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Designing and Analyzing 3D-Printed Personal Steering Controller for Outdoor Electric-Powered Wheelchair Users: A Randomized Controlled Trial on Stroke Patients

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Featured Application: In this clinical study, we highlighted the steering controllers among the issues that are not progressing in the context of electric wheelchairs, and we presented the production of personalized controllers using 3D printing, a relatively new and proper technology for this area.

Abstract: While the physical conditions of stroke patients are diverse, the joystick-type steering controller of the electric-powered wheelchair (EPW) is almost the same, making the user uncomfortable and not fully utilizing the function of the wheelchair. The purpose of this study was to investigate the effects of the EPW steering controller, specifically the so-called joystick type (3DSC; 3D-printed steering controller, conventional steering controllers; CSC), on surface electromyography (sEMG), Wheelchair Skills Test 4.2 (WST), and QUEST 2.0. The participants were 23 hemiplegic stroke patients (14 males and 9 females) (range 40–65 years) recruited from multi-center process. The 3DSC manufacturing process used a scanner (Precision Laser Probe SLP-500) and a modelling program (SOLIDWORKS 2015). The CSC users' muscle activities were generally higher than those of the 3DSC users in both males and females ($p < 0.05$). WST total performance score of CSC is statistically significantly lower than those of 3DSC for both males (3DSC = 49.28 ± 2.19; CSC = 42.85 ± 4.31) ($z = -3.935$; $p < 0.05$) and females (3DSC = 48.17 ± 0.44; CSC = 41.11 ± 0.78) ($z = -1.910$; $p < 0.05$). QUEST 2.0 scores in CSC (male = 2.40 ± 0.70; female = 2.11 ± 0.78) were significantly lower than those of 3DSC (male = 3.50 ± 0.85; female = 2.90 ± 0.51) in effectiveness categories ($p < 0.05$). We suggest that 3DSC contributes to reducing the user's muscle activities and raising the scores of WST performance and QUEST.

Keywords: functional mobility; steering controller; orthotics; usability; wheeled mobility aids; wheelchair transportation

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1. Introduction

The electric-powered wheelchair (EPW) and the steering handle is one of the most common mobility systems for people with disabilities such as stroke, cerebral palsy (CP), spinal cord injury (SCI) and others [1]. Although there is a slight difference between electric wheelchairs manufacturers, most types of electric wheelchairs are similar in overall shape and operation, and they are known as safe, easy-to-use, and able to bring users high mobility efficiency [2].

There was a report that EPW's conventional steering control controllers could be inconvenient for disabled people, especially so-called joysticks or handles are even not proper for each user that has an affected upper arm, hand or even functional skills; because every disability has fundamentally different status and strength [3]. Although there were several attempts made to cope with the issues mentioned above or enhance the performance, many users have to still use only one single-bar type controllers, which are the original product type that is released from the factory [4].

The conventional steering controllers (CSC), such as single-bar type controllers mounted in EPWs, could induce not only present inconvenience to some users, but also result in secondary deformation due to long-term use [1]. Motor control problems, spasm, limited range of motion, spasticity, or even painful CP patients may have trouble when using CSC and not be able to perform excellent control. In other words, it may be necessary to use the entire upper extremity muscle or even the muscles of the trunk to move the fingers [5]. This compensatory movement promotes body fatigue and may cause a change in the posture of the user when used for a long time.

Even when using wheelchairs in outdoor contexts, people have to physically and mentally challenge the various road traffic environments rather than indoors. In environments such as curb, speed bumps, curves, ups and downs, continuous small bumps and other hazards would affect the drivers [6]. They may be exposed those issues when driving on electric wheelchairs [7]. The stability of the steering controller could be an important issue because these parts of the EPW that drive with one hand can cause the hand to deviate from the steering wheel depending on the driving environment or even cause it to travel in a completely unintended direction [8].

Postural deformation due to use of CSC in these vulnerable external environments would cause musculoskeletal disorders such as cervical and back pain [6]. Even poor posture due to long-term use of CSC can lead to scoliosis. In particular, scoliosis of the thoracic spine may cause problems of the respiratory system as well as the autonomic nervous system [6].

Although novel technology is emerging, it is not being commercialized due to its high price, low practicality, lack of ease of management, difficulty in maintenance, and small preference of patients. The so-called novel technology or systems in this issue are, lidar-equipped autonomous wheelchairs, a novel eye-gaze-controlled wheelchair system, tongue driving system, robotic power wheelchair, etc. These new technologies would be difficult to spread to existing wheelchair users due to their high prices and low accessibility to supply channels, and challenge to apply on wheelchairs already in the marketplace as a general practice. In terms of appropriate technology, it could be judged that 3D printing might be an efficient method that customize to patients' musculoskeletal circumstances. Exoskeletal gait devices, despite their development over the years, still struggle to replace EPW because of its versatility [9].

