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The Tongue Enables Computer and Wheelchair Control for People with Spinal Cord Injury

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Abstract

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Materials and Methods

Fig. S1. The regression models for Fitts' law: Movement time (MT) versus effective index of difficulty (IDe).

Fig. S2. Graphical user interfaces for the computer access tasks.

Fig. S3. Experimental setup for driving a powered wheelchair through an obstacle course.

Table S1. Summary of the statistical analysis for center-out tapping and ITR tasks.

Table S2. Summary of the statistical analysis for maze navigation and electric-powered wheelchair driving tasks.

Table S3. Comparison between throughputs of different pointing devices.

Table S4. Index of difficulty in center-out tapping task.

Table S5. Demographic and clinical information about participants with SCI.

Movie S1. Center-out tapping task.

Movie S2. ITR measurement task.

Movie S3. Maze navigation task.

Movie S4. Electric-powered wheelchair driving task.

References (57, 58)

Author contributions: M.G. was the principal investigator (PI) in this study, and A.L., E.R., M. J., and D.W. were co-PIs. All authors contributed to the design and execution of the study. H.P. and J.K. were responsible for developing and troubleshooting the hardware and software. J.K., J.B., E.S., D.R., B.N., D.P., J.H., and J.M. conducted the trials. J.K. and E.V. analyzed the results. J.K. and M.G. wrote the paper and all co-authors edited it.

Competing interests: M.G. is a cofounder and chief technology officer of a startup company, Bionic Sciences Inc. (Atlanta, GA), which intends to bring the TDS to market. The TDS is protected by U.S. patents US8044766 (Tongue operated magnetic sensor based wireless assistive technology) and US8242880 (Tongue operated magnetic sensor systems and methods), and other patents pending.

Data and materials availability: All the raw clinical data are available on <http://www.clinicaltrials.gov>.

The Tongue Drive System (TDS) is a wireless and wearable assistive technology, designed to allow individuals with severe motor impairments such as tetraplegia to access their environment using voluntary tongue motion. Previous TDS trials used a magnetic tracer temporarily attached to the top surface of the tongue with tissue adhesive. We investigated TDS efficacy for controlling a computer and driving a powered wheelchair in two groups of able-bodied subjects and a group of volunteers with spinal cord injury (SCI) at C6 or above. All participants received a magnetic tongue barbell and used the TDS for five to six consecutive sessions. The performance of the group was compared for TDS versus keypad and TDS versus a sip-and-puff device (SnP) using accepted measures of speed and accuracy. All performance measures improved over the course of the trial. The gap between keypad and TDS performance narrowed for able-bodied subjects. Despite participants with SCI already having familiarity with the SnP, their performance measures were up to three times better with the TDS than with the SnP and continued to improve. TDS flexibility and the inherent characteristics of the human tongue enabled individuals with high-level motor impairments to access computers and drive wheelchairs at speeds that were faster than traditional assistive technologies but with comparable accuracy.

INTRODUCTION

About 1 in 50 individuals in the United States is living with some form of paralysis of the upper or lower extremities (1). Leading causes of paralysis include stroke (29%), spinal cord injury (SCI) (23%), multiple sclerosis (17%), cerebral palsy (7%), post-polio syndrome (5%), and traumatic brain injury (4%) (1). About 20% of these individuals are under the age of 40 and need lifelong care by dedicated caregivers or family members (1). According to several studies (2–6), although existing assistive technologies have facilitated daily living and improved the independence of many individuals with paralysis (7), the extent and quality of the access provided is limited and far less than that of able-bodied individuals. This is one of the main reasons for the estimated abandonment rates of 8 to 75% for a variety of assistive technologies (5). These assistive technologies are forsaken because of poor performance, poor matching with user preferences, low reliability, device handling and maintenance difficulty, environmental barriers, poor customer support, and changes in the user's functional abilities (2). Because users have special needs, it is imperative to develop practical and easy-to-use assistive technologies that provide broader functionality and coverage (6).

A number of assistive technologies such as brain computer interfaces (BCIs), electromyography (EMG) switches, eye trackers, head pointers, voice recognition systems, sip-and-puff devices (SnP), sniff control (8), and tooth-click controllers (9, 10) are currently available. Brain signals at various distances from their neural origins are used for BCIs. They provide environmental access for individuals with very limited motor control (11). Electroencephalography (EEG)-based BCIs are noninvasive and have enabled access to computers (12, 13) and powered wheelchairs (14, 15). EEG signals, picked up on the scalp, are far from neurons and have limited bandwidth, resulting in inherently slow response times. Their weak amplitudes also make EEG-BCIs susceptible to interference and motion artifacts (12). Electrocorticogram (ECoG) signals are picked up by brain-surface electrodes. They have higher amplitude and bandwidth than EEG signals. These electrodes may remain

functional over long periods with relatively low risk of brain injury. However, the necessary surgical procedure is invasive and has only been approved for use in individuals who need electrodes for seizure monitoring (16). Intracortical electrodes provide access to the richest brain signals, namely, action potentials and local field potentials. However, they are even more invasive, causing neural tissue reaction in areas damaged by electrode insertion. Therefore, despite successful demonstrations, there is a serious concern about the biostability of this approach (17).

EMG-based switches have also provided users with access to computers (18, 19) and electric-powered wheelchairs (20, 21). They involve electrodes attached to the face, which is neither comfortable nor aesthetically appealing. Eye trackers effectively use eye movements to control mouse cursors on the computer screen (22, 23). Unfortunately, they interfere with visual functions, require a camera mounted in front of the user, and are susceptible to lighting conditions. Head pointers require head and neck movement, which may be limited or cause fatigue in weakened cervical and shoulder muscles (24–26). Voice recognition systems are efficient for typing but are slow and nonintuitive for controlling a computer mouse (27, 28) or a powered wheelchair (29); they are also susceptible to ambient noise. Finally, the SnP, one of the most popular assistive technologies for driving powered wheelchairs because of its low cost and ease of use, offers only four commands. These commands are issued by soft or hard sipping (inhaling) and puffing (exhaling) through a straw to activate a pneumatic switch or pressure sensor that controls the wheelchair movements forward, backward, left, and right. However, it is slow and limited for computer access (30, 31). Moreover, the SnP straw and tubing require frequent cleaning, and it is of limited use to people on mechanical ventilators or diaphragm pacing systems.

The tongue has many inherent capabilities that, if appropriately harnessed, can make it an attractive control modality for individuals with severe physical disabilities. The size of the motor cortex dedicated to the tongue and mouth rivals that of the fingers and hand, providing the tongue with sophisticated motor control and manipulation capability, evident from its role in speech and ingestion (32). The tongue can move rapidly and accurately within the oral space. Its motion is intuitive and, unlike EEG, does not require thinking or concentration (33). The tongue is controlled by a cranial nerve, which generally escapes damage in SCI and many neuromuscular diseases (32). Tongue muscle fibers are quite fatigue-resistant, and a tongue-operated device may be used over a long period (34). The position of the tongue is reflexively adjusted with changes in the body position, and tongue-based devices may be easily operated in any posture, including lying in bed (35). Noninvasive access to tongue motion is readily available. These features have resulted in the development of tongue-operated assistive technologies (7, 36–40), including the Tongue Drive System (TDS) (41).

