Using a 3D-Printed Hand Orthosis to Improve Three-Jaw Chuck Hand Function in Individuals With Cervical Spinal Cord Injury: A Feasibility Study

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Abstract—Individuals with cervical spinal cord injury (C-SCI) often use a tenodesis grip to compensate for their hand function deficits. Although clinical evidence confirms that assistive devices can help achieve hand function improvements, the currently available devices have some limitations in terms of their price and accessibility and the difference in the user's muscle strength. Therefore, in this study, we developed a 3D-printed wrist-driven orthosis to improve the gripping effect and tested the feasibility of this device by assessing its functional outcomes. A total of eight participants with hand function impairment due to a C-SCI were enrolled, and a wrist-driven orthosis with a triple four-bar linkage was designed. The hand function of the participants was assessed before and after they wore the orthosis, and the outcomes were assessed using a pinch force test, a dexterity test (Box and block test, BBT), and a Spinal Cord Independence Measure Version III questionnaire. In the results, before the participants wore the device, the pinch force was 0.26 lb. However, after they wore the device, it increased by 1.45 lb. The hand dexterity also increased by 37%. After 2 weeks, the pinch force increased by 1.6 lb and the hand dexterity increased by 78%. However, no significant difference was observed in the self-care ability. The results showed that this 3D-printed device with a triple four-bar linkage for individual with C-SCI improved pinch strength and hand dexterity in these patients, but did not improve their self-care ability. It may help patient in the early stages of C-SCI to learn and use the tenodesis grip easily. However, the usability of the device in daily life needs further research.

Index Terms—3D printing, cervical spinal cord injury, hand function, tenodesis grip, wrist-driven orthosis.

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I. INTRODUCTION

THE global incidence of spinal cord injury (SCI) is 13–163.4 per million individuals [1]. In Taiwan, the incidence of SCI is 2.46 per 10,000 individuals [2]. SCI affects motion and sensory and autonomic nerve functions. It not only results in disability for individuals but also affects their families and society [3], [4]. SCI is graded according to the International Standards for Neurological Classification of Spinal Cord Injury, which were established by the American Spinal Injury Association (ASIA) [5]. Grades ranging from A to E are assigned according to the ASIA Impairment Scale (AIS).

According to a literature review [1], cervical spinal cord injury (C-SCI) is the most common form of SCI, with incomplete tetraplegia being the main type. C-SCI accounts for 52% of all SCI cases in Taiwan [2]. Individuals with C-SCI usually experience difficulties in their activities of daily living (ADLs), such as feeding and grooming, because of their limb and trunk motor and sensory deficits.

Hand function is a critical factor in daily life independence and quality of life [6]. Although C-SCI affects the motor and sensory function of the limbs and trunk, individuals with C-SCI prioritize hand function recovery [7], [8]. The rate of recovery of the motor and sensory function is fast during the first 3 months after injury, but it plateaus 6 months later [9]. Because a considerable increase in the recovery rate of the nervous system is difficult to achieve, clinical interventions are generally performed in a compensatory manner (e.g., tenodesis grip training and assistive devices) [10], [11].

Tenodesis grip is a common grasping method for patients with C-SCI. Flexor muscles that do not perform active movements, such as the flexor pollicis longus, flexor digitorum superficialis, and flexor digitorum profundus, can perform passive grasping movements by actively contracting innervated extensor muscles, such as the extensor carpi radialis brevis and extensor carpi radialis longus, with active wrist extension movement. Although most patients with C-SCI tend to use a tenodesis grip, only 24% perform a key-using task [12]. The key-using task is quite important. It is necessary to have pinch strength during the key-using task. With the limitation of the tenodesis grip, the lateral pinch was the only pinch pattern that could be performed with the tenodesis grip. However,

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Assistive devices, such as universal cuffs and typing sticks, can help patients with C-SCI perform functional tasks. With the advances made in science and technology, various hand assistive devices have been developed. Several studies have evaluated the design and usability of three types of devices: exoskeleton devices [13], soft-wearable devices [14], and 3D-printed devices [15].

