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Tongue control of a five-DOF upper-limb exoskeleton rehabilitates drinking and eating for individuals with severe disabilities

Mostafa Mohammadi [a,*], Hendrik Knoche [b], Mikkel Thøgersen [a], Stefan Hein Bengtson [b], Frederik Victor Kobbelgaard [c], Muhammad Ahsan Gull [d], Bo Bentsen [a], Kåre Eg Severinsen [e], Benjamin Yamin Ali Khan [e], Lotte N.S. Andreasen Struijk [a]

[a] Center for Rehabilitation Robotics, Department of Health Science and Technology, Aalborg University, Aalborg, Denmark
[b] Department of Architecture, Design, and Media Technology, Aalborg University, Aalborg, Denmark
[c] Department of Planning, Aalborg University, Aalborg, Denmark
[d] Department of Materials and Production, Aalborg University, Aalborg, Denmark
[e] Department of Neurology, Aarhus University Hospital, Aarhus, Denmark

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ABSTRACT

Upper limb exoskeletons (ULEs) are robotic devices that can mobilize a severely disabled individual's arm and help the user perform some activities of daily living independently. Despite advancement in the mechanical design of ULEs, a versatile control interface that enables full and continuous control of a ULE with multiple degrees of freedom for a user with disability in both arms and legs (tetraplegia) still requires further research and development. In this study, ten individuals with tetraplegia used a tongue-based interface to fully control a five degrees of freedom ULE for a drinking and a snacking task. This required moving the ULE hand from a wheelchair armrest position to grasp an object (bottle or strawberry) placed on a table in front of the participant, moving the object towards them until it touched a face shield, and placing the object on the table. All participants successfully controlled the exoskeleton and completed the tasks. The drinking task lasted 149.6 s on the first day and 122.9 s (median) on the second day of using the exoskeleton. The participants performed the snacking task only on the first day of ULE use and achieved a median task time of 167.0 s. The study showed that the tongue interface could provide effective, efficient, and safe control of the exoskeleton.

1. Introduction

Spinal cord injury (SCI) at the cervical level often leads to tetraplegia, i.e., a partial or total loss of motor function of both arms and legs. Besides the various physical and health conditions, individuals with tetraplegia face a significant challenge: regaining independence and autonomy in the activities of daily living (ADLs). In particular in the case of complete functional tetraplegia that the individual possess no motor functions in both arms and hands, performing any ADLs unaided can be life-changing. SCI typically affects younger individuals (Bickenbach et al., 2013) with a survival time of 38 years (median) after the injury (McColl et al., 1997). Individuals with tetraplegia prioritized regaining arm and hand function as the essential factor for improving the quality of life (Anderson, 2004). Furthermore, assistive technologies that mobilize a paralyzed limb do not only enhance the quality of life in performing ADLs but can induce neurological recovery through fostering neuroplasticity (Donati et al., 2016; Pierella et al., 2017). The daily activities that individuals with tetraplegia desired the most to perform independently include drinking, eating snacks, and scratching, which are repeatedly done throughout the day (Kobbelgaard et al., 2021).

Upper limb exoskeletons (ULEs) have the potential to rehabilitate individuals with tetraplegia (in a broad definition by WHO World Health Organization et al., 2021), either through the recovery of the reduced or lost functionalities in a therapeutic setup or by compensating the functionalities and assisting in performing simple ADLs (Benabid et al., 2019; Soekadar et al., 2016,?; Tang et al., 2014; Nann et al., 2021). Even though ULEs offer many opportunities for assisting and rehabilitating, developing a human–machine interface (HMI) that allows severely disabled users to control a multi-DOF ULE for arbitrary ADLs outside laboratories remains a challenge and is critical for the exploration of exoskeletons' potentials by the users. Some of the proposed control methods allowed users to only initiate predefined movements (Barsotti et al., 2015; Brauchle et al., 2015; Nann et al., 2021).

* Corresponding author.
E-mail address: mostafa@hst.aau.dk (M. Mohammadi).

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This includes interfaces that deployed surface electroencephalography (EEG) to detect movement intention through motor imaginary (MI) potentials (Brauchle et al., 2015; Barsotti et al., 2015), steady state visually evoked potentials (SSVEP) (Sakurada et al., 2013), and movement-related cortical potentials (MRCPs) (Bhagat et al., 2016). Control strategies based on surface EEG are beneficial for neurorehabilitation and training, as they can provoke motor plasticity (Gomez-Rodriguez et al., 2011). However, they are limited in the number of control commands for a multi-dimensional control and are often used in a laboratory setup due to susceptibility to environmental artifacts such as electromagnetic noise and displacement of the electrodes. Another approach uses invasive brain–computer interfaces consisting of electrode arrays implanted inside the skull and record brain potentials associated with intention (Wang et al., 2013; Wodlinger et al., 2014; Benabid et al., 2019). An individual with tetraplegia controlled two arms of a ULE with four DOFs in each arm 16 months after implanting a set of 128 electrodes above the sensorimotor cortex and after 122 sessions of training (Benabid et al., 2019). Using brain signals can provide an intuitive control method. Yet, the invasive surgical process entails the risk of complications such as infections. Furthermore, this ULE had no grasp function and as such desirable ADLs like drinking and eating were not included in the study. Both invasive and non-invasive BCIs require long calibrations, training, and re-calibration over time. However, BCIs can be attractive for individuals with severe disabilities or locked-in syndrome who can not use other interfaces, especially if they require only a short training period. Several control modalities employ the residual volitional muscle contraction for exoskeleton control using electromyography (EMG) methods (Li et al., 2017; Hosseini et al., 2017). Gopura et al. used 16 EMG channels to measure the arm muscles' contractions and fully control seven DOFs of a ULE (Gopura et al., 2009) for assisting the user's arm motion. EMG-based interfaces are not applicable for individuals with complete tetraplegia, except by using face or neck muscles (Nam et al., 2014). Furthermore, attaching electrodes to visible parts of the body may distort the normal appearance of the user and is limited by the number of control commands due to the finite available muscles for this purpose.

An approach to overcome the limitations of the above HMIs, such as the low number of control inputs and lack of continuous commands, incorporates more than one input modality. Nann et al. implemented a hybrid interface for a six-DOF ULE based on EEG and electrooculography (EOG) (Nann et al., 2021). Examples of hybrid interfaces include combinations of EEG/EMG (Bhagat et al., 2016) and EEG/eye-tracking (Frisoli et al., 2012). However, multi-modality usually requires mode switching, which adds to the system complexity (Herlant et al., 2016). Another approach uses computer vision for detecting target positions and partially or totally automatizes a grasping task (Frisoli et al., 2012; Nann et al., 2021; Bakri et al., 2018). Although computer vision can reduce the required time and effort for grasping (Bengtson et al., 2020), users may prefer a manual control to have more freedom and flexibility in the control (Kim et al., 2012). Furthermore, computer-vision methods usually detect a limited set of objects and are sensitive to the object color and the environment light intensity (Bengtson et al., 2020), i.e they only assist in a confined setup.

The intraoral tongue–computer interface (ITCI) introduced in Andreasen Struijk (2006) and Andreasen Struijk et al. (2017) enabled full control of a seven-DOF assistive robotic manipulator (Andreasen Struijk et al., 2017) and a five-DOF ULE by means of tongue movements (Mohammadi et al., 2021b). Usually, an SCI does not affect the tongue motor functionality and its fine movement, which makes the tongue a suitable modality for a control interface (Chu et al., 2018; Andreasen Struijk et al., 2017). The ITCI resembles a dental retainer containing 18 inductive sensors and provides a safe and reliable multi-DOF control without the need for long-term training and calibration.