TDS is a wireless, unobtrusive, and wearable assistive technology that can identify the tongue position within certain user-defined locations in real time (42, 43) (Fig. 1A). TDS users can issue commands simply by moving the tongue to one of the predefined positions, such as touching a particular tooth with the tip. An array of magnetic sensors, mounted bilaterally on a pair of headset attachments located near the cheeks of the user (Fig. 1A), measures the magnetic field generated by a small disc-shaped magnetic tracer (4.8 mm

diameter \times 1.5 mm thick), which is attached to the tongue by tissue adhesive or by being embedded in a tongue barbell (44). The sensor signals are transmitted wirelessly to a smartphone or a PC (Fig. 1B) for processing by a sensor signal processing algorithm, which determines the position of the magnetic tracer with respect to the sensor array in real time, translating it to user-defined commands. With a PC/smartphone's built-in wired/wireless connectivity, other devices that are equipped with interfacing hardware in the environment may be controlled through an interactive graphical user interface.

We have previously evaluated TDS performance in 14 able-bodied individuals, using common measures adopted by the human-computer interaction community to assess speed and accuracy (44–46). For the present study, 21 participants with tetraplegia (SCI at level C6 or above) were recruited through two rehabilitation facilities, Shepherd Center in Atlanta and the Rehabilitation Institute of Chicago, to participate in a similar set of experiments. Eleven participants with SCI completed the trial, and their performance was compared with that of able-bodied participants. A detailed description of the performance measures on a subset of able-bodied participants was reported previously (44–46). Here, the goal was to evaluate the usability of the TDS among its target population in comparison with standard computer input devices (keyboard and mouse) as well as a popular assistive technology, the SnP (Fig. 1C). All participants received custom-made titanium tongue barbells with a magnetic tracer embedded in the upper ball (Fig. 1D, inset). Able-bodied and tetraplegic participants completed PC access and powered wheelchair navigation sessions on a weekly basis to measure learning effects.

RESULTS

Computer access: Center-out tapping

Fitts' law (45–48), which considers a combination of speed and accuracy (see Materials and Methods), was applied to a center-out tapping task. Subjects moved the mouse cursor from the center of the screen to select a set of randomly appearing round targets as quickly and accurately as possible. Able-bodied subjects used a mouse, a keypad, and the TDS, whereas those with tetraplegia used either the TDS or the SnP (Fig. 1C). A mouse is the most commonly used computer input device for cursor navigation and point-and-click tasks. All of the able-bodied individuals were familiar with the use of a computer mouse, and therefore, its use was measured only during the first session. This was considered the gold standard for the other devices. The results, including session-by-session statistical analysis, are summarized in table S1.

The throughput of the able-bodied participants using a mouse was 3.66 ± 0.59 b/s (bits per second). This was 1.98 and 2.87 b/s (1.53 and 2.38 times) faster than conducting the same task with the keypad and TDS, respectively. With increasing familiarity with the task using both devices over the five sessions, throughput improved significantly (keypad: $P < 0.001$, TDS: $P < 0.001$, Fig. 2A). Throughput using the keypad increased until the fourth session ($\Delta_{1-2} = 0.38$ b/s, $P < 0.001$, $\Delta_{2-3} = 0.13$ b/s, $P = 0.007$, and $\Delta_{3-4} = 0.14$ b/s, $P = 0.004$) and reached 2.39 ± 0.66 b/s in the fifth session. The throughput using the TDS in the first session was about half that of the keypad, but it increased significantly from the first to the third session ($\Delta_{1-2} = 0.30$ b/s, $P < 0.001$ and $\Delta_{2-3} = 0.19$ b/s, $P = 0.001$) because of increased

familiarity with the device. It did not saturate, but continued to increase at a steep rate up to the fifth session ($\mu_{4-5} = 0.09$ b/s, $P = 0.011$), reaching 1.42 ± 0.47 b/s.

Instead of using a keypad and the TDS, participants with tetraplegia used a SnP device and the TDS to complete the center-out tapping task. Figure 2A shows that participants with tetraplegia achieved 0.29 ± 0.21 b/s of throughput using the TDS during the first session, and this became faster over six sessions to reach 0.72 ± 0.41 b/s. The steepest learning curve occurred between the first and second sessions ($\mu_{1-2} = 0.18$ b/s, $P = 0.010$). The throughput with the SnP device was 0.29 ± 0.19 b/s during the first session, similar to that using the TDS. It became faster from the first to the second session ($\mu_{1-2} = 0.09$ b/s, $P = 0.010$). It was saturated by the fourth session, effectively remaining at 0.50 ± 0.19 b/s during the sixth session, 0.22 b/s slower than the TDS.

The mouse error rate was $3.86 \pm 4.77\%$, one third of the error rate for the keypad and one tenth of that for the TDS during the first session (Fig. 2B). The error rate in selecting targets using the TDS was persistently higher than when using the keypad, but largely decreased over five sessions (keypad: $P < 0.001$, TDS: $P < 0.001$, Fig. 2B). The error rate reduction was less for the keypad than for the TDS ($F = 24.85$, $P < 0.001$). Participants with tetraplegia had an error rate of $64.68 \pm 25.25\%$ and $46.40 \pm 27.38\%$ using the TDS and SnP devices, respectively, during the first session (Fig. 2B). The error rates lessened over six sessions, reaching $41.48 \pm 26.04\%$ with the TDS and $19.51 \pm 15.21\%$ with the SnP. The learning patterns for TDS and SnP were not statistically different ($F = 0.222$, $P = 0.953$), and a comparison of the learning effect using the TDS between the non-SCI and SCI participants showed a similar pattern ($F = 0.215$, $P = 0.646$) over five sessions.

Movement time is defined as the elapsed time between the initiation and termination of the cursor movement in each trial, excluding the target selection time (Fig. 2C). Using the mouse, able-bodied participants were able to select targets within 0.71 ± 0.09 s. It took 1.29 ± 0.27 s using the keypad during the first session (Fig. 2C), but this time significantly shortened between the first and second sessions ($\mu_{1-2} = 0.16$ s, $P < 0.001$) and from the third to the fourth session ($\mu_{3-4} = 0.03$ s, $P = 0.028$). Using the TDS, the cursor movement took 2.07 ± 0.83 s in the first session, and dropped from the first to the second and third sessions ($\mu_{1-2} = 0.32$ s, $P < 0.001$, and $\mu_{2-3} = 0.18$ s, $P = 0.001$). The learning pattern of the TDS movement time was different from that of the keypad ($F = 15.415$, $P < 0.001$), yet both were improved over five sessions (keypad: $P < 0.001$, TDS: $P < 0.001$). It took participants with SCI 4.00 ± 1.41 s and 4.48 ± 1.08 s to reach targets with the TDS and SnP during the first session, respectively (Fig. 2C). These times were significantly reduced over the six sessions (TDS: $\mu_{1-6} = 1.25$ s, $P < 0.001$, and SnP: $\mu_{1-6} = 0.69$ s, $P < 0.001$) but still remained higher than those of the able-bodied group.

The regression models for Fitts' law (47, 48) with the movement time versus index of difficulty (ID) are introduced in Eq. 3 in Materials and Methods, and their empirical models are illustrated in fig. S1. The estimated parameter set of intercept and slope (a , b) for the able-bodied participants using the mouse in the first session was (0.40, 0.13) [which was similar to the results reported in (10)]. In the fifth session, the participants' performances using keypad and TDS fit in the regression models with (a , b) = (-0.28, 0.56) and (0.49,

0.52), respectively (fig. S1A). These parameters show that the mouse, the reference device, was the most efficient device with the smallest (a , b) as expected (48). The (a , b) set for participants with tetraplegia using TDS and SnP in the sixth session were (2.10, 0.59) and (2.18, 0.89), respectively (fig. S1B). Although the intercept parameter, a , which indicates the pure reaction time without movement to a target, was larger for tetraplegic participants using TDS, their throughputs were very close to those of the able-bodied participants and 1.5 times higher than those obtained using the SnP device.