Indeed, that the quantitative number of electric wheelchairs related studies for 3D printing has not been long since it has been applied to the rehabilitation medical field [10]. The 3D-printed steering controller (3DSC), designed to compensate for the shortcomings of CSC, could improve the satisfaction of EPW users and the prementioned problems according to the fact that 3DSC has the concept of patient-specific custom-made steering controller, it will require less effort than CSC. Wheelchairs with some of the existing problems that have been solved would be delicately and comfortably controlled by users [11,12]. These benefits will reduce the muscle fatigue of the user and be able to travel more secure by securing a more comprehensive view. It would also be beneficial to prepare for secondary deformities or musculoskeletal disorders caused by using the steering wheelchairs.

This clinical trial aimed to design a 3D-printed custom steering controller for EPW users. Since the functional status of stroke patients is represented by a variety of forms, it is important to identify the usability of controllers from EPWs with aspects using scores obtained from the data on the orthodox basis of clinical research. Many have a desire to apply new technology to their field, and we believe that this research will contribute to this area. We developed 3D-printing-based steering controllers and investigated their clinical efficacy with proven evaluation tools.

2. Methods and Technologies

2.1. Research Design and Procedures

This study was designed as a cross-sectional, prospective, case-control clinical study. All the participants were asked to use CSC and 3DSC through drawing the plastic rods, which contained each number for randomizing turns. Once one's first draw was finished with CSC, the next type of steering controller was addressed 3DSC. After each draw, sEMG sensors were attached to the participants, and they directly entered the power wheelchair skills test field, which is conformed with WST 4.2 regulations. Test participants were asked to drive at the most comfortable positions and angles of their affected arms. There were 20 min of resting time between 3DSC and CSC. The participants finally assessed with the Korean Version of QUEST 2.0. Therefore, final raw data determined as two virtual data groups, 3DSC and CSC.

The surface electromyogram (sEMG) data were measured by Trigno wireless sEMG (Delsys, Boston, MA, USA). We conjugated Wheelchair Skills Test (WST, version 4.2, power chairs, Dalhousie University, Halifax, Nova Scotia, Canada, 2013) ("Wheelchair Skills Program (WSP) Manual and Forms–Wheelchair Skills Program," n.d.) for evaluating outdoor use of electric-powered wheelchair performances. We also assessed an assistive device satisfaction part of the Korean Version of QUEST 2.0 (The Quebec User Evaluation of Satisfaction with assistive Technology 2.0; ©) [13,14] for determining the usability of 3DSC.

This study is preliminarily reviewed and approved by the Institutional Review Board, and the study was conducted according to ethical standards outlined in the Helsinki Declaration. The participants were recruited from the community through advertising, provided voluntary consent, and did not receive financial benefits. There was no disadvantage in giving up the experiment halfway through.

2.2. Participants

Stroke patients diagnosed as hemiplegia from medical doctors participated in this study. Thirty-eight research participants were recruited, and 15 of them were eliminated. The figure was tallied at eight cases of mild diseases such as colds, three people moving to hospitals, and four simple changes. The final participants of this study had 23 people (14 males and nine females) consisting of stroke patients recruited from multi-center; 1 general hospital, rehabilitation centers, a local community healthcare center. This research was conducted with those who understood the study purpose and who agreed to participate in the sessions after reading through the research manual and giving their written consent. General characteristics and medical information were demonstrated (Table 1).

The following inclusion criteria were adopted: (1) informed consent; (2) alert and sufficient cognitive status for the instructions; (3) between <6 months and >12 months at onset of disabilities; (4) more than stage 4 of Brunnstrom Stages of Stroke Recovery (arm and hand); (5) right dominant hand side; (6) no previous experience of customized steering handles.

2.3. Designing and 3D-Printing the 3DSC

Object casting, 3D-scanning, 3D-mechanical modelling, and 3D-printing process were established for making 3DSC. Since every patient showed different grasp patterns and posture, we casted each hand in controlling position from every single subject using cured resin clay (object casting). The resin size was approximately 150% of the volume (oz.) of the subject's target hand, and prehension was performed for 10 s, followed by 3D scanning based on the naturally acquired shape. Most of the measurements were made in the neutral position from anatomical hand posture, but if the deformation has already progressed and it is irreversible, the measurement was made in the posture as it is at the time. The researcher used Precision Laser Probe SLP-500 (SURVEYOR® 3D Laser Probes, LDI) (DarTec-Reverse-Engineering-Service, n.d.) (Figure 1) which is 3D Short-Range Laser/CMM Scanning $+/-$ 0.08 mm (0.003") accuracy and supports 63 mm depth of field, accuracy around 20μm and sampling rate at 75,000 total points per second for reverse engineering on each resin cast

(3D-scanning, Figure 2). We also conduct mechanical modelling with SOLIDWORKS 2015 version (Dassault Systèmes, French) for cutting, shaping, and part designing, including the post reverse design process (3D-mechanical modelling, Figure 3). Stratasys Object Connex350 was used for fabricating and rapid prototyping the final 3DSC handle modelling CAD (computer-aided design) files (3D-printing).

Table 1. Examination of homogeneity for general characteristics of the participants.