In a previous study (Mohammadi et al., 2021b), ten able-bodied individuals controlled the EXOTIC ULE with five DOFs using an adapted version of the commercially available ITCI, iTongue (TKS, Denmark).

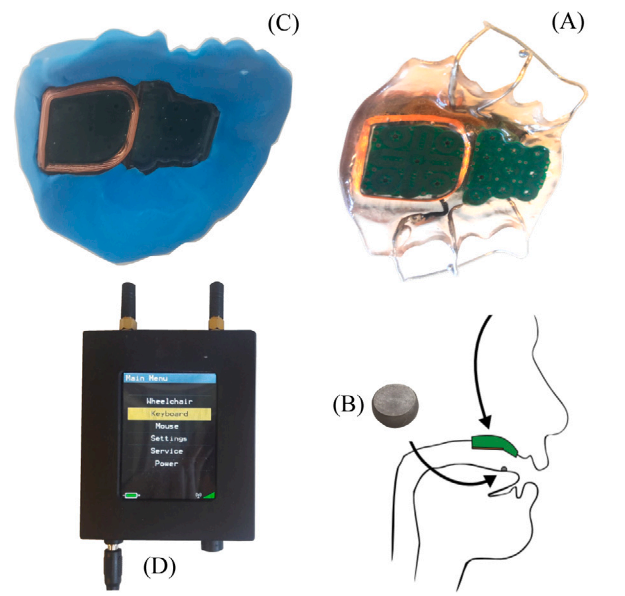

Fig. 1. (A) The commercial version of the ITCI mouthpiece with an acrylic brace and dental wires that hook around the teeth. (B) The activation unit. (C) The temporary mouthpiece produced with dental putty (the blue substance). (D) The central unit.

The interface provided continuous and full control of all five DOFs of the EXOTIC Exo in a single control mode both with and without visual feedback of the interface. However, no study has evaluated the use of a tongue interface for the full voluntary control of a five-DOF ULE by individuals with complete functional tetraplegia. Such clinical evaluation is a critical step in developing and realizing any assistive device as it illustrates crucial insights into the real potentials and deficits of an assistive device. Yet, clinical evaluation is still missing for many of the currently proposed solutions or it has only been performed with a small group of disabled participants.

Therefore, this study evaluated a tongue-based control scheme for the five-DOF EXOTIC Exo in a clinical setup where ten individuals with tetraplegia controlled the EXOTIC Exo to perform two ADLs desired by the users including a drinking task adopted from Mohammadi et al. (2021b) and a snacking task that was performed with the exoskeleton for the first time in this study. To our knowledge, this study, for the first time, evaluated a tongue interface of an assistive five-DOF ULE with a cohort of ten individuals with tetraplegia that could enable participants even with complete functional tetraplegia requiring a ventilator to fully and continuously control all DOFs of the ULE and perform ADLs.

2. Methods

2.1. Intraoral tongue–computer interface

We developed a control interface for the EXOTIC Exo using an adopted iTongue, which is the commercial version of the ITCI (Andreasen Struijk et al., 2017). The mouthpiece unit (MPU) of the ITCI resembles a dental retainer with embedded electronics and is mounted intraorally at the hard palate (Fig. 1). It contains 18 inductive sensors located in two multi-layer printed board circuits (PCBs). The contact of a metal activation unit (AU), pierced or glued to the tip of the tongue, changes the voltage over the inductive sensors. The produced signals are processed and transmitted through wireless communication to a central unit (Fig. 1). The central unit further processes the sensor signals and provides control of an effector, e.g., a wheelchair, computer, or a robot (Lontis et al., 2016; Andreasen Struijk et al., 2017; Andreasen Struijk et al., 2017). The AU consists of a cylindrical alloy with a diameter of 5 mm and a height of 3 mm. The commercial

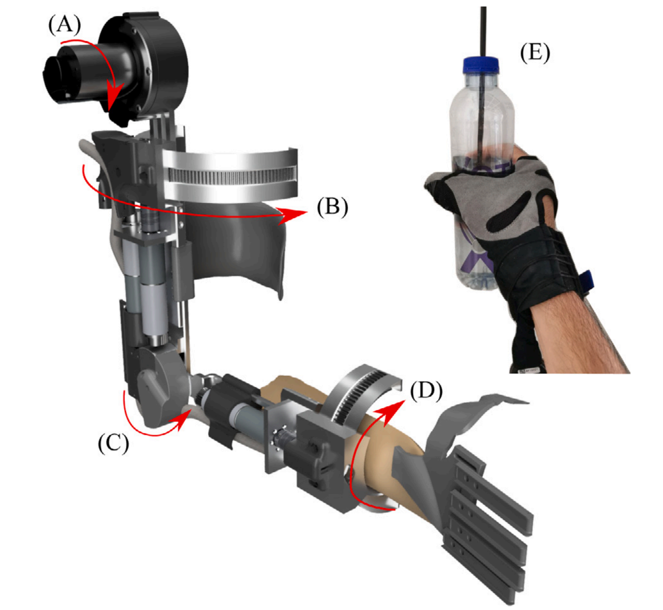

Fig. 2. The EXOTIC Exo consisted of five actuated DOFs: (A) shoulder flexion/extension, (B) shoulder external/internal rotation, (C) elbow flexion/extension, (D) wrist supination/pronation, and (E) CarbonHand glove for closing the hand.

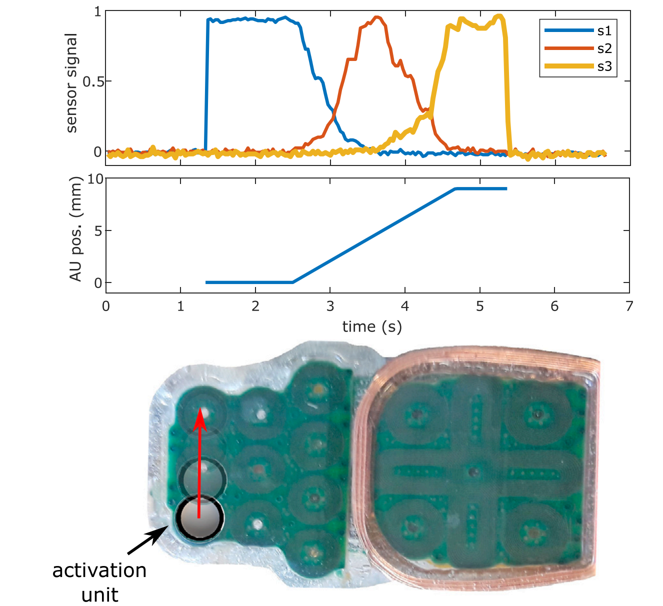

Fig. 3. Normalized sensor signals (top) from three sensors over time when the AU moved from sensor 1 to sensor 3 (bottom).

version (iTongue) is custom made for each user using dental acrylic and orthodontic wires (Fig. 1). For this study, we created a temporary MPU for each participant using a dental putty (ImpressA Putty, TopDent). ImpressA consists of two soft components that form a silicon rubber material. After mixing the two components, we pressed the putty and the electronic core of the MPU towards the palate of the participants for two minutes until the putty solidified (rubber like) as a palate impression (Fig. 1). This method enabled us to make a quick custom MPU and reuse the electronic MPU for several participants.

2.2. EXOTIC upper limb exoskeleton

The EXOTIC Exo (Fig. 2) consisted of four actuated joints on the right arm namely shoulder flexion/extension, shoulder external/internal rotation, elbow flexion/extension, wrist supination/pronation (Thøgersen et al., 2020, 2022). A CarbonHand (BioServo, Sweden) exoskeleton closed the hand for grasping objects, and a passive elastic mechanism opened the hand (Thøgersen et al., 2020). The exoskeleton was designed considering safety, ergonomic physical interaction, and the user desires and preferences, including compactness, easy donning/doffing, and functionality (Kobbelgaard et al., 2021). Two orthopedic braces carried the upper arm and the forearm weight, and we strapped only the wrist and the hand brace to the user to avoid provoking autonomic dysreflexia and ensure easy donning and doffing.