Computer access: Information transfer rate

The information transfer rate (ITR) quantifies how quickly and accurately a command is issued following a visual or auditory cue. It is a widely used measure to evaluate and compare BCIs (13, 49). The percentage of correctly completed commands (CCC%), the number of commands that are simultaneously available to the user (N), and the time interval (T) within which a command needs to be issued are used to calculate the ITR in bits per minute. Here, there were six commands available for the TDS and four commands for the SnP. The time intervals for the TDS were 1.0, 0.7, and 0.5 s, and for the SnP were 1.2, 1.0, and 0.7 s. Most participants with SCI could not operate the SnP at 0.5-s intervals. Figure 3 compares the results for 9 of 23 able-bodied subjects using TDS with those of 11 participants with SCI using TDS and SnP. The results, including session-by-session statistical analysis, are summarized in table S1.

Able-bodied participants achieved $\text{CCC}\% = 93.5 \pm 6.47\%$ during the first session for the longest period ($T = 1.0$ s), which dropped for shorter T 's, as expected ($T = 0.7$ s: $93.2 \pm 6.5\%$, $T = 0.5$ s: $91.2 \pm 8.9\%$). This measure increased over time ($T = 1.0$ s: $P = 0.003$; $T = 0.7$ s: $P = 0.001$; $T = 0.5$ s: $P = 0.046$) and reached $T = 1.0$ s: $96.9 \pm 4.6\%$, $T = 0.7$ s: $96.9 \pm 4.6\%$, and $T = 0.5$ s: $96.9 \pm 4.6\%$ during the fifth session (Fig. 3A). The greatest increase occurred between the first and second sessions ($T = 1.0$ s: $P = 0.002$, $T = 0.7$ s: $P = 0.006$, $T = 0.5$ s: $P = 0.021$). These rates correspond to an ITR of 249.0 ± 58.1 bits/min during the first session and 283.1 ± 37.5 bits/min in the last session, both achieved at $T = 0.5$ s (Fig. 3D).

For those with SCI, the first session resulted in an average TDS $\text{CCC}\% = 75.1 \pm 11.0\%$ during the longest time ($T = 1.0$ s) (Fig. 3B). This increased significantly over subsequent sessions ($P < 0.001$). The other times showed similar or lower $\text{CCC}\%$ ($T = 0.7$ s: $77.2 \pm 10.0\%$, $T = 0.5$ s: $69.7 \pm 12.5\%$) during the first session. By the sixth session, $\text{CCC}\%$ had increased across all times ($93.0 \pm 7.3\%$ with $T = 1.0$ s; $89.6 \pm 11.5\%$ with $T = 0.7$ s; and $78.3 \pm 14.0\%$ with $T = 0.5$ s). The highest ITR during the first session was 121.7 ± 51.0 bits/min when $T = 0.5$ s. It increased significantly over all subsequent sessions for each time ($T = 1.0$ s: $P < 0.001$; $T = 0.7$ s: $P < 0.001$; $T = 0.5$ s: $P = 0.001$), reaching 171.6 ± 77.8 bits/min in the last session (Fig. 3E).

A comparison of the ITR results between TDS and SnP (Fig. 3, E and F) is interesting because 7 of 11 participants with SCI were already using the SnP daily to control their powered wheelchairs. In the first session, $\text{CCC}\% = 59.2 \pm 23.3\%$ was recorded at $T = 1.2$ s and dropped during shorter periods to $38.9 \pm 28.1\%$ at $T = 0.7$ s (Fig. 3C). The results rose over time with a significant increase between the second and third sessions for $T = 1.2$ s ($P =$

0.006) and $T = 1.0$ s ($P = 0.004$). The ITR, 27.3 ± 24.4 bits/min with $T = 1.2$ s during the first session, increased over six sessions, reaching 56.4 ± 50.1 bits/min at $T = 1.0$ s. This was less than a third of that of the same group of individuals using the TDS (Fig. 3F). Thus, the TDS may offer greater bandwidth for control purposes compared to the SnP.

Computer access: Maze navigation

The maze navigation task involved two-dimensional cursor movement on a computer screen over a path with a randomly selected pattern consisting of horizontal and vertical segments that became gradually narrower from start to finish (43). Speed and accuracy were measured by completion time and the total area traversed outside of the path [measured by sum of deviations (SoD)], respectively. The actual cursor movements for one of the participants with SCI using TDS are shown with a blue trace over the yellow path in Fig. 4A (first session) and Fig. 4B (sixth session). The results and statistical analysis are summarized in table S2.

Figure 4C shows the average completion time for the able-bodied participants from the first session at 19.2 ± 1.2 s and 24.6 ± 8.7 s to the fifth session at 13.0 ± 2.4 s and 13.6 ± 3.1 s, using keypad and TDS, respectively. The learning trends showed significant shortening of the completion times, particularly for TDS ($P < 0.001$). The 5.40-s difference in the first session was eliminated by session 5. In terms of accuracy (Fig. 4D), the participants did significantly better with the keypad (SoD = 2.72 ± 4.17) compared to TDS (SoD = 17.42 ± 16.64) during the first session. However, maze navigation skills improved more rapidly with the TDS than the keypad, ending at 3.03 ± 3.03 versus 0.78 ± 1.20 in the fifth session, respectively ($P < 0.001$). The most significant reduction occurred between the first and second sessions ($t_{1-2} = 10.89$, $P < 0.001$). Ten of 23 able-bodied subjects were able to complete this task with TDS at the same level of accuracy as the keypad.

During the first session, participants with SCI completed the maze navigation task with the TDS in 30.1 ± 9.2 s versus 49.6 ± 27.0 s with the SnP. The completion time consistently declined using the TDS, eventually reaching 17.76 ± 4.64 s during the sixth session ($t_{1-2} = 4.31$ s, $P_{1-2} = 0.023$ and $t_{2-3} = 2.96$ s, $P_{2-3} = 0.038$). With the SnP, the completion time dropped significantly from the first to the second session ($t_{1-2} = 1.8$ s, $P = 0.006$); it was saturated from the fourth session, remaining at 31.7 ± 9.7 s during the last session. SoD = 29.47 ± 18.07 using the TDS during the first session and was less than that using the SnP (SoD = 27.49 ± 19.93). Performance with both devices improved over time ($P < 0.001$); however, participants with SCI did better with the TDS in the sixth session (SoD = 8.68 ± 5.71) compared to SnP (SoD = 10.87 ± 8.76).

Wheelchair access: Driving a powered wheelchair

Individuals with tetraplegia depend on electric-powered wheelchairs to move around, and it is imperative for a universal assistive technology to provide smooth and safe driving of powered wheelchairs (50). The experimental setup for driving electric-powered wheelchairs is shown in fig. S3, A to C. The powered wheelchair control strategy was set to the latched mode, which is commonly used by individuals with SCI. The 50-m-long obstacle course included 13 turns and 24 obstacles, requiring the demonstration of navigational skills such

as making a U turn, backing up, and negotiating a loop. The results and statistical analysis are summarized in table S2.

Able-bodied individuals rode through the obstacle course using the TDS in 260.7 ± 10.4 s during the first session. By the fifth session, the average completion time had shortened to 207.7 ± 8.2 s ($P < 0.001$, Fig. 5A). This performance showed the greatest change between the first and second sessions ($t_{1-2} = 39.6$ s, $P < 0.001$). The number of navigation errors (sum of the number of collisions and out-of-track incidents) was 5.5 ± 5.1 during the first session, reaching a low of 2.1 ± 2.5 during the fifth session, again with a significant reduction between the first and second sessions ($t_{1-2} = 0.94$, $P = 0.001$).