Exoskeleton robotic devices with rigid linkages, which mimic bone alignment, can control movements and easily transmit forces. This soft glove-based cable-driven robot provides independent actuation of the hand using a remote actuator assembly [16], [17]. Bos et al. developed a dynamic hand orthosis called SymbiHand, where the user's hand motor intention is decoded by means of surface electromyography, enabling the control of an electrohydraulic pump for actuation [18]. Xiong and Diao [19] reported that the cable-driven rehabilitation devices (CDRDs) can deliver high-intensity training while therapists usually cannot. Additionally, with human-robot interaction techniques, CDRDs are more interesting and motivating to trainees than conventional manual rehabilitation therapies. Lotti et al. [16] developed a hand orthosis with human-machine interfaces capable of sensing musculoskeletal states.

These devices offered many different functions in development of hand orthosis. However, exoskeleton robots are usually heavy, expensive, and difficult to equip with different hand sizes, which is why they are often used only in clinical settings [14], [20]. Soft-wearable devices are usually glovelike devices. They are divided into two types: fabric-based devices [14] and polymer-based devices [21]. Fabric-based devices are soft but entail some hygiene-related problems, whereas polymer-based devices are easier to clean but are less commercialized and researched.

Although several exoskeleton and soft-wearable devices have been developed, they are not accessible to users. This is because these devices are usually expensive, unportable, and uncommercialized. To overcome these barriers, a manufacturing method called 3D printing was introduced. Among the advantages of 3D printing are its customizability, easy manufacturing process, and environmental friendliness [18], [19].

Several devices have been manufactured using 3D printing [15], [22], [23], [24], [25], [26]. For example, Portnova et al. [15] developed a 3D-printed, open-source, wrist-driven orthosis for patients with SCI to improve their functional grip. They highlighted the potential of 3D-printed orthosis applications but did not evaluate the long-term usability of this device after the user is adequately trained in adapting to the device. In another study, McPherson et al. [27] developed an orthosis with a double four-bar linkage and



Fig. 1. Triple four-bar linkages including part A (link 1-2-3-4), part B (link 4-5-6-7) and part C (link 7-8-9-10). Part A and B were guided to complete wrist extension and finger flexion. Part C was guided to complete a movement of griping object in between index finger and thumb.

a motor. This device was sensitive to any change in the movement angle from the wrist to the fingers and could grasp some objects encountered in daily life. The results demonstrated some improvements in the grasping force and function of healthy participants but not in patients with SCI.

"In fact, the hand consists of the wrist, MCP (metacarpophalangeal), PIP (proximal interphalangeal) and DIP (distal interphalangeal) joints. Each joint had its own independent kinematics, but previous devices [15], [24], [25], [26] offered only one or two movement patterns. As a result, the hand movement in previous devices is not as natural as the real hand. In order to improve this problem, the study aimed to create triple four-bar linkages to control the wrist and MCP joint and to add the function of grasping the object, as shown in Figure 1. The triple four-bar joints would make the hand movement more natural as it consisted of the movement of the MCP and PIP joints plus the opposition grasp. Especially in part C, it was an "8" shape four-bar linkage and its characteristic made link 7 and 10 closer. Therefore, it could bring the thumb and distal phalange closer to the grasped object. In addition, to improve the strength of the grasped object for C-SCI, silicone finger cots were added to increase friction during grasping. To accommodate different hand sizes, adjustable finger parts and joints were designed to fit different hands. To confirm performance, we tested the feasibility of a newly developed 3D printed hand orthosis. Therefore, the experiment consisted of two parts. First, we designed and tested a 3D-printed hand orthosis. Second, we evaluated the improvement elicited by this device in hand function and functional independence in daily living and quantified the results with status assessments. Our goal was to confirm whether this 3D-printed hand orthosis can help achieve hand function improvements and functional independence in daily living in individual with C-SCI.

II. MATERIAL AND METHODS

This study was divided into two phases: (1) design and manufacturing of the 3D-printed hand orthosis and (2) a clinical experiment.