2.3. Control interface

The control interface provided a velocity control of the right hand in the body Cartesian coordinate frame enabling the user to move in the five DOFs, including forward/backward (x-axis), left/right (y-axis), up/down (z-axis), rotate the wrist clockwise/counterclockwise, and open/close the hand. We set the maximum hand linear velocity to 45 mm/s to ensure safe and smooth control based on a study with able bodied participants (Mohammadi et al., 2021b).

We adopted an interpolation technique to create virtual buttons and joysticks based on the data from the 18 inductive sensors from which we could estimate the AU position in contact with the MPU sensors with 1 mm accuracy (Mohammadi et al., 2019). First, the raw sensor values were normalized within their range of variation (Fig. 3). Then, a moving average filter was applied to reduce the noise. Finally, the interpolation method detected the sensor that had the highest level of excitation (i) and averaged the positions of the sensor and its neighbor sensors weighted on the normalized sensor values (S_t) (Mohammadi et al., 2019) to estimate the AU position (p_t):

$$p_t = \frac{(S_t \circ NS_i) \times P_{sensors}}{S_t . NS_i} \tag{1}$$

In Eq. (1), $\circ$ was the Hadamard product, and NS_i was a vector with 18 elements, valued 1 for sensor i and its neighbors and 0 for other sensors. For example, only sensors 2, 4 and 5 were located in sensor 1 (top-left in Fig. 4, A) neighborhood:

$$NS_1 = [1, 1, 0, 1, 1, 0, \dots, 0] \tag{2}$$

$P_{sensors}$ was an 18 × 2 matrix containing the XY positions of all sensors. Through this approach, the AU was tracked continuously, and the ITCI acted as two touchpads instead of a set of 18 switches.

The participants issued control commands by pointing the AU to different areas of the ITCI PCBs (Fig. 4, A &B) and the commands were recognized using the Boundary Lines method (Mohammadi et al., 2021a). First, the AU position vector (p_t) was multiplied to a matrix containing the constants of a set of n lines (a, b, c):

$$l_i(x, y) : a_i x + b_i y + c_i = 0 \tag{3}$$

which confined the areas related to each control command (Fig. 4). Then, the sign function was applied to the result, and it was multiplied by a matrix containing m rows (number of commands in the control layout) and n columns. The rows represented the relation of the command area to the lines with one of −1, 0, or 1 values, indicating that the area was located on one of the line sides or had no relation to the line. We used five lines to define each area uniquely; thus, only one of the elements in the result of this multiplication ($R_{m\times1}$) was equal to five. The index of this element specified which area the AU pointed to.

$$R_{m\times1} = \begin{bmatrix} 0 & -1 & 1 & \cdots & 0 \\ \vdots & \vdots & \vdots & \vdots & \vdots \end{bmatrix}_{m\times n} \times sign(\begin{bmatrix} a_1 & b_1 & c_1 \\ \vdots & \vdots & \vdots \\ a_n & b_n & c_n \end{bmatrix}_{n\times3} \cdot \begin{bmatrix} p_t \\ 1 \end{bmatrix}) \tag{4}$$

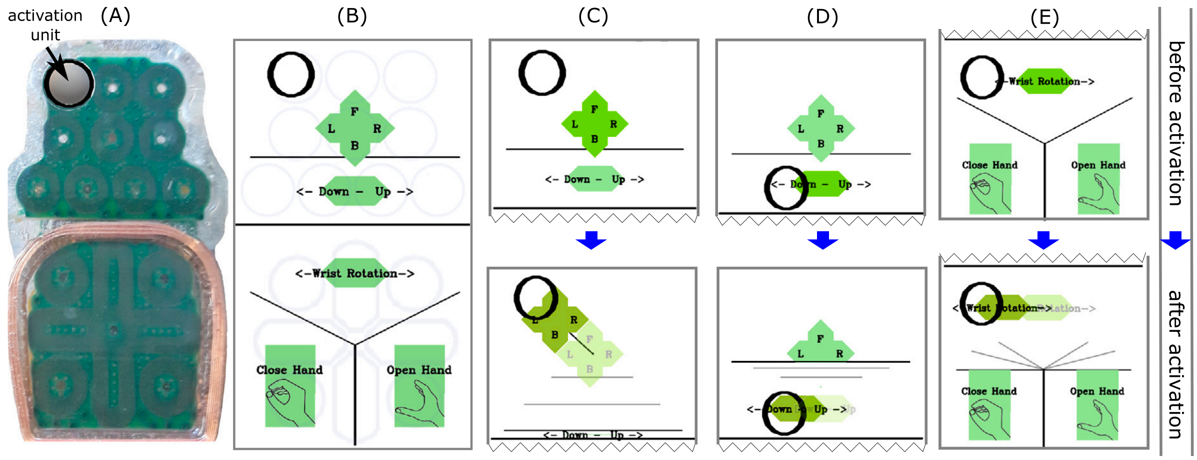

Fig. 4. (A): The 18 inductive sensor on the two MPU's PCBs. (B): Control layout. (C-E): Different controls before and after activation, changing size and color. The black circle indicated the AU position in contact with the tongue interface. (C): A joystick-like control moved the exoskeleton in the horizontal plane (XY plane). (D): A lever-like control moved the hand up and down (Z axis). (E): Similar to (D), this control rotated the wrist joint.

The choice of the control scheme was based on a previous study with ten able-bodied participants controlling the EXOTIC Exo with the ITCI and was adopted from Mohammadi et al. (2021b). A 2D joystick-like control (Fig. 4, C) enabled continuous control of the hand velocity and direction in a horizontal plane (XY-plane) (Mohammadi et al., 2021a). Similarly, two lever-like controls moved the hand up/down and rotated the wrist (Fig. 4, D & E). For all these controls, the AU pointer distance to the center of the control specified the velocity between zero and the maximum speed, i.e., the farther the pointer was placed, the faster the exoskeleton moved. Commands for opening and closing of the hand were issued through two virtual buttons (Fig. 4). During selection, the control areas increased in size to ease the manipulation and simultaneously accommodate all controls in a single control mode (Fig. 4, C–E). After the AU was pointed to a control area, a control command was sent to the exoskeleton with a 0.5 s delay. We applied this latency to reduce issuing faulty commands based on Andreasen Struijk et al. (2018). The exoskeleton immediately stopped after releasing the control. Three different shades of green signified the states of the control, including *not selected*, *selected before activation* (0.5 s latency), and *activated* (Fig. 4, C-E).

We developed the control interface software for the EXOTIC Exo using the Robot Operating System (ROS Kinetic). The software communicated with the motor drivers at 100 Hz through a CAN communication sending control commands and receiving position feedback from incremental encoders on each motor. Furthermore, absolute encoders measured the actuated joint angles. The software received the user input at 30 Hz from the ITCI. We used *MoveIt* (Coleman et al., 2014) and *jog_control* (Tajima et al., 2020) ROS packages for inverse kinematics and trajectory planning, resulting in velocity control in a Cartesian frame. More details of the low-level control are described in another paper (Thøgersen et al., 2022).

2.4. Participants

Ten individuals with tetraplegia participated in this study (mean age 53.3, range 23–69, one female). The inclusion criteria were:

1. Age of between 18–75.
2. Absence of or reduced motor function in the upper extremities and in particular the right arm due to SCI or ALS.
3. Tongue functionality must not have been affected by the impairment.
4. Must not be able to grab a bottle of water from a table while seated on a chair and drink from it.