On average, it took participants with tetraplegia 253.2 ± 60.9 s and 179.9 ± 24.1 s to complete the obstacle course using the TDS during the first and sixth sessions, respectively ($P < 0.001$, Fig. 5A). Over the same period, the number of navigation errors dropped from 9.5 ± 6.6 to 1.7 ± 2.0 using the TDS (Fig. 5B). Before the study, 6 of 11 SCI participants regularly used SnP for driving their powered wheelchairs. Their initial completion times (239.6 ± 72.3 s) using this device were shorter with fewer errors (4.5 ± 3.1) than those for the rest of the group. Overall, performance with the SnP was saturated from the third session, eventually remaining at a completion time of 182.4 ± 22.3 s with 2.6 ± 2.2 errors during the sixth session. However, comparing the navigation performance of the SCI participants during the fifth and sixth sessions showed they did better overall with the TDS than the SnP.

DISCUSSION

The TDS is an assistive technology that is designed to supplant upper extremity function with tongue motion (43). The goal was for the TDS to provide intuitive, efficient, and accurate computer access and control of a powered wheelchair. These are two key enablers for people with severe disabilities: potentially increasing independence in mobility and access to computers, smartphones, and automated environment control (for example, lights, television, room temperature, and doors). Able-bodied participants were included in the experimental design as an independent source of data as well as a control group for the target end-user population. Here, all 23 able-bodied participants and the 11 participants with tetraplegia completed the protocol and were able to use the TDS after 30 min of training. There was a rapid learning curve for every task, which, in most cases, was the steepest between the first and second sessions with continued learning occurring during the last session. The learning trends suggested that users' performance with the TDS would continue to improve with additional experience and continuous usage. The able-bodied individuals were recruited from a young adult population who were familiar with the use of computers, mice, and keyboards. However, they were naïve with respect to TDS. This may explain the superior results using keypad versus TDS over the 5-week period (Figs. 2 and 3). The subjects with tetraplegia were generally older and not as familiar with computers, which may have influenced their computer access performance using the TDS.

In comparison to previous studies with a similar setup for center-out tapping (table S3), the throughput of able-bodied participants using a mouse was slightly higher than reported here (18, 53), but in the same range considering the SD (3.66 ± 0.59). Keypad results (2.4 ± 0.6

b/s) were better for able-bodied participants than when they used regular video game controllers (51), and TDS throughput was considerably better than using head orientation or EMG commands (18). Overall, participants with tetraplegia performed better on powered wheelchair driving tasks than able-bodied participants did, probably because of their extensive previous experience with driving powered wheelchairs. As expected, the able-bodied computer-savvy participants generally did better with the computer access tasks, whereas individuals with tetraplegia performed better driving powered wheelchairs. These findings highlight the influence of previous experience and familiarity with target devices on task execution. Considering the upward learning curves for most of the performance measures during these 5- or 6-week trials, it is likely that the gap between the performances of these two cohorts would narrow or even disappear after extended TDS usage.

A limitation of this study is that the target TDS end-user population and able-bodied controls were not matched in terms of age and previous experience with computers and powered wheelchairs. Therefore, differences in performance can be partially attributed to previous experience rather than solely to the usability of the devices under test. Also, trials with able-bodied participants were conducted ahead of those with disabilities rather than simultaneously, but did use the same setup and research personnel. Other limitations include the heterogeneity of the SCI group, which varied in the amount of time since the original SCI and also in the neurological level of the injury. There are marked functional differences between individuals with cervical SCIs because each preserved segment of the spinal cord contributes additional motor and sensory capacity. Severe SCI at the highest cervical levels results in the most loss of motor and sensory functions, leading to the most profound functional limitations. Time since injury translates into experience driving powered wheelchairs and using assistive technologies. Additionally, previous experience of researchers with the TDS as well as access to technical support was different between the sites in Atlanta and Chicago. Researchers at Shepherd Center in Atlanta had direct access to developers of the TDS, and some of them had participated in previous TDS studies. Researchers at the Rehabilitation Institute of Chicago had no previous experience with the TDS and only remote access to the development team. Therefore, instructors' experience with the system may have influenced outcomes.

It is difficult to compare the results of the driving tasks using TDS with those reported for other assistive technologies. There were substantial differences in the experimental setup, particularly in the complex obstacle course and details of the tasks. To create a more realistic environment, this study included simulated emergency stops initiated by an alarm that sounded at random during each driving session. Moreover, occasionally, the researcher activated a handheld emergency stop switch when there was a risk of hitting a hard object, such as a wall or column. These emergency stops were included in the completion time. Despite these limitations, in the final sessions, the able-bodied participants drove the powered wheelchair at an average speed of 15.9 m/min, whereas those with tetraplegia achieved an average speed of 17.4 and 16.7 m/min with the TDS and SnP, respectively.

Although six participants with tetraplegia were previous daily SnP users, their control was better with the TDS than with the SnP by session 5. Overall performance also improved with the SnP in terms of completion time, but this improvement was mainly attributable to the

five participants who were regular joystick users (Fig. 5C). Dividing the participants with tetraplegia into two groups, the experienced SnP users and those who were new to the SnP (Fig. 5D) revealed that the TDS was easier to use than SnP in terms of both speed and accuracy.

The TDS headsets used in this study and shown in Fig. 1A were the experimental versions built around adjustable headgear. Hence, they are not representative of the anticipated appearance of this assistive technology when it will be offered to potential end-users. TDS electronics, mechanical design, and appearance continue to evolve. The ergonomic design of the latest TDS headset can be found in (52). Moreover, an intraoral version of the TDS (iTDS) is under development, with the first prototype presented in (53).

A combination of TDS flexibility and inherent characteristics of the human tongue enabled individuals with severe motor impairments to access computers and drive wheelchairs at speeds that were faster than traditional assistive technologies such as SnP, but with comparable accuracy.

MATERIALS AND METHODS

The external TDS headset had four 3-axial magnetic sensors, two on each side held near the wearer's cheeks (Fig. 1A). Signals were sampled at 50 Hz and sent wirelessly to a PC or smartphone by a control unit on the top of the headset (Fig. 1A). During the course of the trial, participants were all wearing magnetic tongue barbells. By touching six user-defined positions in their mouths, subjects were able to change the magnetic field around their mouths, which resulted in the associated TDS commands being detected and executed by the computer or smartphone.

To evaluate computer input devices and assistive technologies for speed and accuracy, tasks based on Fitts' law (for example, center-out tapping) (movie S1) and ITR measurement (movie S2) were defined and conducted by able-bodied participants using mouse, keypad, and TDS, and by tetraplegic participants using SnP and TDS (Fig. 1C). The maze navigation task (movie S3) was designed to compare the TDS efficiency in navigation with that of the other devices. Finally, a powered wheelchair driving task was conducted on a custom-designed 50-m obstacle course to verify the TDS efficacy in controlling a powered wheelchair in comparison with SnP (movie S4).

Tongue piercing and experimental schedule

Tongue piercings were conducted in medical facilities at two sites (Shepherd Center in Atlanta and on Northwestern University Medical Campus in Chicago), the details of which are reported in (44). Before tongue piercing, all individuals were screened using glued-on magnetic tracers to ensure ability to use the TDS. The piercing procedure for the participants with disability was similar to that for the able-bodied participants, except that the recruited participants with SCI stayed in the hospital for three nights to monitor for side effects, for example, tongue swelling, and in case there was an emergency (54). Later, this stay was reduced to one night. A long tongue barbell was initially inserted to allow for the anticipated tongue swelling. This was exchanged for a shorter magnetic barbell, at the fourth week post-

piercing visit. This barbell was custom-made with an 8-mm × 3.5-mm ellipsoid-shaped titanium ball containing a 4.8-mm-diameter and 1.5-mm-thick rare earth magnet (K&J Magnetics) welded onto one end of a 12-gauge (2.05-mm) titanium post with a length of 12 to 21 mm (Anatometal) (Fig. 1D, inset). A subset of able-bodied participants, who already had tongue piercings, simply exchanged their existing tongue jewelry for a magnetic barbell at the beginning of the first session, and kept it over the course of the trial.