Fig. 2. Triple four-bar linkage mechanism (link 1-2-8-9, 5-6-7-8 and 2-3-4-5). Link 1 was fixed (ground link). When link 2 was driven during a wrist extension movement to reduce the angle Θ , links 8 and 9 of the first group in the triple four-bar linkage moved simultaneously and drove links 5, 6, and 7 of the second group. The thumb movement was controlled by link 3, with link 4 providing a connection and transferring the movement of the triple four-bar linkage.

A. Development of the 3D-Printed Hand Orthosis

Patients with C-SCI can passively perform grasping and pinching tasks through a tenodesis grip, but this technique is not practical. 3D-printed hand orthoses can provide external support to the fingers to improve the grasping and pinching performance during a tenodesis grip. These devices can be customized for different hand sizes by installing parts of different sizes. And the devices were controlled by wrist extensor muscle of the participant.

The mechanism of a 3D-printed hand orthosis basically relies on a four-bar linkage, and this technique has been used in some products and in a previous study [10]. The hand contains not only metacarpal joints but also interphalangeal joints. To simulate movement in a normal hand, we designed a triple four-bar linkage, as highlighted by Andrew et al. [27], which can sensitively transfer the wrist movement angle to the finger movement angle. We used the mechanism simulation software Working Model (Design Simulation Technologies, Canton, MI, USA) to simulate and ensure the trajectory and function of the triple four-bar linkage. This triple four-bar linkage included three groups of links: links 1-2-8-9, 5-6-7-8 and 2-3-4-5 (Fig. 2). Four key points in the triple four-bar linkage were used to define anatomical landmarks, including the center of the wrist joint, the metacarpophalangeal joint of the thumb and index finger, and the proximal interphalangeal joints. The lengths of the other links were tested and calculated using the Working Model software.

To allow the 3D-printed hand orthosis to fit the shape of a hand, we scanned a real hand with an iSense 3D scanner (3D Systems, Rock Hill, SC, USA). The hand was fixed at wrist extension at 35° with a three-jaw chuck pinch to obtain a larger grasp force (Fig. 3) [28]. Because patients with C-SCI could not place their hands in the scanning position, we used a single-hand model from healthy individuals and adjusted its size by using the Meshmixer software (Autodesk, San Francisco, CA, USA). To match users with different hand sizes, we asked the participants to naturally lay their hands on the table and then measured their palm widths. Three sizes of hand shells were prefabricated for users with palm widths



Fig. 3. 3D-printed hand orthosis. (a) Hand scanning. (b) The numbers shown indicate the assembly sequence of the hand orthosis. (c) Orthosis with silicone finger cots (arrow indicate).

of 7.5–8.0, 8.0–9.0, and 9.0–9.5 cm, respectively. Although no previous studies have mentioned a special design of the finger pulp to increase the frictional force during grasping, we added silicone finger cots to our device to increase the friction during grasping (Fig. 2c). Kang et al. reported that joint alignment during movement can affect the performance of assistive devices [10]. Therefore, we also used an adjustable prefabricated wrist-driven flexor hinge orthosis (WDFHO) with slot and hole. With many holes to adjust the angle of wrist extension, it was fitted to each subject throughout the experiment by a certified occupational therapist. We fitted each subject from the radial side of the MCP joint to the distal tip of the radial styloid in the index finger.

The hand shells and finger cots used with the 3D-printed hand orthosis were printed using a Flashforge Finder 3D printer (Zhejiang Flashforge 3D Technology, Shenzhen, China). The printing parameters involved a layer thickness of 0.2 mm, a filling density of 15%, a printing speed of 60–80 mm/s, and a printing temperature of 200°C. Transparent acrylic linkages with a thickness of 3 mm were cut using a FLUX Beambox laser cutting machine (The FLUX Team, Taipei, Taiwan). We took approximately 4 h to create the 3D-printed hand device, including the manufacturing and assembly processes. The total production cost was approximately US\$65, and the overall weight of the device was approximately 202 g.