The main exclusion criteria were:

Table 1
Participants demographic and clinical assessment scores.

Subject	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10
Gender	M	M	M	M	M	M	M	M	M	F
Age	59	52	38	23	55	50	59	65	69	63
Years since injury	0.6	31.9	27.2	0.8	2.2	28.0	0.5	12.3	5.7	8.1
Injury level	C4	C5	C1	C2	C4	C5	C1	C4	C2	C2
Complete/inc.	I	C	C	I	I	C	I	I	I	I
ASIA score	D	A	A	C	D	A	C	C	C	C
UER motor score	8	23	0	3	10	10	11	12	4	11

1. A treatment-required depression or previous psychosis with a non-somatic origin.
2. Arm muscle spasms or contractures that impede the function of the exoskeleton.
3. Significantly altered alertness caused by the use of drugs.

None of the participants had used the ITCI before the experiment. A neurologist assessed the impairment level of all participants before inclusion using the International Standards for Neurological Classification of SCI (ISNCSCI) and recorded the ASIA impairment scale (Table 1). A score of lower than 25 on the Upper Extremity Right sub-score (UER) indicated a reduced motor function in the right arm. Further information of the study cohort is presented in Table 1. The study was conducted under the Helsinki Declaration and was approved by the local ethical committee (registration number N-20210016). All participants signed a consent form before participating in the experiment.

2.5. Experiment setup and procedure

We conducted the study at the Spinal Cord Injury Center of Western Denmark. The experiment consisted of three experimental sessions on consecutive days. The participants received information about the study and the exoskeleton in a meeting before deciding to participate and at the first session.

In the first session, we made the ITCI mouthpiece as described above and then glued the AU on the participant's tongue tip using a surgical tissue glue (Histoacryl, B.Braun Surgical S.A., Spain). The participants practiced using the ITCI by controlling a computer simulation of the EXOTIC Exo presented on a screen (Fig. 5). Four tasks were performed consisting of grasping an object (bottle or strawberry) on a table in front of the exoskeleton. In addition, the last two tasks required moving the object towards the mouth and touching a dummy lib. Due to lack of depth representation on the screen, an arrow from the hand to the

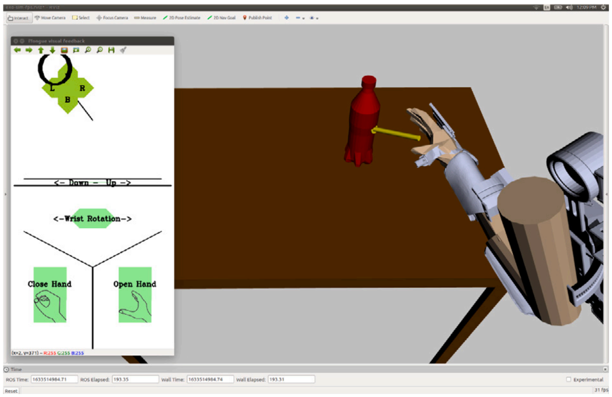

Fig. 5. The participants practiced using the tongue interface by performing grasping tasks in a simulation environment on a screen. The ITCI visual feedback was presented on the left side of the scene. In this figure, the participant was moving the hand to the left-forward to reach the bottle.

center of the target guided reaching the target. Furthermore, the target objects turned green when the hand position and orientation were suitable for grasping. Visual feedback of the AU contact with the ITCI mouthpiece was also presented on the screen in the form of a pointer that activated the control commands (Fig. 5). The participants repeated the tasks eight times or fewer if they felt fatigued and could take breaks for resting when desired.

In the second session, the participants used the exoskeleton for the first time. We adjusted the exoskeleton height, upper arm length, and lower arm length to fit the participant's arm. The size of the Carbon-Hand glove was also selected according to hand size. The participants were located in front of a table while sitting in their wheelchairs and in one case in a chair. After donning the exoskeleton, we adjusted the table height to allow the participant to move the wheelchair close to the table. Furthermore, we moved the table such that a white circle marking was located in front of the participant (Fig. 6). A screen on the table showed the ITCI visual feedback. We glued the AU onto the participants' tongue and asked them to wear a face shield to protect their face and eyes. In addition, to emergency stop buttons allowed two experimenters to immediately stop the exoskeleton. We asked the participants to perform eight repetitions of a drinking task similar to a previous study (Mohammadi et al., 2021b) followed by eight repetitions of a snacking task. If the participant dropped the target object or pushed it out of reach, we repeated the task to achieve eight successful trials. However, we recorded a lower number of repetitions if the participant preferred to stop due to a low level of energy and fatigue. The tasks were defined based on highly prioritized ADLs, including eating and drinking (Kobbelgaard et al., 2021). The exoskeleton was positioned similarly to placing the hand on the wheelchair armrest (Fig. 6) before starting the trials (home position). The drinking task started with grasping a bottle filled with 250 mL of water. The bottle stood in front of the participant at the center of a white circle with a diameter of 20 cm and had a straw 10 cm long above the bottle lid. The participants moved the bottle towards their mouth until the straw tip touched the face shield and then replaced the bottle on the table inside the circle (Fig. 6). The snacking task aimed at evaluating the exoskeleton control for ADLs that required a more precise and nuanced control of the hand. The task resembled the drinking task, except we replaced the bottle with a plastic strawberry, which required moving the hand closer to the face and more wrist rotation compared with the drinking task.

In the third session, gluing the AU and donning the exoskeleton was conducted identical to the second session. The participants performed one drinking task as training, followed by three drinking tasks. The third evaluated the learning effect on the drinking task and measured how much the performance varied compared to the second session. We only recorded the drinking task because users highly prioritized it in several studies, and it was commonly used in many other studies for evaluating ULEs (Kobbelgaard et al., 2021; Nann et al., 2021; Pedrocchi et al., 2013). The snacking task was not performed in the third session due to the limited available time of the participants.

2.6. Data acquisition and processing

We recorded the exoskeleton joint angles, the hand position (obtained from the forward kinematic model and the joint angles), and the control commands from the participants through the ITCI during all trials. The *task time* was obtained by measuring the interval between the first control command issued and the instant that the participants opened the hand to release the object (bottle or strawberry) on the table. The task time was divided into *moving time* when the exoskeleton was moving and *pause time* when the exoskeleton was stopped. The *trajectory length* represented the length of the path that the hand traveled in the Cartesian space. Further, the *number of commands* that the participants issued during each trial was recorded. A new command was counted if the participant selected a command on the control layout (Fig. 4) and then released the contact or pointed to another command. Failure and success rates for each task were obtained by dividing the number of failed and successful trials by the total number of recorded trials, respectively. Failure could happen due to pushing the target object out of reach or dropping the object. If a trial was restarted due to a loose or detached AU from the tongue, we did not count it as a failed trial because the actual users of the ITCI system will have a tongue piercing, and gluing the AU is a temporary attachment for the experiment.

We measured the above outcome variables for each trial and obtained single-subject descriptive data by averaging values of all trials for each subject in each experimental session without removing outliers. To evaluate the learning effect from the second session to the third session, we used the paired t-test with a significant level of 0.05. To meet the required assumptions for a paired t-test, including normality (assessed by Shapiro–Wilk's test), we removed participant S8 from the data as an outlier. Statistical analyses were performed on the remaining nine participants' data.

