging of the components given the limited intraoral space. Autodesk's AutoCAD electrical software was used to arrange the components to minimize the electronic footprint. A custom flexible circuit board was designed once an ideal arrangement was determined prior to component assembly.

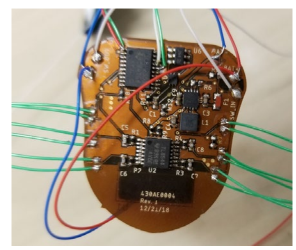

FIGURE 4: FLEXIBLE CUSTOM CIRCUIT BOARD.

2.2 Battery Selection

Several options for powering the Mouth Mouse were evaluated. Batteries manufactured for internal use exposed to bodily fluids similar to the Mouth Mouse use special encasement materials and manufacturing procedures to protect the battery from environmental ingression. Due to the specific requirements for each device, these batteries are typically custom made and require significant development lead time and costs before a production model can be manufactured. For these reasons, commercially available lithium ion coin cell batteries were chosen for prototype development. Coin cell lithium batteries have a fully encased metal seal for the battery chemicals similar to housings used for medical devices, and they provide excellent recharge and discharge capabilities for the size of the battery. Importantly, the relatively small size of the battery made it possible to fully encase the battery within the retainer along with the control circuitry. How to recharge the battery after it was encased is described in the next section.

FIGURE 5: COIN CELL BATTERY SHOWN RELATIVE TO A QUARTER.

2.3 Waterproofing

A custom retainer was built using a mold of the PI's mouth. A pliable sheet of acrylic was placed over the mold and pressed to conform to the teeth and dental arch (ie, roof of mouth). The assembled electronics (Figure 4) were then placed within the concavity and another sheet of acrylic was layered over top the circuitry taking special care to pass sensor leads through the material before hardening the acrylic using a light curing process. At this stage the electronics were completely sealed within a protective cocoon of acrylic designed to keep the electronic components waterproof for extended use in the mouth. The one point of vulnerability for moisture ingression was the need for a recharging port providing access to the coin cell battery. A barrel plug was molded into the back side of the retainer as shown in Figure 6. The opening was sealed with a rubber stopper. The efficacy of this sealing method was evaluated early on by constructing a simple electronic circuit (ie, dummy device) powered by the same battery identified for use during component selection. The "dummy" retainer with simple circuitry was submerged in a glass of water for 1 hour after which the battery was tested through the charging port using a voltmeter to determine if the electronics were intact. Results of this simple test confirmed the acrylic encased barrel plug with battery charging port plugged with a rubber stopper was an effective and practical solution for the prototype device. The same design was used in subsequent iterations and there have been no electrical issues to date.

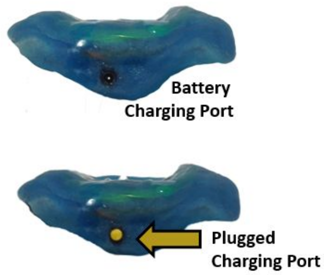

FIGURE 6: A RUBBER STOPPER SEALS THE CHARGING PORT.

A concern that arose during circuit design was that a mechanical on/off switch would be a possible entry point for saliva. For this reason, it was decided to use an inductive magnetic reed switch to turn the Mouth Mouse on and off. A magnet placed in close proximity to the bottom right corner of the retainer engages the switch turning off the power circuit. This design required a separate stand with an embedded magnet as shown in Figure 7. Accudyne designed and 3D printed the stand that also serves as a convenient storage location for the unit when not in use. Future work will include an inductive charging coil within the stand to wirelessly charge the battery and eliminate the barrel plug altogether.

FIGURE 7: RETAINER CHARGING STAND WITH INSET MAGNET.

2.4 Sensor Tuning

Force applied to the sensing area of the FlexiForce sensor causes a change in resistance and consequently output voltage. The analog signal was converted to bit values onboard the microprocessor and the current bit value for each sensor was compared to a "move" / "no-move" cursor bit value threshold. In this way the cursor should not move until the bit value exceeded a pre-defined threshold, beyond which the cursor moves proportional to the change in voltage. Early testing however revealed the cursor would occasionally drift even when the tongue was not in contact with a sensor. The process of adhering the sensor to the retainer and the fact that each sensor was mounted to a surface with a slightly different curvature resulted in internal strains that pre-loaded the sensor beyond the baseline unloaded bit value used to set the cursor move / no-move threshold. The initial attempt was to expand the no-move bit value range, however the effect of doing so was the tongue force that had to be applied to initiate cursor movement for one sensor was noticeably different than for another sensor. The challenge at this stage was the micro-controller was fully-encased within a protective acrylic housing and it was not possible to access the pins to reprogram the microcontroller. A simple yet effective solution was implemented in subsequent iterations by leaving a temporary wire-lead providing access to the micro-controller pins to adjust the sensor sensitivity. The wire lead was cut after all sensors were balanced and the entry point was sealed with acrylic as show in Figure 8.

FIGURE 8: A TEMPORARY WIRE LEAD ALLOWED RE-PROGRAMMING OF THE MICROCONTROLLER. AFTER WHICH THE LEAD WAS CUT AND SEALED.