B. Clinical Experiment

This study had a one-group with no device testing prettest and the device testing posttest. To evaluate the usability of



Fig. 4. Flowchart of the clinical evaluations.

our hand orthosis, eight patients with chronic C-SCI meeting the following criteria were included: (1) age between 20 and 65 years, (2) C-SCI onset of at least 6 months, (3) diagnosis of C-SCI with hand function impairment, and (4) muscle strength of the wrist extensor above 3 with manual muscle testing (MMT). The exclusion criteria were as follows: (1) severe hand physical distortion or spasticity (Modified Ashworth Scale score 2), (2) coexisting neurological injuries (e.g., stroke, brain injury, or cerebral palsy), and (3) other unstable medical conditions. Subjects with severe hand deformities or coexisting neurological injuries were excluded because they were not able to control the wrist-controlled orthosis for the neurological injuries well, or a special orthosis had to be designed for the hand physical distortion. The study protocol was approved by the Institutional Review Board of National Yang-Ming University (YM110031F). All participants provided informed consent before participating in the study.

As shown in Table I, the demographic data, SCI level, range of motion, muscle tone, and muscle strength of the hand were recorded before the device was fitted. The SCI level was graded from C3 to C7, with seven patients having ASIA grade A, which meant complete injury. The MMT results indicated a wrist extension muscle strength score above 4 and a finger muscle strength score of 0 among all subjects.

The baseline assessment involved testing without the device, and the posttest assessment was performed with the device worn after proper rest on the same day (Fig. 4). The evaluation included hand function and functional independence. Participants took their own device home to use in daily life for 2 weeks, and the 2-week follow-up assessment was conducted with the device. In addition to hand function and functional independence, the evaluation included the level of satisfaction with the assistive device.

1) Hand Function Assessments:

a) Force: A pinch gauge (AliMed, Dedham, MA, USA) was used to measure the three-jaw chuck pinch force. Pinch gauges are a frequently used clinical assessment tool with

 TABLE I

 BASIC INFORMATION OF THE PARTICIPANTS

Subject	Gender	Age (y/o)	Injury time (year)	Injury level	Impairment scale (AIS)	Wrist extensor (MMT)	Finger flexor (MMT)	Abnormal tension in finger (MAS)
1	М	48	4	C3~5	А	5	0	1
2	Μ	33	7	C5~6	А	5	0	1
3	М	33	7	C6~7	А	4+	0	0
4	Μ	26	10	C5	А	5	0	0
5	М	23	1	C4~6	А	5	0	0
6	F	40	23	C5~7	D	5	0	0
7	F	31	15	C5~6	А	5	0	tightness
8	М	42	26	C4~6	А	5	0	tightness

MMT: manual muscle testing (muscle strength measure); MAS: Modified Ashworth Scale (finger tension measure); AIS: ASIA Impairment Scale.



Fig. 5. (a) Pinch force measurement. (b) Dexterity test.

favorable test-retest and interrater reliability [29]. The participants were asked to sit on a chair or wheelchair and to use their thumb, index finger, and middle finger to pinch. As shown in Fig. 5(a), we helped the participants hold the pinch gauge. In practical observation, the participant with C-SCI was able to complete a task of grasping a small object within ten seconds with the orthosis. To avoid fatigue in the extensor muscle, the time to grasp the object was increased to 20 seconds. The repetition of the three times and one minute trials was granted to have sufficient rest and to expect reasonable results under the average of the three times. The participants started to exert their maximum effort to pinch three times with a 1-min resting period between each trial.

b) Dexterity: The Box and Block Test (BBT) was used to evaluate hand dexterity. This test strongly correlates with daily life independence [30] and is widely used because of its favorable test-retest and interrater reliability [31], [32]. The participants were asked to move one block at a time from one box to another across the midline board, as shown in Fig. 5(b), and a 15-s practice time was provided. The total number of blocks moved in 1 min was calculated as the test score.

c) Functional independence: The Spinal Cord Independence Measure Version III (SCIM-III) questionnaire was used to assess the daily life independence of patients with SCI through interviews [33]. This questionnaire contains three subscales: self-care, respiration and sphincter management, and mobility. Here, the self-care subscale was used to evaluate the self-care abilities of the participants, including feeding, bathing, dressing, and grooming, through interviews or observations. The score of the self-care subscale was then recorded.