Characteristics		**Subjects (n = 23)**	
		Male (n = 14) n **(%) or M ± SD**	**Female (n = 9)** n **(%) or M ± SD**
Age			
	40–49	5 (35.7)	4 (44.4)
	50–59	7 (50.0)	4 (44.4)
	60–65	2 (14.3)	1 (11.1)
Brunnstrom Stages			
	4	8 (57.1)	2 (22.2)
	5	4 (28.6)	6 (66.7)
	6	2 (14.3)	1 (11.1)
Paretic Arm			
	Left	3 (21.4)	1 (11.1)
	Right	9 (64.3)	8 (88.9)
	Both	2 (14.3)	0 (0)
Vascular Territories			
	ACA	4 (28.6)	2 (22.2)
	MCA	9 (64.3)	5 (55.6)
	PCA	0 (0)	1 (11.1)
	BA	1 (7.1)	1 (11.1)
Stroke types			
	Hemorrhage	4 (28.6)	3 (33.3)
	Infarction	10 (71.4)	6 (66.7)
MMSE-K	Score	27.18 ± 1.47	26.17 ± 1.13

M: mean; SD: standard deviation; ACA: anterior cerebral artery; MCA: middle cerebral artery; PCA: posterior cerebral artery; BA: basilar artery; MMSE-K: mini-mental state examination; Korean version.

Figure 1. Precision laser probe 3D scanning.

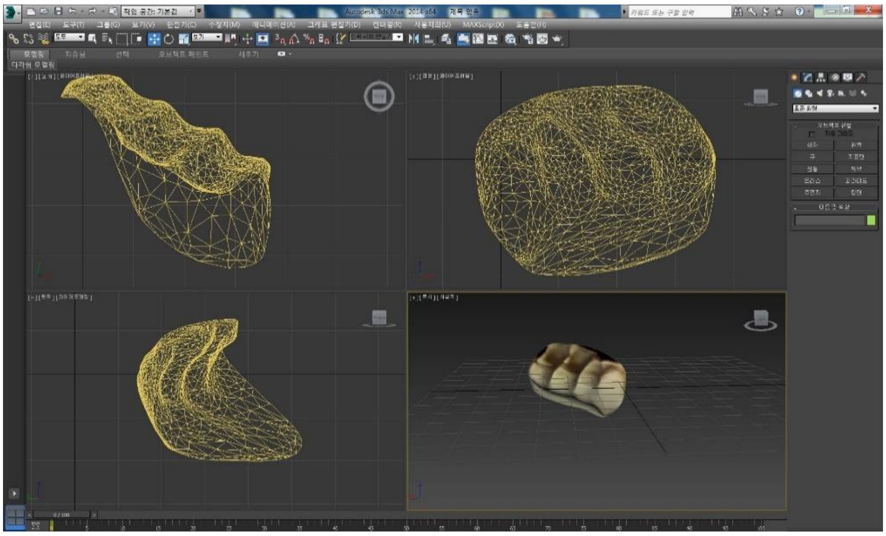

Figure 2. Casting hand grasp formation and 3D scanning.

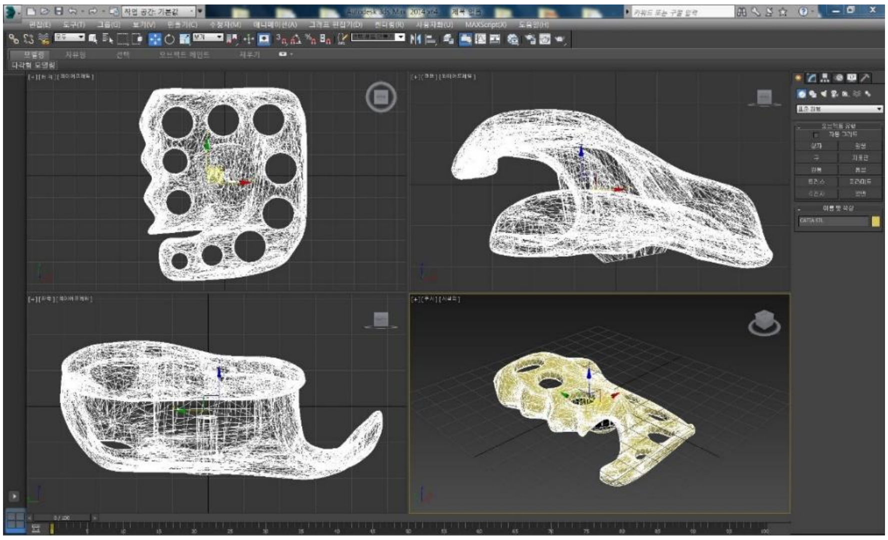

Figure 3. Designing and modelling for 3D printing process of steering controller.

The printing duration for each STL file produced in the 3D modeling phase averaged 4.5 h, representing a layering thickness with an average in 0.3 mm, 40% of stacking density. The injection diameter was 0.3 mm in size and 421 g of ABS resin was consumed for the manufacturing of the subjects. The ABS resin used in the trial is styrene resin, consists of acrylonitrile, poly-butadiene, and styrene.