After the exchange, able-bodied participants were scheduled for five consecutive TDS trials with intervals ranging from 2 to 10 days. Each testing session took about 2.5 hours, including TDS calibration, training, computer access, and powered wheelchair navigation tasks. Participants with tetraplegia needed more time for preparation. Thus, the testing sessions were divided into computer access and powered wheelchair navigation within a week, over 6 weeks.

Center-out tapping task based on Fitts' law

Throughput was the main performance metric used to evaluate computer access. It is a measure of information delivery to the computer from the user via each input device. Throughput is defined as the ratio between the targets' index of difficulty (ID) and the movement time (MT) to reach them (47, 48),

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

We adopted the effective index of difficulty (ID_e), defined on the basis of Shannon's formula in Eq. 2, to accommodate for spatial variability observed in the responses (45, 47),

$$ID_e = \log_2 \left(\frac{D_e}{W_e} + 1 \right) \quad (2)$$

Effective distance (D_e) represents the mean of actual distance along the task axis, and effective width (W_e) is $4.133 \times \text{SD}$ of x , which is the distance between the location of the user's selected position and the center of the target (45–47). The MT and ID can also be estimated using a regression model (48),

$$\text{MT} = a + bID_e \quad (3)$$

The regression models for the able-bodied and tetraplegic participants using mouse, keypad, TDS, and SnP are summarized in fig. S1, A and B.

There were a total of 48 targets with three different widths, $W = 30, 61,$ and 122 pixels (fig. S2A), which randomly appeared, one at a time, along the cardinal and ordinal directions at three distances, $D = 61, 122,$ and 244 pixels, from the center of a 610×610 -pixel screen on a 22-inch LCD monitor, shown in Fig. 1D (45). The targets' ID_e 's are summarized in table S4. Every trial was repeated three times after an initial practice round. In each round, able-bodied and tetraplegic participants were asked to move the cursor as fast and as close to the

center of 48 of 48 and 16 of 48 targets, respectively. For mouse, keypad, and TDS, participants clicked the left mouse button, pressed the selection key, and issued a selection command. With the SnP, they dwelled on the target for 0.5 s to select it because SnP only offers four directional commands.

ITR task

ITR is a measure of how quickly and accurately a command is issued within a designated period using an input device. The ITR task measures are the CCC% and ITR in bits per minute. To calculate the ITR, we used Wolpaw's formula,

$$\text{ITR} = \frac{1}{T} \left(\log_2 N + P \log_2 P + (1 - P) \log_2 \frac{1 - P}{N - 1} \right) \quad (4)$$

in which T is the time interval to issue the requested command (TDS: 1.0, 0.7, and 0.5 s, and SnP: 1.2, 1.0, and 0.7 s), N is the number of commands (TDS: 6 and SnP: 4), and P is the CCC% (55). Figure S2, B and C, shows the ITR task graphical user interfaces for TDS and SnP, respectively. Participants kept their tongues stationary in the resting position for a 1-s "waiting time" while the round cursor in the center of the screen was red and the randomly requested command was also red. When the cursor in the center turned green (visual cue), participants were expected to issue the requested command as fast and as accurately as possible by moving the tongue to the command's predefined position. Participants were able to correct their tongue positions during T while receiving visual feedback on the selected command, toward which the cursor started moving. At the end of the allowed interval, the cursor turned yellow and participants were expected to return the tongue to the resting position in preparation for the next attempt. If the tongue moved during the waiting period, an alarm sounded and invalidated that attempt. A total of 20 commands were issued in each round for the able-bodied participants with TDS. For the participants with tetraplegia, 18 and 12 commands were issued with TDS and SnP, respectively.

Maze navigation task

Participants were instructed to use four directional commands (left, right, up, and down) to move the mouse cursor as fast and accurately as possible on a maze consisting of 12 narrowing segments (width: 38, 30, 23, and 15 pixels) for a total length of 1815 pixels. One of eight maze patterns was randomly selected in each round (for example, fig. S2D). The performance measures were the completion time from start to end and the SoD from the track. SoD was calculated as the sum of all areas between the actual trajectory of the cursor when it was out of the track and the closest edge of the track divided by 1000 pixels² (46).

Powered wheelchair driving task

Participants navigated a center-wheel drive powered wheelchair (Quantum 6000, Pride Mobility) using TDS and SnP in latched-speed driving mode through an obstacle course, the floor plan of which is shown in fig. S3, A and B. Figure S3C shows a participant with tetraplegia sitting in a powered wheelchair and wearing a TDS headset. Figure S3D depicts the graphical user interface running on an iPhone that was mounted below the powered wheelchair display, above the right armrest, in front of the user. This graphical user interface

informs the TDS user about any issued command as well as the status of the linear speed and rotation control vectors (44). A head-operated mechanical switch was mounted on the headrest to shut down the powered wheelchair in case of an emergency. As a safety measure, an operator, holding an emergency stop switch, walked next to the powered wheelchair. There were five linear speed levels: forward-1 (0.95 km/hour), forward-2 (1.25 km/hour), forward-3 (1.6 km/hour), stop (0 km/hour), and backward (-0.95 km/hour). Issuing the forward or backward commands changed the linear speed vector from one level to the next. When the powered wheelchair speed was latched “on,” participants could continue driving the powered wheelchair even if the tongue returned to the resting position, or they could steer the powered wheelchair by issuing left or right commands. The speed of rotation was constant at 27°/s. The researcher recorded completion times and the number of navigation errors, which included collisions with obstacles as well as powered wheelchair wheels moving out of track. When an alarm sounded at a random time during each round, users were instructed to stop the powered wheelchair immediately by pressing the head-activated emergency stop. This time was also included in the completion time.

Able-bodied participants drove the powered wheelchair using only the TDS, whereas the participants with tetraplegia used both the TDS and SnP. Able-bodied participants operated the powered wheelchair with a laptop placed on a lap tray in front of them (46). While driving, the laptop lid was closed in order not to block the user’s field of view. For participants with tetraplegia, the sensor signal processing algorithm was running on an iPod (Apple), which was mounted on the armrest (44). Therefore, participants could receive visual feedback from the graphical user interface (fig. S3, C and D).

Human subjects

This study was conducted in three phases and at four locations. By the end, 23 able-bodied volunteers (aged 18 to 32 years, mean age 23.5 ± 3.9 years; 15 females) and 11 volunteers with tetraplegia (aged 27 to 56 years, mean age 38.6 ± 9.8 years; 7 at Shepherd Center in Atlanta, 4 at the Rehabilitation Institute of Chicago; 2 females) completed the study by participating for 5 ± 1 and 6 ± 2 consecutive weeks. All participants provided written informed consent to procedures approved by the Institutional Review Boards of record for Georgia Institute of Technology and Shepherd Center in Atlanta, Northwestern University Medical Center in Chicago, and the Rehabilitation Institute of Chicago.