After recording the trials in the third session, we helped the participants fill in two questionnaires. The first questionnaire measured the intuitiveness of the exoskeleton control interface (INTUI, Ullrich and Diefenbach, 2010) based on a multifactorial approach. The INTUI survey assesses the four sub-components of intuitive interaction: effortlessness, verbalizability, gut feeling, and magical experience through 16 questions. Furthermore, an additional question measures the global rating of intuitiveness. The participants answered each question between two contradicting statements on a 7-point scale between 1–7 (e.g., "using the product was easy" vs. "...was difficult"). An overall score obtained by averaging the relevant question scores measured each sub-component such that a higher score indicated higher intuitiveness.

The second questionnaire measured the perceived task load (NASA TLX, Hart (2006)) of drinking with the exoskeleton. The NASA TLX consists of six sub-components: mental demand, physical demand, temporal demand, performance, and frustration. After reading the description, the participants rated each sub-component on a 0–100 scale with 5-point granularity. A higher score indicated a higher task load for all sub-components.

3. Results

All participants finished the experiment and successfully performed the drinking task and snacking task. In total, over the two experimental sessions, the trials were re-performed 16 times (8.4% failure rate) due to dropping the target object and three times (1.6% failure rate) due to pushing the object out of reach (Fig. 7). Participant S7 continued

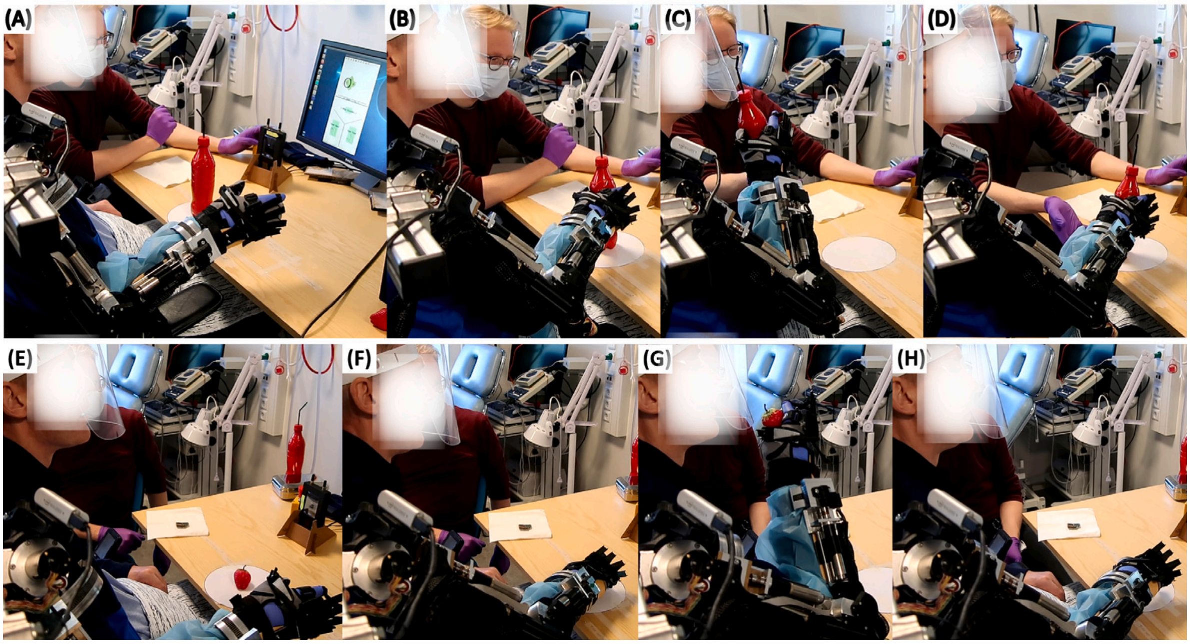

Fig. 6. Experimental setup and the procedure of the drinking task (A–D) and the snacking task (E–H). A,B: The participant's hand was located in the home position when the task started, similar to placing the hand on the wheelchair armrest. B,F: The participant moved his hand towards the target object and grasped it. C,G: Then he moved the object close to the mouth touching the face shield. D,H: He returned the object to the table.

controlling the exoskeleton and performing the task after dropping the object. Thus, the experimenter re-positioned a dropped object in his hand without stopping the trial in five trials. Therefore, this did not affect the performance measures. In total, the target object was dropped from the participants' hands 21 times (10.9% of the total trials).

The first and the second sessions lasted for approximately three hours each, and the third session approximately one hour. No side effects, pain, or discomfort were reported after using the exoskeleton and the tongue interface. If the participant asked for a break (mainly for taking out the tongue interface) or the AU detached from the tongue in the middle of a trial, we subtracted the break duration from the task time. Except S6 and S10, other participants rarely asked for a break (only S4: two times, 15 and 13 s; and S7: three times: 11, 47, and 12 s). S6 had nine breaks through the experiment (mean 58 s) and S10 had six breaks (mean 18 s).

3.1. Drinking task

The participants performed the drinking task in 147.9 s in the second session and 121.6 s in the third session (mean task time of all participants excluding S8), thus reducing the time by 18% after one session of using the exoskeleton (Fig. 8). The paired t-test of the task time revealed a reduction close to the significant level ($t(8) = 1.853$, $p = 0.051$). Furthermore, we observed significant improvement from the second to the third session (Fig. 8), resulting in a decrease of 22% in pause time ($t(8) = 1.990$, $p = 0.041$) and 17% in number of commands ($t(8) = 2.178$, $p = 0.031$). However, the decrease of 11% in moving time ($t(8) = 1.249$, $p = 0.124$), and 11% in trajectory length ($t(8) = 1.257$, $p = 0.122$) were not statistically significant.

3.2. Snacking task

The snacking task required slightly more time to complete compared with the drinking task as could be expected due to the required precision. The participants achieved a median snacking task time of 167.0 s, moving time of 80.6 s, pause time of 89.9 s, and trajectory length of 268 cm (Fig. 9). Similar to the drinking task, a median of 21 commands was issued to finish the snacking task (see Fig. 9).

3.3. Intuitiveness and task load scores

On average, the participants rated the intuitiveness of the tongue control at 5.4 on the 1 to 7 scale (Fig. 10). Within the INTUI subcomponents, the Magical Experience was rated the highest (mean 6.0) followed by Verbalizability (mean 5.2), Effortlessness (mean 4.2), and Gut Feeling (mean 3.0).

An average overall NASA TLX score of 40 was obtained for controlling the exoskeleton with the ITCI, grasping the bottle, bringing it towards the mouth, and returning it to the table. The Mental Demand and Effort contributed the most to the task load with average scores of 62 and 52 respectively, while the Physical Demand was rated lowest (average 25) among the factors (Fig. 10).

4. Discussion

In this study, we evaluated a tongue-based full control of a five-DOF ULE with a group of ten participants with tetraplegia. The participants trained using the ITCI control in the first session by controlling a computer simulation of the EXOTIC Exo. In the second session, the participants used the ITCI to control the EXOTIC Exo and move their right arm to grab a bottle of water or a plastic strawberry, bring the item close to their face, and place it on the table. The study showed that the proposed tongue interface could enable individuals with complete functional tetraplegia to control a five-DOF ULE in a 3D space and perform ADLs such as drinking and snacking without any automation.