Most wheelchairs provided by the Ministry of Health and Welfare, a government-affiliated organization in South Korea, follow the VR-2 joystick module and R-net joystick module system, and these joystick mounting bars have common dimensions of 4.0–4.5 mm in diameter and 16.0–17.0 mm in length. Whenever 3DSC was manufactured, the hole size could be easily applied with the basic tolerance within 0.3 mm.

The researchers employed chemicals process (fumigating with dimethylglyoxime 1% ethanol) on printed outputs and performed post-processing to smooth the surfaces of the parts in contact with the human body. In the case of commercialized products are developed in the future, additional layers of other materials would be considered, on the contrary to this, in this experiment, we solely accepted 3D printing materials aimed of minimizing the impact from confounding variables on experiments.

Participants in the experiment had to give time to adapt to controllers built in a new method, we gave them a total of five days of experience in use.

2.4. Driving Test Modules

All the driving trials were made at the Disability Experience Center in National Rehabilitation Center (NRC). The driving modules that reproduced the actual road conditions provides as state-run facilities. We conducted every test under safe supervision of three agents. A total of four simulation modules were adapted; (a) speed bumps, braille beam block, general-purpose road curb, (b) ramps of similar standards to those installed in Korean public institutions and outdoors, (c) various types of flooring panels with different materials and roughness; and (d) general curve reflecting road conditions in Korea. The experiment was accomplished on the same path in each situation of equipped with CSC and 3 DSS. All the trials were carried out under the supervision of at least three safety personnel (Figure 4).

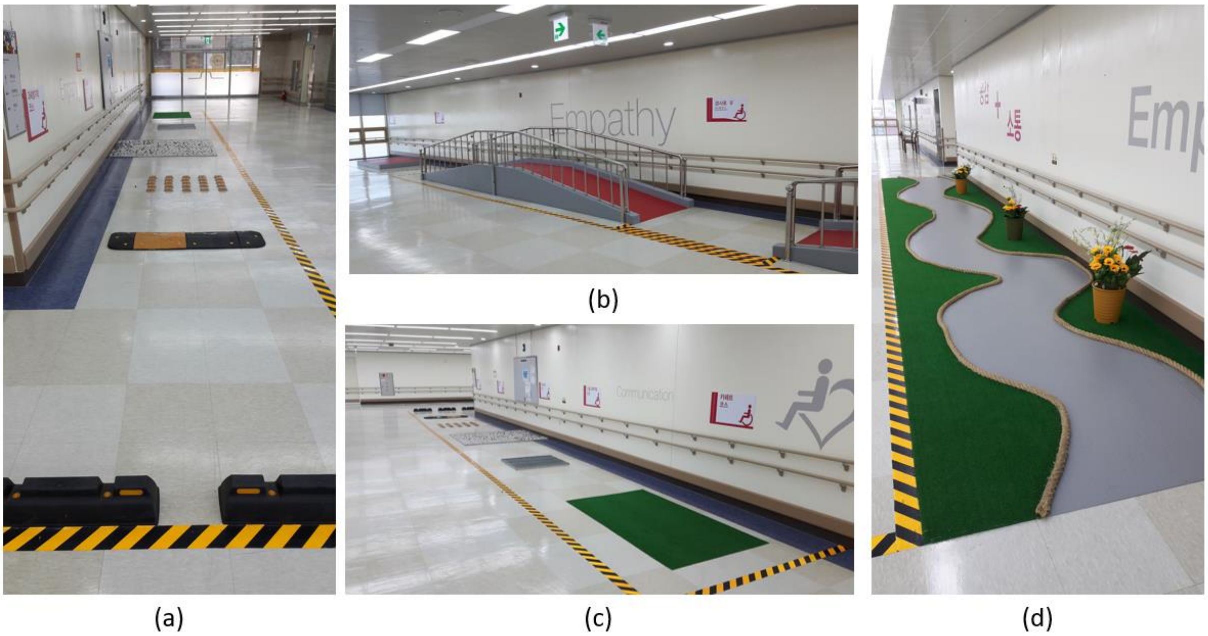

Figure 4. (**a**) speed bumps, braille beam block, general-purpose road curb; (**b**) ramps of similar standards to those installed in Korean public institutions and out-doors; (**c**) various types of flooring panels with different materials and roughness; and (**d**) general curve reflecting road conditions.

2.5. Clinical Evaluation Tools

2.5.1. sEMG

Surface electromyography (sEMG) data were measured by Trigno wireless EMG (Delsys, Boston, MA, USA), bipolar electrodes (Ag/AgCl), a pre-gelled diameter of 20 mm, and the inter-electrode distance was around 3 cm. The essential raw EMG signals were sampled at 1000 Hz and were handled into a root mean square (RMS) with a window of 50 ms. A bandpass filter of 20–450 Hz was used together with notch filters at 60 Hz. Every muscle was measured by RMS of a 5 s for normalization of sEMG data collected from the maximal voluntary isometric contraction (MVIC) for the muscles at the manual muscle test-position, followed by Kendall and McCreary (2005) [14].