2.5 Testing Protocol

Efficacy of the Mouth Mouse as a computer input device was evaluated using a center-out-tapping protocol described in Georgia Tech publications [7-9]. Comparing throughput (bit/s), a measure of cursor movement speed and accuracy to the TDS is only valid if the testing protocols are near identical. Georgia Tech has reported parameters of their protocol(s) in great detail and therefore it was possible to develop our evaluation software to be near identical to theirs. The center-out-tapping protocol involved moving the cursor from the center of the screen to 48 randomly appearing targets of different size and distance. The goal was to move the cursor as quickly and as close to the center of the target as possible. A left mouse click (or Enter key) was used to indicate target selection. Only one target appeared at a time and after it was selected the cursor was automatically repositioned to the center of the screen and a new target appeared.

$$\text{Throughput} = \text{ID} / \text{MT} \quad (1)$$

$$ID = log_2\left(\frac{D}{W} + 1\right) \quad (2)$$

where ID is the index of difficulty, MT is movement time, D is the distance along the task axis, and W is the effective width defined as 4.133 x the standard deviation of the distance between the user's selected position and the center of the target [9].

3. RESULTS AND DISCUSSION

The PI performed the center-out-tapping protocol first using a standard computer keyboard. This initial test was done to confirm the evaluation software for the Mouth Mouse was near identical to TDS. Throughput using the keyboard was compared to data reported for 23 able-bodied Georgia Tech subjects. There is no reason the PI, an able-bodied adult male should perform differently than the Georgia Tech subjects, unless of course different parameters were implemented in the testing software. Said differently, assuming the evaluation software was coded near-identically, throughput for the PI should be similar to values for the Georgia Tech subjects.

The PI also completed the center-out-tapping task using the Mouth Mouse. The PI was familiar with the protocol having completed many rounds of testing using incremental prototypes developed during the R & D process. It was decided that collecting multiple test-sessions to quantify learning effects using the final device would be misleading and therefore learning data were not collected.

3.1 Keyboard Throughput

Mean throughput for the 23 able-bodied Georgia Tech subjects was 2.38 ± 0.61 bits/s. Throughput for the PI was 2.23 bits/s and within the 95% confidence interval (2.13 to 2.63) for the Georgia Tech data. It was concluded the evaluation software was coded similarly and therefore comparing throughput for the Mouth Mouse and TDS would be a valid comparison of relative efficacy.

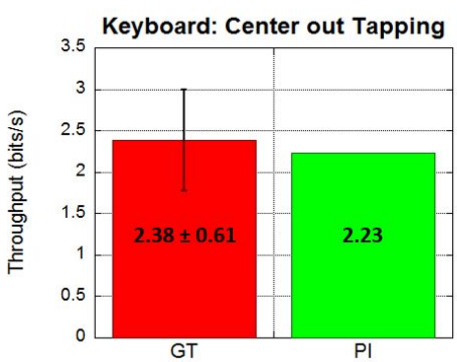

FIGURE 9: KEYBOARD THROUGHPUT FOR 23 ABLE-BODIED GEORGIA TECH (GT) SUBJECTS AND THE PI.

3.2 Mouth Mouse Performance

The ability to generate diagonal and curved trajectories combined with proportional control are key features that distinguish the Mouth Mouse from the TDS. The TDS moves the cursor at a constant rate and in only one of 4 directions at a time (Up, Down, Left & Right). In theory, the ability to move diagonally and with curved trajectories should translate to better performance since the cursor path is more direct than sequential straight line paths using the TDS.

3.2.1 Significance of Diagonal and Curved Trajectories

The PI used the Mouth Mouse to complete the center-out-tapping protocol but purposely restricted cursor trajectories to straight line paths mimicking the capabilities of the TDS. Throughput using straight line paths only was 1.48 bits/s. The same protocol was repeated using the Mouth Mouse but this time the PI used diagonal and curved trajectories. Throughput increased by 54% to 2.28 bits/s. Cursor trajectories for each task are shown in Figure 10. It is difficult to appreciate the real world significance of this improvement when reported in bits/s. To put it in perspective, consider that total movement time to complete the task using straight line paths was 79 seconds compared to 56 seconds for the curved trajectories. Computer users with complete tetraplegia average approximately 5 hours of daily computer use [5]; therefore, a 54% improvement in throughput would greatly increase productivity taking less time to perform the same amount of work.

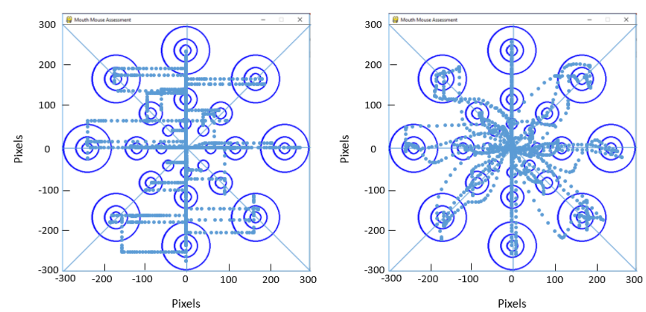

FIGURE 10: LEFT PANEL SHOWS CURSOR TRAJECTORIES USING STRAIGHT LINE MOVEMENTS ONLY (THROUGHPUT = 1.48 BITS/S). COMPARED TO 2.28 BITS/S WHEN USING CURVED TRAJECTORIES.