The glove did not produce a strong grasping force on the bottle for S3 and S7 due to stiffness and deformity of their finger joint. Therefore, an experimenter manually supported the bottle from the bottom in some trials to avoid dropping it on the participant as the goal of this study was not to measure the glove's performance in grasping. In fact, the poor performance of the hand opening and closing mechanism was the main reason for the failing trials. In some cases, the glove did not apply sufficient force to the object to hold it, and in some cases, the mechanism did not open the hand enough to get the fingers around the bottle. In the latter case, some participants adopted a method of approaching the bottle from the lid as it was narrower in this position

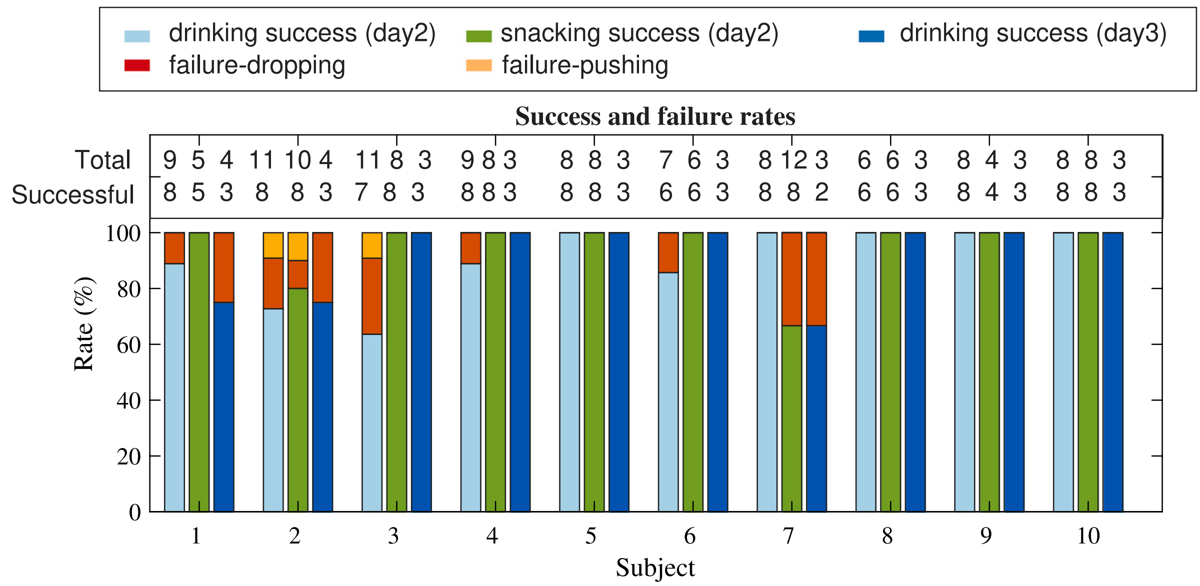

Fig. 7. Success and failure rates for the drinking and snacking tasks for each subject. The total number of recorded trails and the number of successful trials are reported above each bar.

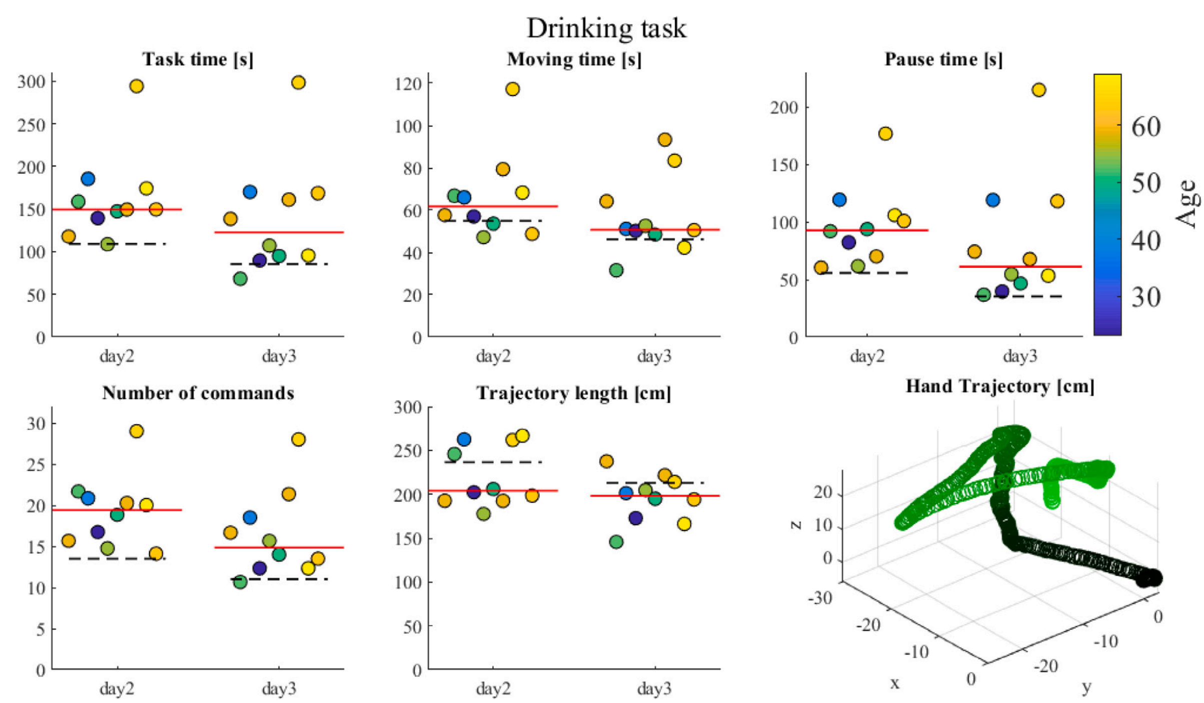

Fig. 8. Data points show the performance measures of the drinking task for the ten participants. The red line signifies the median and the black dashed line signifies the median of an able-bodied group (Mohammadi et al., 2021b). The markers are color-coded based on the participants' age. Furthermore, data points are sorted on the X-axis from left to right, respective to the subject number (Table 1). The figure at the right-bottom shows an example of the hand trajectory throughout the drinking task (from black to light green).

and then moved the hand down to grab the bottle. Therefore, further improvement of the hand opening and closing mechanism is required.

The use of the putty-based mouthpiece instead of the main ITCI product (iTongue) caused incidences of the MPU loosening from the palate, in particular for S6 that the MPU detached approximately one time during each trial. However, using the putty facilitated fast and easy preparation of a mouthpiece for each participant and therefore was a successful approach. In the rare cases of the MPU detaching from the palate, we stopped the trial and continued after replacing and fixing the MPU.

We identified the important ULE interface attributes reported in the state-of-the-art and presented them in Table 2. The gap for a clinical study of a ULE interface enabling individuals with complete functional tetraplegia to control a multi-DOF exoskeleton fully and continuously for performing several ADLs in a single modal, direct, and aesthetic manner is highlighted in this table and filling this gap was the main purpose of this study. Even though the other studies in Table 2 lacked one or more of the attributes, they can be optimal for a specific level of disability. For example, Benabid et al. (2019) used an implanted BCI to control eight DOFs of a two-arm exoskeleton for a reach-and-touch task in a 3D space that did not require any residual motor function. However, the exoskeleton did not provide grasping, which is crucial for most of the ADLs. Furthermore, we did not find the task completion time data, and only the success rate (70.9% for 3D control) and the ratio

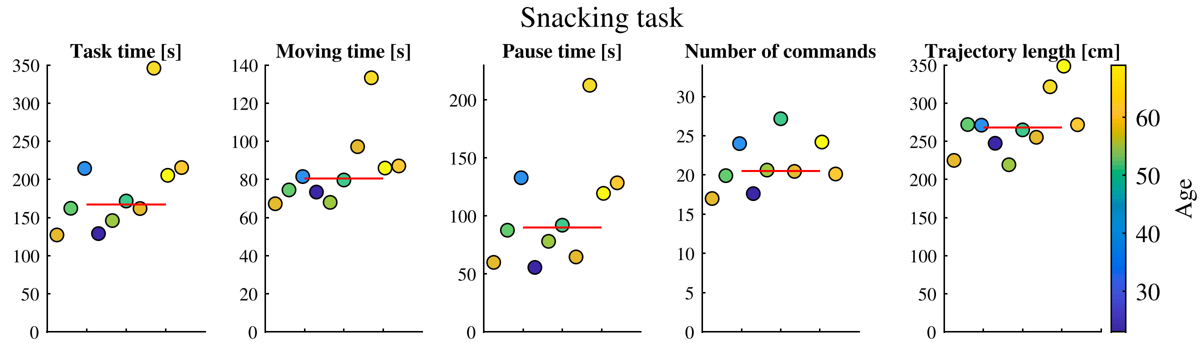

Fig. 9. Performance measures for the snacking task in the second session. The red line shows the median. The markers are color-coded based on the participants' age. Furthermore, data points are sorted on the X-axis from left to right respective to subject number (Table 1).