Collected raw data were presented by 60 Hz bandwidth according to the phase definitions for drinking tasks modified for the trial. Single sEMG makers were attached to upper trapezius, deltoid middle part, biceps brachii, triceps brachii, extensor carpi radialis longus.

2.5.2. WST

The WST 4.2 was intended for manual or powered wheelchairs, operated by wheelchair users or caregivers. Throughout the WST Manual, to simplify descriptions, it has been assumed that the wheelchair being used, whether manual or powered in type, is one with rear-wheel drive, i.e., large diameter wheels in back and smaller diameter swivel casters in front [15]. We use WST as "Powered Wheelchairs Operated by Their Users". Once the first draw was finished, the next steering controller was addressed after 20 min for the rest. Three occupational therapists with more than ten years of clinical experience conducted all the assessments. After more than five meetings before the evaluation, they discussed every process to make it a more reasonable and equal assessment.

2.5.3. Assistive Device Satisfaction Part of the Korean Version of QUEST 2.0

The Korean version of QUEST 2.0 was developed as an outcome measurement test to evaluate a person's satisfaction with a wide range of assistive technology devices (ATD). Intended to serve as a clinical and research instrument, this rating scale provides practitioners with a means of collecting satisfaction data to document the real-life benefits of ATD and to justify the need for it. QUEST 2.0 has become vital outcome assessment to capture user satisfaction in the field of assistive technology. The approach and outcome of the mediation that the medical team thought might differ from what the patient felt and judged, so this point was intended to be accurate.

The Korean version of QUEST 2.0 had been calculated for internal consistency and construct validity. Cronbach's alpha coefficient for internal consistency was 0.702, 0.668, and 0.778 in assistive technology device, assistive technology service, and overall scores of this version of the QUEST [16]. Construct validity of the Korean version of QUEST included translation, back translation, verification committee, test for comprehending instructions. The Correlation coefficient of sub-scales to investigate construct validity was over 0.505, and the significant statistically ($p < 0.01$) [14]. In this study, researchers used only the assistive device satisfaction part inferred from the study and excluded sub-items from service satisfaction questionnaires.

2.6. Data Analysis

Based on the results from our preliminary study on 12 stroke hemiplegic patients, among the data related to the analysis of this study, G*Power 3.0.10 (Franz Faul, Kiel University, Düsseldorf, Germany) was operated and confirmed. At least 22 stroke hemiplegic patients of sample size were recommended (α-error = 0.05, β = 0.05 (power = 95%), effect size = 1.08, drop-out rate = 11%). Considering the drop-out rate, the sample size for this study was selected as 29. Since 6 drop-outs occurred due to patient rejection, change of plan, or other procedures.

Final data was handled with the average values of each evaluation. All the data were statistically analyzed through IBM SPSS 20th ver. software (SPSS Inc., Chicago, IL, USA), and for assessing each section, descriptive statistics and paired t-test were used; the standard deviation of 8% and a two-sided alpha of 0.05 and a power of 0.80. The significance level p-value was set as 0.05 or below. We did not conduct any post-hoc because there was no expectation of significant clinical meanings in sex, age, vascular territories, or even stroke types, but only actual steering manipulation performance was the focus.

3. Results

With CSC and 3DSC, the researchers had carried out all the pretentious experimental procedures (Figures 5 and 6). There were no adverse effects reported or observed during or following intervention. Table 1 shows the homogeneity for the general characteristics of the participants. The assumption of normality was not violated in any data set ($p > 0.05$).

Figure 5. (**a**) Conventional steering controller (CSC); (**b**) Mounted 3D-printed steering controller. (3DSC) (blue part).

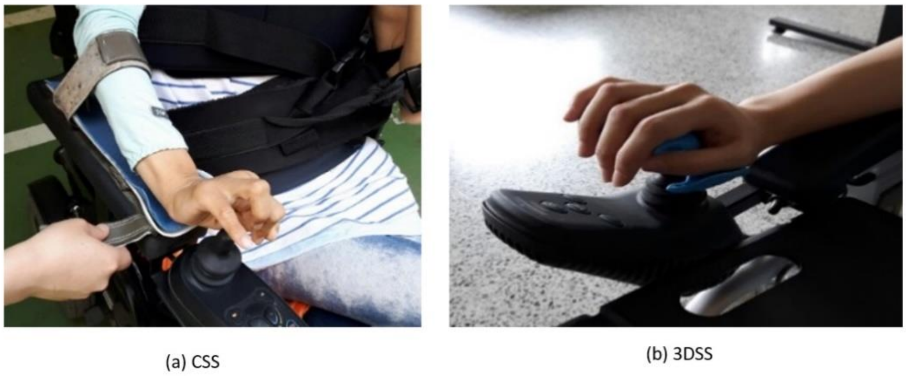

Figure 6. (**a**) Applicating conventional steering controller (CSC); (**b**) Mounted 3D-printed steering. controller (3DSC).