In the first phase, 16 able-bodied volunteers, who had already been wearing tongue jewelry for at least 3 months, were recruited. Two individuals did not complete this phase, because they were lost to follow-up. Fourteen participants (aged 18 to 32 years, mean age 24.1 ± 3.9 years; 9 in Atlanta, 5 in Chicago; 10 females) completed five consecutive sessions, each of which included both computer access and powered wheelchair navigation tasks. In phase 2, 24 able-bodied subjects who wished to receive a tongue piercing and participate in the study were recruited. Nine participants (aged 19 to 29 years, mean age 22.6 ± 4.0 years; 5 in Atlanta, 4 in Chicago; 5 females) completed the trials from the initial TDS screening sessions, through the tongue-piercing procedure, the exchange for a magnetic tongue barbell to the end of the fifth session. Thirteen individuals dropped out soon after the tongue-piercing procedure. Five expressed dissatisfaction with the location of the tongue-piercing

tract, two stated that the piercing tract closed because the barbell was lost, two simply did not return after the tongue-piercing procedure, and three were excluded during the initial screening because of a short anteriorly placed tongue frenulum (ankyloglossia) limiting tongue motion for the functions of the TDS. Two further individuals dropped out later during this phase when they failed to show for scheduled visits. In the third phase, 21 participants with tetraplegia were recruited, and 11 completed the study. Two stated that they had lost interest in continuing the trial, three had scheduling problems related to transportation and caregiver issues, two were disqualified (one because of cognitive problems and the other because of impaired tongue control related to cerebral palsy), one had the barbell fall out after piercing, and two had medical issues unrelated to the study. None of the participants reported any problems with the magnetic barbell attracting metal eating implements in the mouth. This is because the magnetic tracer was very small and separated from any metal object in the mouth by 1 to 2 mm of titanium casing. Detailed information about the participants with disability who completed the trial is summarized in table S5.

Statistical analysis

Outlier data points were eliminated when the points were outside the interquartile range (56). Repeated-measures ANOVA was used to evaluate the learning effects related to using various devices for computer access and powered wheelchair navigation. Session-by-session effects were analyzed using least significant difference pairwise comparisons to interpret the significance of changes. Data sets within each group were individually tested, and factors with significant effect on the learning curve were analyzed. Analysis was done with IBM SPSS Statistics (v.21) software.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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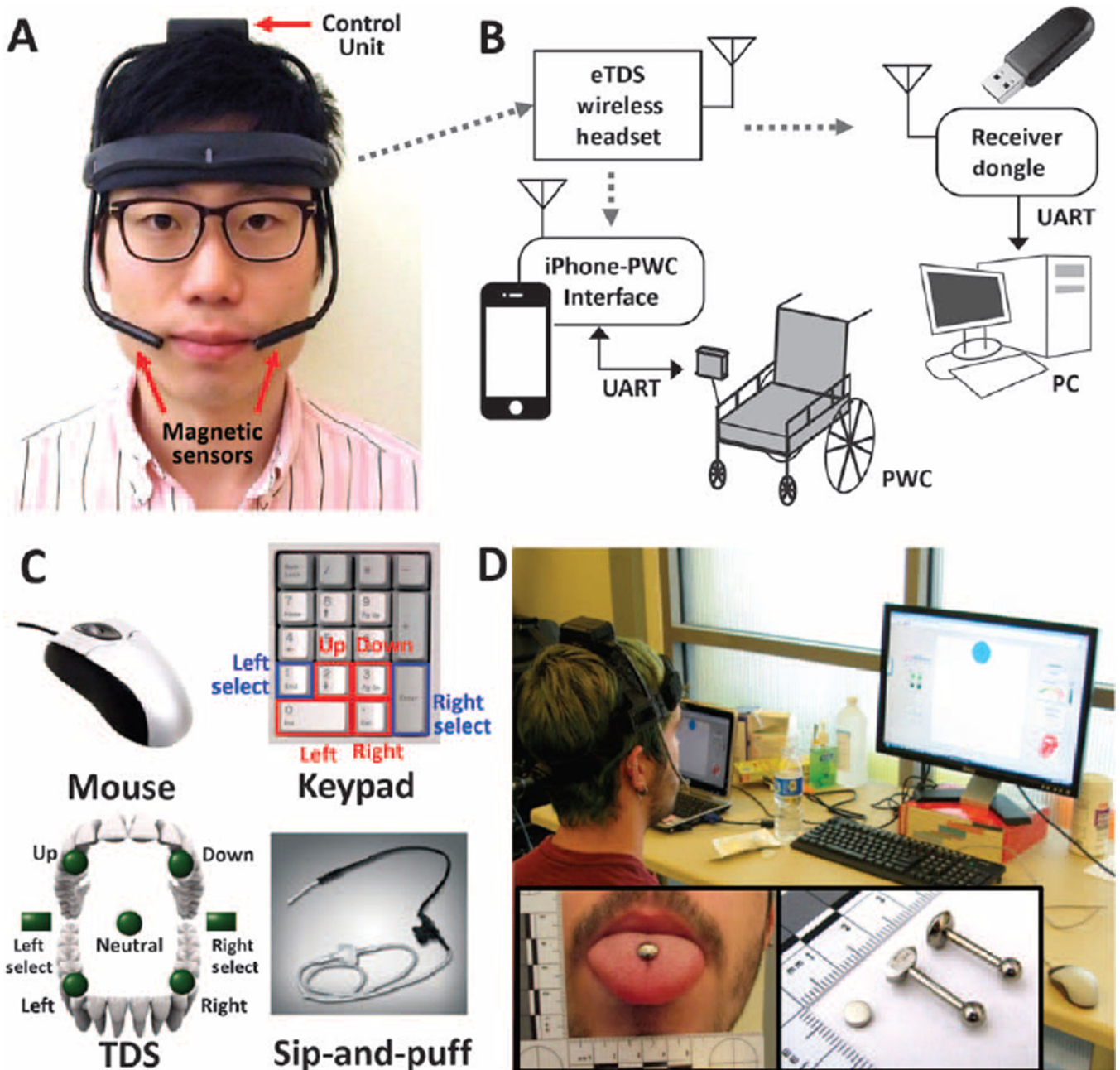


Fig. 1. TDS headset and experimental setup

(A) One of the authors wearing the TDS headset that has four magnetic sensors, two on each side, held near the cheeks. (B) System-level diagram of the TDS. The TDS headset collects data from four magnetic sensors and transmits it to a receiver USB dongle for PC or the iPhone-wheelchair interface for an electric-powered wheelchair on the basis of the universal asynchronous receiver/transmitter (UART) protocol (44). (C) Four control devices were used for this study: a computer mouse, a keypad, the TDS, and the SnP device. (D) Test setup for computer access, showing an able-bodied participant performing the center-out tapping task. The subject wore a magnetic tongue barbell made of titanium, which contained a small disk-shaped magnetic tracer (4.8 mm diameter \times 1.5 mm thick).