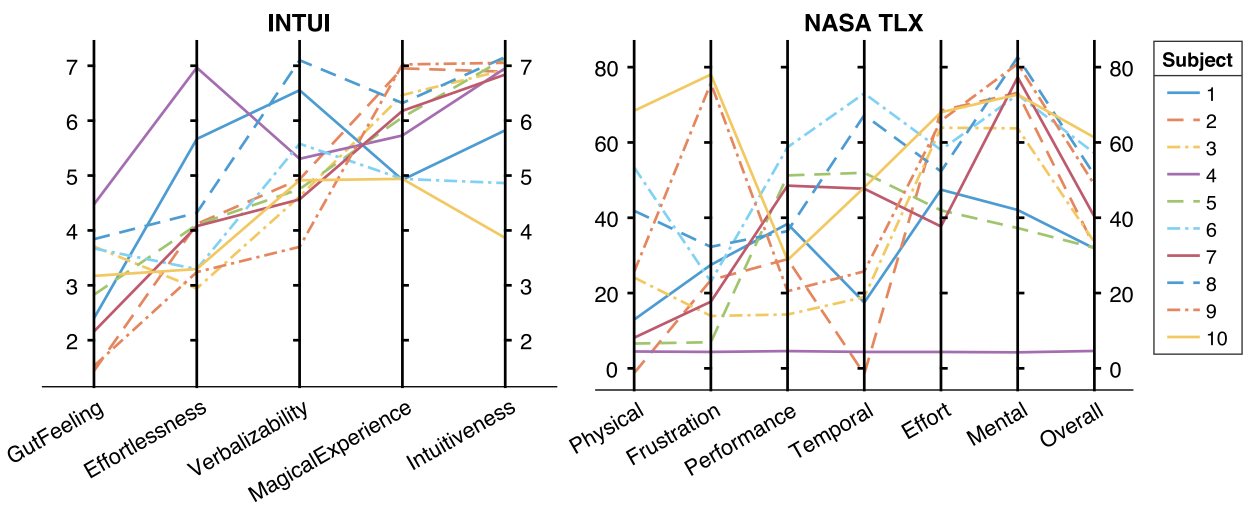

Fig. 10. Intuitive interaction (INTUI) and task load (NASA TLX) questionnaires.

between the distance traveled and the shortest distance between origin and target (lowest 5.3 for 3D control) were reported (Benabid et al., 2019). Moreover, only one participant was recruited for the study, and the first time he tried a 3D control was five months after having the BCI implanted. Another tongue-exoskeleton interface provided control of a two-DOF ULE and controlled the hand in a horizontal plane (Zhang et al., 2021). However, the proposed system cannot be used for assisting in ADLs. Furthermore, the interface required wearing a headset, which interfered with the regular appearance of the user.

Three other studies presented ULE interfaces that enabled individuals with complete tetraplegia to perform ADLs (Nann et al., 2021; Barsotti et al., 2015; Sakurada et al., 2013) (Table 2). Nann et al. (2021) incorporated computer vision to detect the position of a cup, and a hybrid EEG/EOG interface was used to trigger the exoskeleton movement. The cup was automatically guided to the user's mouth after grabbing, which did not allow fine adjustment of the cup for drinking. Similarly, Barsotti et al. and Sakurada et al. used EEG signals to initiate movements of a ULE for reaching, grasping, and releasing (Barsotti et al., 2015; Sakurada et al., 2013). Using computer vision and automation makes performing the task possible when sufficient control inputs are not available. However, these methods are limited to a predefined task, and thus cannot be used outside a laboratory for multiple ADLs.

The state-of-the-art in ULE interfaces for disabled individuals is presented in Table 2. However, there are other interfaces that can potentially be used for ULE control yet not explorer in scientific articles for this application. For example, shoulder and head movements can be mapped to control commands for assistive devices such as robotic manipulators (Aspelund et al., 2020) and electric wheelchairs (Thorp et al., 2016). Another study used a sequence matching algorithm to detect user inputs for controlling an assistive manipulator with a sip-and-puff input device (Schweitzer and Campeau-Lecours, 2020). In order to adopt these approaches for a ULE control, import and specific requirements of this application should be considered. For example, high robustness and safety are critical for ensuring a safe human–ULE physical interaction, avoiding unintended commands, and potentially damaging the user.

Using automation schemes imposes risks of collision or injury if the user does not possess the movement control in every instance (continuous control). Therefore, in this study an important feature of the proposed tongue interface was that the users controlled the exoskeleton entirely and continuously. The absence of any exoskeleton failure or side effects on the participants demonstrated the safety and reliability of the system for assisting users through the ADLs.

Subjective assessments of the NASA TLX task workload and interface intuitiveness (INTUI)revealed an overall workload of 40/100 and intuitiveness of 5.4/7 for the drinking task. To our knowledge, no other study has used these questionnaires for evaluations of a ULE interface by individuals with tetraplegia. But studies of assistive devices in different setups relied on the NASA TLX (Chung et al., 2017; Hortal et al., 2014; Park et al., 2020; Grice and Kemp, 2016). For example, Grice et al. asked an individual with tetraplegia to teleoperate a mobile two-arm robot (PR2) with a head-tracking mouse and a thumb activated button to perform the Action Research Arm Test. The participant rated the workload at 70/100 (Grice and Kemp, 2016). Similarly, four able-bodied participants rated a workload of 69.1/100 for a BCI-controlled 2D robot for a task consisting of reaching four points in a plane (Hortal et al., 2014). Another study used the standard hand-controlled joystick of an assistive robot to perform a set of tasks

Table 2
State-of-the-art ULE interfaces for disabled individuals.