In male (n = 14) muscle activity, 3DSC was higher than CSC in the upper trapezius, but 3DSC was significantly lower than CSC in the deltoid middle, biceps brachii, triceps brachii, and extensor carpi radialis longus. Muscle activity in females (n = 9) was lower in 3DSC than in CSC and significantly lower in triceps brachii and extensor carpi radialis longus ($p < 0.05$) (Table 2). The researchers completed a random double-blind test of men and women and presented it with data in the matter of analyzing the results.

WST performance comparison of males (n = 14), the total scores of 3DSC were significantly higher than those of CSC. Specifically, rolls backwards (2 m) and maneuvers sideways (0.5 m) of 3DSC were significantly lower than those of CSC. However, the 'Avoids moving obstacles, descends 5° incline, Rolls across side-slope (5°), Gets over gap (15 cm) and Descends low curb (5 cm)' of 3DSC were significantly higher than those of CSC. In the other variables, no significant differences were found between groups. In the WST performance comparison of females (n = 9), all variables of 3DSC except for 'Selects drive modes and speeds' and 'Turns in place (180°)' were higher than CSC. Among these values, 3DSC's 'Maneuvers sideways (0.5 m), Reaches high object (1.5 m), Avoids moving obstacles, ascends 10° incline, Rolls on soft surface (2 m), Gets over gap (15 cm) and Ascends low curb (5 cm)' were significantly higher than those of CSC ($p < 0.05$) (Tables 3 and 4).

QUEST 2.0 in male (n = 14) scores showed 'adjustments, safety, easy to use, comfortable, effectiveness' of 3DSC was significantly higher than those of CSC, while 'weight' of 3DSC was significantly lower than those of CSC. There were no statistically significant differences in terms of 'dimension' and 'durability'. For women (n = 9), the QUEST 2.0 scores were significantly higher in the 3DSC's 'dimension, adjustments, safety, comfort, and effectiveness' than in the CSC ($p < 0.05$). There were no significant differences in 'weight, durability, easy to use' (Table 5).

Table 2. Comparison of Muscle Activities (%MVIC) during sEMG measurement.

Target Muscles	3DSC	CSC	t	p
	M ± SD	M ± SD		
Male (n = 14)				
upper trapezius	12.07 ± 2.96	11.14 ± 2.73	−1.129	0.194
deltoid middle part	4.30 ± 1.34	5.12 ± 1.34	−0.103	0.035 *
biceps brachii	2.99 ± 0.73	3.74 ± 0.71	−1.347	0.018 *
triceps brachii	0.95 ± 0.31	1.21 ± 0.72	−1.973	0.053 *
extensor carpi radialis longus	2.21 ± 0.36	2.71 ± 1.19	−1.703	0.019 *
Female (n = 9)				
upper trapezius	9.21 ± 1.64	9.45 ± 2.11	−0.314	0.621
deltoid middle fiber	3.10 ± 0.31	3.89 ± 1.65	−0.183	0.762
biceps brachii	2.65 ± 0.63	2.83 ± 0.71	−1.505	0.218
triceps brachii	0.89 ± 0.51	1.60 ± 1.03	−2.109	0.019 *
extensor carpi radialis longus	1.23 ± 0.34	2.95 ± 1.02	−2.110	0.037 *

MVIC: maximum voluntary isometric contraction; sEMG: surface electromyography; M: mean; SD: standard deviation; 3DSC: 3D-printed steering controller; CSC: conventional steering controller. * $p < 0.05$.

Table 3. Comparison of WST Performances (Version 4.2) in each system-Male (n = 14).

Outcome Assessment	3DSC	CSC	z	p
	M ± SD (n = 14)	M ± SD (n = 14)		
Moves controller away and back	2.00 ± 0.00	1.78 ± 0.57	−1.440	0.150
Selects drive modes and speeds	1.78 ± 0.42	2.00 ± 0.00	−1.800	0.072
Operates body positioning options	1.85 ± 0.36	1.85 ± 0.53	−0.514	0.608
Disengages and engages motors	1.92 ± 0.26	1.57 ± 0.75	−1.516	0.130
Rolls forwards (10 m)	1.85 ± 0.36	1.78 ± 0.57	−0.076	0.940
Rolls backwards (2 m)	1.50 ± 0.51	1.85 ± 0.53	−2.245	0.025 *
Turns while moving forwards (90°)	2.00 ± 0.00	1.92 ± 0.26	−1.000	0.317
Turns while moving backwards (90°)	1.85 ± 0.36	1.71 ± 0.61	−0.552	0.581
Turns in place (180°)	2.00 ± 1.85	1.85 ± 0.36	−1.441	0.150
Maneuvers sideways (0.5 m)	1.85 ± 0.36	0.85 ± 0.77	−3.454	0.001 *
Gets through hinged door	2.00 ± 0.00	1.92 ± 0.26	−1.000	0.317
Reaches high object (1.5 m)	2.00 ± 0.00	1.64 ± 0.74	−1.797	0.072
Rolls 100 m	1.92 ± 0.26	1.64 ± 0.63	−1.484	0.138
Avoids moving obstacles	1.85 ± 0.36	1.55 ± 0.36	−1.000	0.021 *
Ascends 5° incline	2.00 ± 0.00	1.85 ± 0.36	−1.441	0.150
Descends 5° incline	2.00 ± 0.00	1.35 ± 0.84	−2.694	0.007 *
Ascends 10° incline	2.00 ± 0.00	1.78 ± 0.57	−1.440	0.150
Descends 10° incline	1.85 ± 0.36	1.17 ± 0.61	−0.552	0.581
Rolls across side-slope (5°)	2.00 ± 0.00	1.64 ± 0.63	−2.117	0.034 *
Rolls on soft surface (2 m)	1.87 ± 0.36	1.64 ± 0.63	−0.965	0.334
Gets over gap (15 cm)	1.64 ± 0.49	0.57 ± 0.64	−3.601	0.000 *
Gets over threshold (2 cm)	1.92 ± 0.26	1.85 ± 0.36	−0.600	0.549
Ascends low curb (5 cm)	1.71 ± 0.46	1.21 ± 0.69	−1.797	0.072
Descends low curb (5 cm)	2.00 ± 0.00	1.83 ± 0.21	−2.021	0.043 *
WST total scores	49.28 ± 2.19	42.85 ± 4.31	−3.935	0.000 *