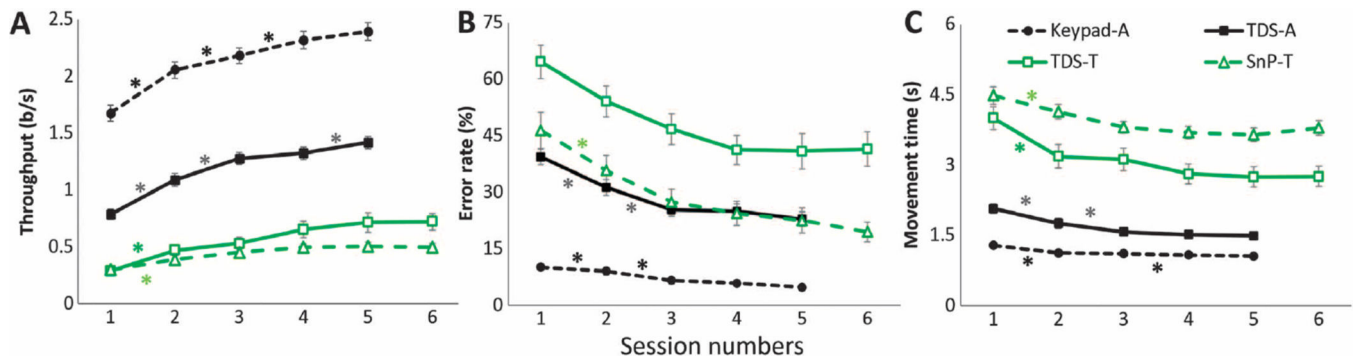


Fig. 2. The center-out tapping task for able-bodied versus tetraplegic participants

The center-out tapping task measures a combination of speed and accuracy by asking the subject to move the cursor from the center of the screen and then select a randomly appearing target by clicking as close to its center as possible using a keypad versus TDS or a TDS versus SnP for able-bodied and tetraplegic participants, respectively. (A) Average throughput, which measures the information delivered to the computer through the input device, is defined as the ratio of the index of difficulty of targets and the movement time to reach them in terms of bits per second. (B) Error rate (%) is the ratio of the number of targets that were clicked outside of their boundaries and the total number of targets. (C) Movement time is defined as the elapsed time between the initiation and termination of the cursor movement for the center-out tapping task Able-bodied (A) and tetraplegic (T) participants completed five and six sessions, respectively. Error bars represent \pm SEM. * $P < 0.05$, repeated-measures analysis of variance (ANOVA) and least significant difference pairwise comparisons for session-by-session effects.

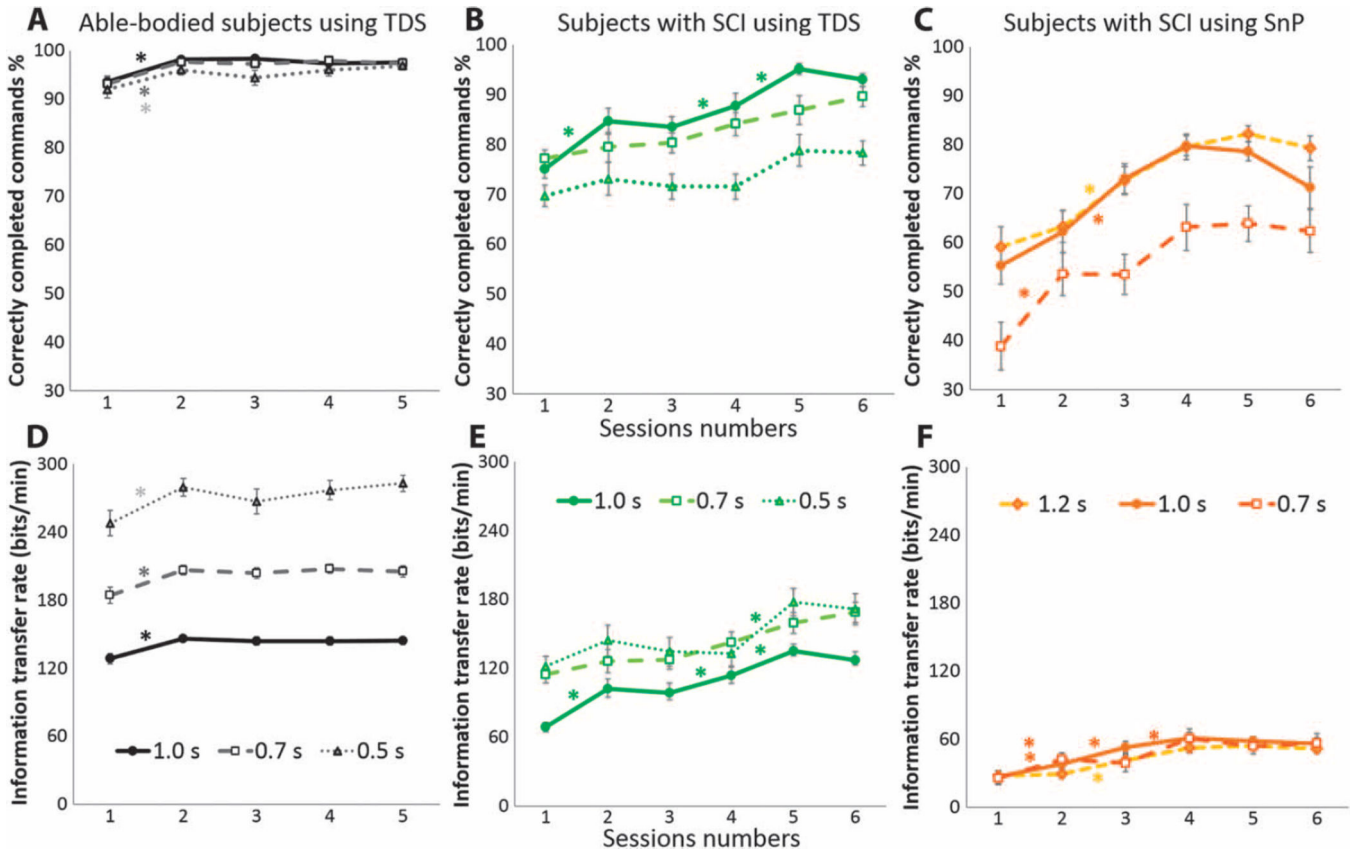


Fig. 3. ITR for able-bodied versus tetraplegic participants

Shown are CCC% and ITR, which quantifies how quickly and accurately a command is issued within a given period. (A) CCC% and (D) ITR for 9 of 23 able-bodied participants using TDS. (B) CCC% and (E) ITR for participants with tetraplegia using TDS. (C) CCC% and (F) ITR for subjects with tetraplegia using SnP. Error bars represent \pm SEM. $*P < 0.05$, repeated-measures ANOVA and least significant difference pairwise comparisons for session-by-session effects.