3.2.2. Mouth Mouse performance compared to TDS

The PI completed three rounds of center-out-tapping using the Mouth Mouse. Mean throughput is reported in Table 1. Note the PI did not actually test the TDS and is reporting performance values published by Georgia Tech [8]. Comparing performance in this manner is valid since keyboarding results suggest the Mouth Mouse testing protocol was near identical to TDS. Mean throughput for the Mouth Mouse was 41% greater than for able-bodied subjects using the TDS. This improvement was attributed to the Mouth Mouse's inherent ability to generate diagonal and curved trajectories. Note that TDS throughput for able-bodied subjects (1.52 bits/s) was nearly identical to Mouth Mouse throughput when limited to straight line paths (1.48 bits/s). It is unclear why throughput for spinal cord injured (SCI) participants using TDS (0.77 bits/s) was significantly lower compared to able-bodied subjects (1.52 bit/s). This disparity complicates comparing the Mouth Mouse to Sip & Puff (SCI);

thus, we hesitate to compare our findings to TDS (SCI). Nonetheless, we are confident based on data reported in Table 1 that the Mouth Mouse is a more effective input device than TDS and Sip & Puff control.

Table 1: CENTER-OUT-TAPPING THROUGHPUT FOR ABLE-BODIED SUBJECTS USING TDS SERVED AS A REFERENCE OF RELATIVE THROUGHPUT. RELATIVE THROUGHPUT FOR THE MOUTH MOUSE WAS 41% GREATER THAN TDS. (SCI = SPINAL CORD INJURED. A-B = ABLE-BODIED).

Device	Throughput (bits/s)	Relative Throughput
Sip & Puff (SCI)	0.51 ± 0.18	0.34
TDS(SCI)	0.77 ± 0.41	0.51
TDS (A-B)	1.52 ± 0.37	1.00
Mouth Mouse (A-B)	2.14 ± 0.13	1.41

4. CONCLUSION

Customer discovery and a thorough review of the literature has identified user needs and wants of an assistive computer input device for people with severe upper-limb impairment. The Mouth Mouse was designed from the outset with these considerations in mind. Efficacy of the Mouth Mouse was compared against TDS, the accepted industry leader in tongue control technology. Our testing revealed the Mouth Mouse allows for a 41% increase in throughput over TDS. It is important to note only the PI to date has used the device intra-orally. Expanded testing of able-bodied participants and individuals with severe upper-limb impairment are planned in subsequent research activities. The results of our Phase I testing establishes robust proof-of-concept for tongue control as an effective tool for assistive computing, and the Mouth Mouse as a promising technology.

ACKNOWLEDGEMENTS

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REFERENCES

[1] Armour, B.S., Courtney-Long, E.A., Fox, M.H., Fredine, H. and,Cahill, A., 2013, "Prevalence and Causes of Paralysis-United States", Am J Public Health, **106**(10), pp. 1855-1857.
[2] Association, A.L.S., 2019, "Quick Facts about ALS".
[3] Center, N.S.C.I.S., 2019, "Spinal Cord Injury Facts and Figures at a Glance".
[4] Sussman, M., 2002, "Duchenne muscular dystrophy", J Am Acad Orthop Surg, **10**(2): pp. 138-151.
[5] Gottlieb, A., Plotnik,M., Kizony, R., Katsarou, Z., Bostantjopoulou, S. and Zeilig, G., 2019, "Identification of clinically related requirements of a novel assistive device for people with a high spinal cord injury", PLoS One, **14**(6): e0218393.
[6] Robin, D.A., Goel, A., Somodi, L.B. and Luschei, E.S., 1992, "Tongue strength and endurance: relation to highly skilled movements", J Speech Hear Res, **35**(6): pp. 1239-1245.
[7] Huo, X.L. and Ghovanloo, M., 2010, "Evaluation of a wireless wearable tongue-computer interface by individuals with high-level spinal cord injuries", Journal of Neural Engineering, **7**(2): 26008.
[8] Kim, J., Park, H., Bruce, J., Sutton, E., Rowles, D., Pucci, D., Holbrook, J., Minocha, J., Nardone, B., West, D., Laumann, A., Roth, E., Jones, M., Veledar, E. and Ghovanloo, M., 2013, "The Tongue Enables Computer and Wheelchair Control for People with Spinal Cord Injury", Science Translational Medicine, **5**(213): pp. 213ra166.
[9] Yousefi, B., Huo, X., Veledar, E. and Ghovanloo, M., 2011, "Quantitative and Comparative Assessment of Learning in a Tongue-Operated Computer Input Device", IEEE Transactions on Information Technology in Biomedicine, **15**(5): pp. 747-757.