WST: wheelchair skills test; M: mean; SD: standard deviation; 3DSC: 3D-printed steering system; CSC: conventional steering controller. * $p < 0.05$.

Table 4. Comparison of the WST Performances (Version 4.2) in each system-Female (n = 9).

Outcome Assessment	3DSC M ± SD (n = 9)	CSC M ± SD (n = 9)	z	p
Moves controller away and back	1.89 ± 0.33	1.56 ± 0.73	−1.156	0.248
Selects drive modes and speeds	1.78 ± 0.44	1.78 ± 0.44	0.000	1.000
Operates body positioning options	1.89 ± 0.33	1.78 ± 0.67	−0.081	0.936
Disengages and engages motors	1.89 ± 0.33	1.56 ± 0.73	−1.156	0.248
Rolls forwards (10 m)	1.89 ± 0.33	1.67 ± 0.71	−0.680	0.496
Rolls backwards (2 m)	1.67 ± 0.50	1.44 ± 0.88	−0.338	0.750
Turns while moving forwards (90°)	2.00 ± 0.00	1.89 ± 0.33	−1.000	0.317
Turns while moving backwards (90°)	1.78 ± 0.44	1.56 ± 0.73	−0.620	0.535
Turns in place (180°)	1.67 ± 0.71	1.67 ± 0.71	0.000	1.000
Maneuvers sideways (0.5 m)	1.81 ± 0.14	1.02 ± 0.67	−1.910	0.026 *
Gets through hinged door	1.89 ± 0.33	1.78 ± 0.44	−0.615	0.539
Reaches high object (1.5 m)	2.00 ± 0.00	1.33 ± 0.87	−1.837	0.029 *
Rolls 100 m	1.78 ± 0.44	1.56 ± 0.53	−0.511	0.331
Avoids moving obstacles	1.78 ± 0.44	0.72 ± 0.34	−3.101	0.000 *
Ascends 5° incline	2.35 ± 0.20	1.56 ± 0.73	−1.458	0.066
Descends 5° incline	1.89 ± 0.33	1.56 ± 0.53	−1.102	0.125
Ascends 10° incline	2.00 ± 0.00	1.33 ± 0.87	−1.837	0.029 *
Descends 10° incline	1.89 ± 0.33	1.56 ± 0.73	−1.156	0.248
Rolls across side-slope (5°)	2.00 ± 0.00	1.56 ± 0.73	−1.837	0.066
Rolls on soft surface (2 m)	1.89 ± 0.53	1.00 ± 0.87	−1.627	0.015 *
Gets over gap (15 cm)	1.67 ± 0.50	0.61 ± 0.71	−2.692	0.007 *
Gets over threshold (2 cm)	1.73 ± 0.41	1.67 ± 0.50	−0.511	0.609
Ascends low curb (5 cm)	1.89 ± 0.33	1.21 ± 0.43	−1.627	0.039 *
Descends low curb (5 cm)	1.67 ± 0.50	1.22 ± 0.67	−1.491	0.136
WST total scores	48.17 ± 0.44	41.11 ± 0.78	−1.910	0.047 *

WST: wheelchair skills test; M: mean; SD: standard deviation; 3DSC: 3D-printed steering system; CSC: conventional steering controller. * $p < 0.05$.

Table 5. Comparison of the QUEST 2.0 scores.