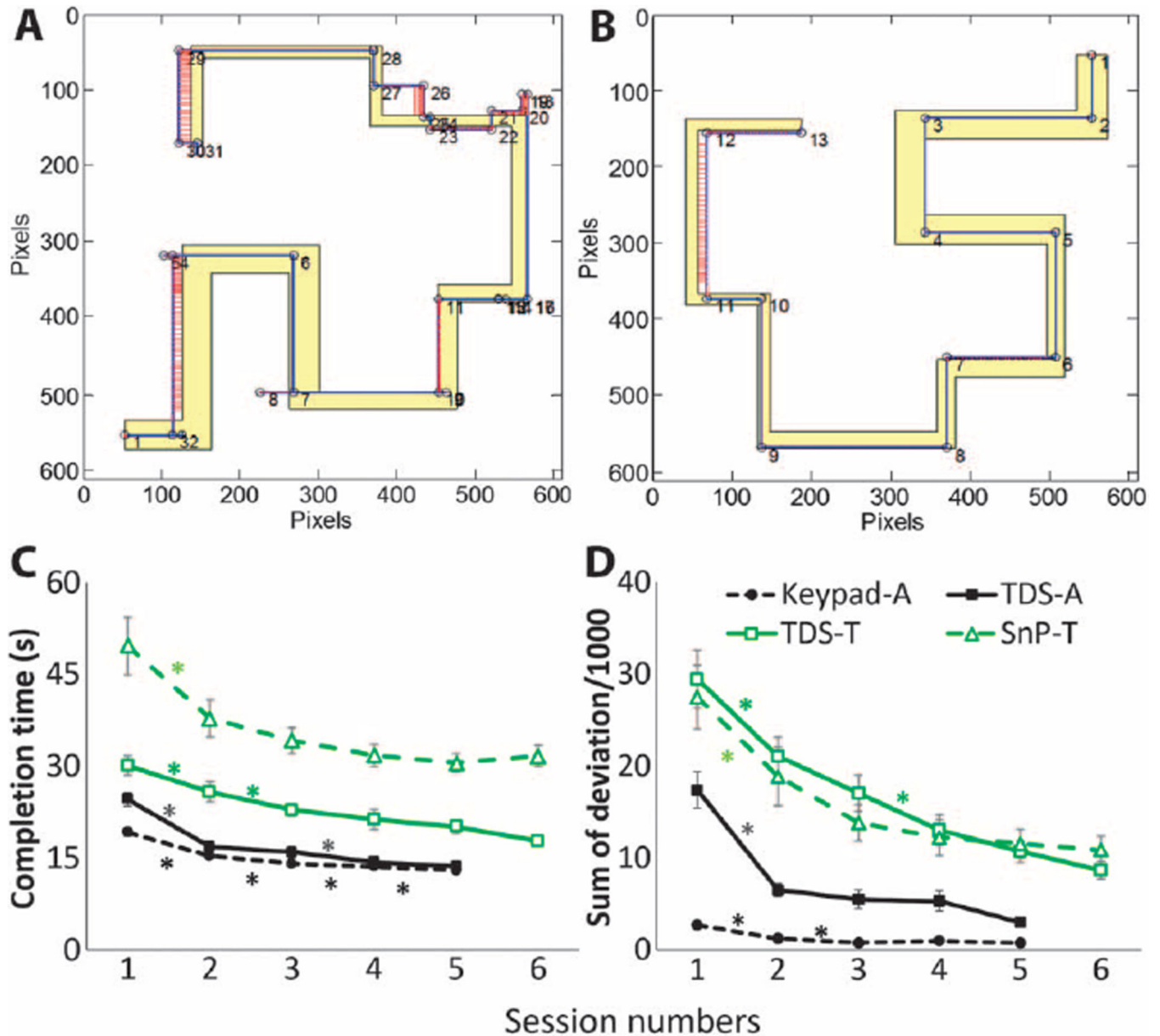


Fig. 4. Maze navigation task for able-bodied versus tetraplegic participants

Shown are the results for the maze navigation task with keypad and TDS for able-bodied participants versus TDS and SnP for tetraplegic participants. (A) Maze navigation result of one of the individuals with tetraplegia in the first session. The yellow path is the maze, randomly selected out of eight patterns; the blue lines indicate the actual cursor trajectory; and the red-dashed area represents the SoD. (B) A result from the same individual in the sixth session showing less deviation from the path than observed in the first session. (C) Average completion time for maze navigation from the start to the end. (D) Average SoDs from the yellow path per 1000 pixels² (SoD). Error bars represent \pm SEM. * $P < 0.05$, repeated-measures ANOVA and least significant difference pairwise comparisons for session-by-session effects.

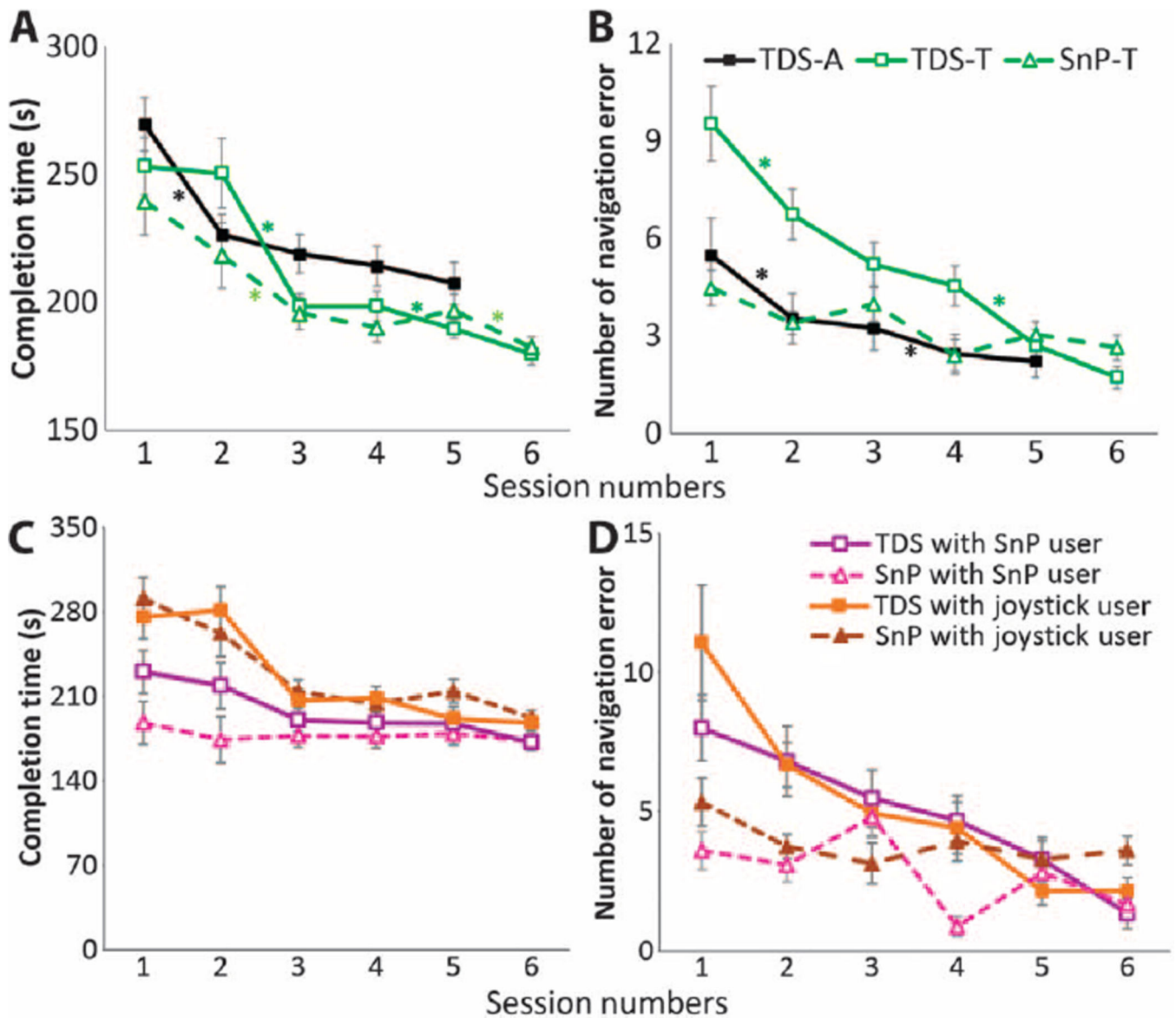


Fig. 5. Powered wheelchair driving task for able-bodied versus tetraplegic participants
 Shown are the task results for TDS use by able-bodied participants versus TDS and SnP use by tetraplegic participants. (A) Average completion time for an obstacle course from the start to the end, including the time for the simulated emergency stops. (B) Average number of navigation errors is the total number of collisions and out-of-track incidents. (C) Average completion time for the powered wheelchair driving task for tetraplegic participants using TDS or SnP compared to tetraplegic participants who had used the SnP previously or who had not (that is, had only used a joystick device with their personal wheelchair). (D) Average number of navigation errors by participants with tetraplegia using the TDS or SnP compared with the SnP and joystick users. Error bars represent \pm SEM. * $P < 0.05$, repeated-measures ANOVA and least significant difference pairwise comparisons for session-by-session effects.