Studies	Input modality	System supported ADLs for complete functional tetraplegia	Actuated DoFs	Number of commands[a]	Single modal	Continuous[b]	Direct[c]	Full control[d]	Interface usable for complete functional tetraplegia	Calibration and algorithm training	Clinical study sample size	Aesthetics cost	Subjective user feedback
This study	ITCI	✓	5	10D or 2D+4J	✓	✓	✓	✓	✓	Not required[e]	10	Not visible	✓
Zhang et al. (2021) and Ostadabbas et al. (2016)	Tongue drive system	–	≤2	4D or 2J	✓	✓	✓	✓	✓	More than four minutes	2 (Zhang et al., 2021), 3 (Ostadabbas et al., 2016)	Headset	–
Benabid et al. (2019)	Invasive BCI	–	4 + 4[f]	8D + 8D[f]	✓	✓	✓	✓	✓	Months	1	Headset	–
Gandolla et al. (2021) and Dalla Gasperina et al. (2018)	Finger-controlled joystick	–	4	2J + 1D	✓	✓	✓	✓	–	Minutes or less than one minute	13 (Gandolla et al., 2021), 3 (Dalla Gasperina et al., 2018)	Visible, but discreet	✓
Lotti et al. (2020), Schabron et al. (2021), Johan et al. (2020), Straathof et al. (2016), Nam et al. (2020), Gopura et al. (2009) and Little et al. (2019)	EMG/FMG	–	≤8	≤16D	✓	✓	✓	✓	–	From minutes to hours	1 (Straathof et al., 2016), 15 (Nam et al., 2020), 1 (Johan et al., 2020)	EMG electrodes on the arm	Schabron et al. (2021) and Straathof et al. (2016)
Chia et al. (2020), He et al. (2017), Charoenseang and Panjan (2018), Wu and Wang (2017), Sui et al. (2017) and Bai et al. (2017)	Force/torque control using residual arm ability	–	≤8	≤6J	✓	✓	✓	✓	–	Not reported	38 (Longatelli et al., 2021),	Not visible	Charoenseang and Panjan (2018)
Dalla Gasperina et al. (2018)	Eye-tracking	–	4	11D	✓	✓	–	✓	✓	Minutes	3 (Dalla Gasperina et al., 2018)	Visible, but discreet	✓
Gandolla et al. (2021) and Dalla Gasperina et al. (2018)	Voice command	–	4	11D	✓	–	✓	✓	✓	Not reported	3 (Dalla Gasperina et al., 2018), 1 (Gandolla et al., 2021)	Visible, but discreet	✓
Frisoli et al. (2012)	EEG & eye-tracking	–	4	1D[g]	–	✓	✓	–	✓	One training session	4	EEG cap	✓
Barsotti et al. (2015), Brauchle et al. (2015), Sakurada et al. (2013), Li et al. (2019), Irimia et al. (2016) and Webb et al. (2012)	EEG	Barsotti et al. (2015)[h] and Sakurada et al. (2013)[h]	≤8	≤6D	✓	–	✓	–	✓	From minutes to hours	2 (Brauchle et al., 2015), 3 (Barsotti et al., 2015)	EEG cap	–
Nann et al. (2021)	EEG & EOG	✓[h]	7	2D	–	✓	✓	–	✓	From minutes to hours	4	EEG cap	✓

[a]D: Discrete switch-like commands, J: A control of a DOF that allows multiple velocity values within the velocity range. For example, a joystick is usually 2J.
[b]Continuous: The user possesses control at all instances and the ULE does not move automatically.
[c]Direct: The user does not need to look at a screen to issue a command.
[d]Full control of all DOFs without automation or predefined trajectories.
[e]The ITCI sensors are continuously calibrated during use and did not require initial calibration. However, an initial calibration could be done in less than 1 min.
[f]The exoskeleton consisted of two arms, each with four DOFs.
[g]The user could also select a target object through eye-gaze.
[h]These systems performed ADLs using automation through computer vision or predefined trajectories and are limited to the specific experiment setup.

including pushing buttons and turning a door handle and a knob and reported a 33/100 workload (Chung et al., 2017). The lower task load of controlling a robot with a hand-controlled joystick than our tongue control could be expected because all participants in Chung et al. (2017) were electric wheelchair users and were experienced in using the joystick. In a previous study, ten able-bodied individuals controlled the EXOTIC Exo with a hand-controlled joystick for the drinking task similar to this study and rated an overall NASA TLX of 17.5/100 (median), while the tongue control was rated 38.4/100. However, a direct comparison of the workload obtained in this study and other publications requires a similar setup and task which is not the case in any of the available publications. A limitation of this study in the subjective evaluation of the system was the lack of enough female participants. A more balanced cohort between males and females can result in a more reliable assessment.

During the experiment with S8, we realized that the participant had issues understanding the tasks and with oral communication, and required step-by-step guiding and instruction. Later his spouse stated that the participant had suffered some cognitive impairments after the incident of the SCI. This may explain the outlier data points in the performance data (box plots in Fig. 8), which all are related to S8. A more homogeneous cohort can be achieved by considering cognitive status of the volunteer participants in the inclusion criteria of the future studies. Still, none of the other participants showed any cognitive deficits.

In a previous study in which ten able-bodied individuals performed the drinking task in the same setup with the EXOTIC Exo and the ITCI, a median task time of 85.6 s was achieved on the second day of using the exoskeleton (Fig. 8). The able-bodied group performed 30.4% faster compared with this study with a median task time of 122.9 s. One of the main factors contributing to the difference between the two studies was the soft glove that opened/closed the hand. Even if the exoskeleton joints were not backdrivable, i.e., participants could not force to move it, the glove allowed the able-bodied participants to assist with opening and closing the hand. On the contrary, this study's participants faced several challenges with grasping objects with the glove due to the rigidity of the finger joints. . Another explanation for the difference in task times may be the mean age of the two cohorts (able-bodied group: mean 24.7 years, participants with tetraplegia: mean 53.3 years). The younger participants who were experienced computer users, especially within gaming, may perform faster than the older participants.

A limitation of the ITCI system for the end users is that it requires piercing the AU on the tongue. One-third of the disabled participants interviewed in a previous study reported that they were not interested in using the ITCI due to the need for a piercing (Caltenco et al., 2012). We presented a non-invasive approach of using the ITCI system in a pilot study (Kirtas et al., 2021), and this new method is still under development.

5. Conclusion

This study showed that ten severely disabled individuals, even some with complete functional tetraplegia, could use the proposed tongue interface to fully control the five DOFs of the EXOTIC Exo and perform highly prioritized ADLs such as drinking from a bottle and eating a snack. Moving the hand from the wheelchair armrest position towards a bottle of water in front of the user, grasping it, moving it towards the mouth, and returning it to the table took 122.9 s (median) on the second day of using the exoskeleton. Similarly, grasping a plastic strawberry, bringing it close to the mouth, and returning it to the table required 167.0 s on the first day. The control interface provided a 2D joystick-like control of the hand in the transverse plane and continuous control of the velocity between zero and maximum value for the vertical axis and the wrist rotation. Furthermore, we showed that it is safe to use the system for drinking and snacking, as no side effects, pain, or discomfort were reported after a group of ten individuals with tetraplegia used the exoskeleton. Controlling the exoskeleton required no long training or calibration period, and the participants only trained the tongue interface for around two hours before using the exoskeleton. Thus the tongue control of the exoskeleton facilitated the two ADLs for severely disabled individuals, who could not otherwise perform the tasks. Through full continuous possession of any possible exoskeleton motions, the proposed system can enable many other ASLs with a high degree of usability.

CRediT authorship contribution statement

Mostafa Mohammadi: Conceptualization, Methodology, Software, Investigation, Formal analysis, Writing – original draft, Writing – review & editing, Visualization. **Hendrik Knoche:** Conceptualization, Methodology, Writing – review & editing, Visualization, Supervision. **Mikkel Thøgersen:** Conceptualization, Methodology, Software, Investigation, Writing – review & editing. **Stefan Hein Bengtson:** Conceptualization, Methodology, Software, Investigation, Writing – review & editing. **Frederik Victor Kobbelgaard:** Conceptualization, Investigation, Writing – review & editing. **Muhammad Ahsan Gull:** Conceptualization, Writing – review & editing. **Bo Bentsen:** Conceptualization, Methodology, Writing – review & editing. **Kåre Eg Severinsen:** Methodology, Resources, Writing – review & editing, Validation, Supervision. **Benjamin Yamin Ali Khan:** Methodology, Resources, Writing – review & editing, Investigation. **Lotte N.S. Andreasen Struijk:** Conceptualization, Methodology, Writing – review & editing, Formal analysis, Visualization, Supervision, Validation, Project administration, Funding acquisition.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Lotte N. S. Andreasen Struijk has patent Tongue based control method and system issued to Lotte N. S. Andreasen Struijk.

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Appendix A. Supplementary data

Supplementary material related to this article can be found online at https://doi.org/10.1016/j.ijhcs.2022.102962.

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