Subcategories	3DSC M ± SD (n = 23)	CSC M ± SD (n = 23)	t	p
Male (n = 14)				
dimension	2.50 ± 0.53	2.70 ± 0.87	−1.00	0.317
weight	2.90 ± 0.88	3.40 ± 0.70	−2.24	0.025 *
adjustments	2.80 ± 0.79	2.00 ± 0.82	−2.27	0.023 *
safety	3.20 ± 0.78	1.70 ± 0.67	−2.71	0.007 *
durability	3.30 ± 0.82	2.60 ± 1.43	−1.33	0.185
easy to use	3.90 ± 0.88	1.90 ± 0.81	−2.62	0.009 *
comfortable	3.80 ± 0.92	2.30 ± 0.67	−2.60	0.008 *
effectiveness	3.50 ± 0.85	2.40 ± 0.70	−2.21	0.027 *
Female (n = 9)				
dimension	2.91 ± 0.88	2.70 ± 0.87	−2.62	0.009 *
weight	1.90 ± 0.82	1.70 ± 0.63	−1.79	0.196
adjustments	3.90 ± 0.75	2.10 ± 0.81	−2.14	0.002 *
safety	3.90 ± 0.82	2.70 ± 0.87	−2.50	0.009 *
durability	3.20 ± 0.78	2.60 ± 1.43	−1.71	0.097
easy to use	3.70 ± 0.98	2.10 ± 0.81	−2.18	0.017 *
comfortable	3.80 ± 0.59	2.10 ± 0.61	−2.97	0.003 *
effectiveness	2.90 ± 0.51	2.11 ± 0.78	−2.02	0.018 *

MVIC: maximum voluntary isometric contraction; sEMG: surface electromyography; M: mean; SD: standard deviation; 3DSC: 3D-printed steering controller; CSC: conventional steering controller. * $p < 0.05$.

4. Discussion

This study suggests that 3DSC contributes to reducing muscle activity in upper limb muscles and increasing total scores in 'WST Performance 4.2' and 'QUEST 2.0'. In both men and women, the 3DSC users' muscle activities were generally lower than those of the CSC users. There was no significant difference between the groups, both men and women, in the activity of the upper trapezius. The reason for this is probably that the use of 3DSC or CSC is related to the activity of the upper trapezius [17], however, the degree of impact is weak. Moreover, subjects will be able to grasp custom 3DSC more easily than CSC. In this process, 3DSC recruit less motor units than CSC, reducing muscle fatigue [18], and this will allow more delicate and accurate control of 3DSC.

Wheelchair driving has been reported to differ greatly from gender, even if it is an use in affected side of upper extremities [6]. Since the strength, overall height and body size of male are higher than female, these aspects also affect wheelchair driving. In this study, the results of sEMG showed that men had differences in muscle activation in deltoid middle parts, biceps bracii, triceps bracii, and extensor carpi radialis longus compared to women. For those reasons, there were similar reports of working with ordinary male on wheelchair-guided outdoor driving capabilities compared with elite female individuals [19]. In this research, stroke male showed overwhelming differences in ability to maintain position the body shaking, arm and hand coordination, which was occurred when climbing bumps, turns, curves and slopes. We assumed this disparity would affect the results and other unexpected portion.

Reflecting on the benefits of this 3DSC, the WST performance score is statistically significantly higher than CSC for both males and females. The reason for this is probably that 3DSC is more manipulative and demonstrates better task performance than CSC. It is assumed that 3DSC users scored better than CSC users in most of the WST performance [20]. It is also assumed that WST Performance is related to user satisfaction, such as QUEST 2.0 scores. This is because QUEST 2.0 scores in 3DSC were significantly higher than CSC in most categories. Interestingly, it is thought that muscle activation and WST performance and user satisfaction will be closely related [21]. In other words, the low muscle activity of the upper limb muscle allows the user to operate the wheelchair well, and the user's product satisfaction increases when the wheelchair is handled well [22]. This is clinically important because when a wheelchair user can handle a wheelchair well with less muscle strength, this ensures patient satisfaction as well as safety during travel [17,23].

The large number of experimental participants are required for a detailed study that conforms to the subject and content of this study however, the number of samples of subjects was no longer available and could not be prevented from dropping outs due to ethical problems. Moreover, kinetic design, such as three-dimensional motion analysis, might be required, but it was not done in this study remains challenges. This study is a RCT and we were concerned that the massive gap between men and women in wheelchair operation would be so severe that it would have a significant impact on the overall data synthesis process.

We anticipate, based on this result, clinicians may have a basis for prior learning about the issues of clinically applying a new technology called 3D printing, which helped in the clinical decision-making process. Subsequent studies require a more significant larger number of samples and a wider variety of clinical assessment measures to be conducted.

5. Conclusions

More than 50 years have passed since power wheelchairs were used in general, but they have not developed much from their early form, concept, and driving style. The problem with steering handles, one of the most important parts of motorized wheelchairs, is that they are uniformly using the same steering controller compared to different physical conditions for each stroke patient. A patient should not have to fit himself into an electric wheelchair. It is true that 3D printing technology is being commercialized and disseminated well, saving a great deal of time and money in the way it is produced after the production of a traditional mold. In this research, using new techniques, patient-specific steering-handle designs were attempted. For its clinical usefulness, assessment tools, such as sEMG, WST, and QUEST, were used and 3D-printed handles could be driven (lower muscle activity) with less effort and increased patient satisfaction. Future research will require materials, rigidity and long-term tracking, and better design.

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