2) Statistical Analysis: Because of our small sample size, a nonparametric statistical test was used. The Friedman test



Fig. 6. Pinch force results. *Significant difference between groups (p < .05).

was used to compare the differences of hand function and functional independence within a group at different time points. The Wilcoxon signed-rank test was used to compare the differences in significant difference parameters between the two groups. Descriptive statistics were used to summarize the demographic characteristics and user satisfaction levels with the assistive devices. All statistical analyses were performed using IBM SPSS Statistics 24.0 (IBM, Armonk, NY, USA), and statistical significance was set at .05.

III. RESULTS

A. Hand Pinch Force

The results of the three-jaw chuck pinch force are presented in Fig.6. During the baseline assessment, five patients had a pinch force of 0 lb, and the rest of the patients had pinch forces of 0.5, 0.6, and 1.0 lb, respectively. The average was 0.26 lb at baseline, but it increased to 1.71 lb after the assistive device was worn. During the 2-week follow-up assessment, the average was 1.86 lb. Statistically significant differences (p = .011, .011) were observed, indicating that wearing the assistive device may immediately significantly improve the performance of the three-jaw chuck pinch force. However, no statistically significant difference (p = .066) was observed between the posttest assessment and 2-week follow-up assessment.

B. Dexterity

Regarding the hand dexterity performance, the number of blocks taken within 60 s was 13 ± 3.83 at baseline and 17.75 ± 7.96 in the posttest. During the 2-week follow-up assessment, the number of blocks taken was 23.13 ± 7.26 . A statistically significant difference was observed in hand dexterity between patients wearing the assistive device and patients not wearing the assistive device (baseline) (p = .012, .012), indicating that wearing an assistive device can improve the performance of hand dexterity (Fig.7).

Compared with the posttest assessment, the difference in hand dexterity improvement during the 2-week follow-up assessment was statistically significant (p = .028), indicating that the hand dexterity performance may still improve after 2 weeks.



Fig. 7. BBT results. *Significant difference between groups (p < .05).

 TABLE II

 SCIM-III SELF-CARE SUBSCALE RESULTS

SCIM-Ⅲ item	Baseline	Post-test	Follow-up	p-value
Feeding	1.5 ± 0.54	1.5 ± 0.54	1.5±0.54	N/A
Bathing	1.38 ± 2	1.38 ± 2	1.38 ± 2	N/A
Dressing	1.13 ± 2.48	1.13 ± 2.48	1.13 ± 2.48	N/A
Grooming	1 ± 0.93	1.25 ± 0.71	1.25 ± 0.71	0.135
Total score	5±5.45	5.25 ± 5.29	5.25 ± 5.29	0.135

N/A indicates that the scores were the same, hence precluding any statistical analysis.

C. Functional Independence

The results of the self-care abilities are presented in Table II, which are divided into four items, with a full score of 20 points. The average scores were 5 ± 5.45 , 5.25 ± 5.29 , and 5.25 ± 5.29 points during the baseline, posttest, and 2-week follow-up assessments, respectively.

Among the four items mentioned earlier, the average of grooming was 1 ± 0.93 points at baseline and 1.25 ± 0.71 points after the assistive device was worn during both the posttest and 2-week follow-up assessments. The average scores of the remaining three items were the same as those at baseline. The differences in all items and total scores between groups were not statistically significant.

IV. DISCUSSION

A. Hand Pinch Force

The three-jaw chuck pinch force significantly increased to 1.71 lb (558%) in the posttest assessment and 1.86 lb (615%) in the 2-week follow-up assessment compared with 0.26 lb (100%) at baseline. Kang et al. [10] analyzed the biomechanical parameters of patients with C-SCI by using a commercially available wrist-driven assistive device. They determined that the average three-jaw chuck pinch forces were 0.14 and 1.6 lb without and with the assistive device, respectively. In another study, Portnova et al. [15] examined the effects of a 3D-printed, open-source, wrist-driven orthosis. The results indicated that when the orthosis was used, the three-jaw chuck pinch force of two of the patients increased by 122.2% and 13.3%, respectively. Our results conform with those of previous studies, confirming that the assistive device

helped transfer the force of the wrist extension to the palm and fingers thanks to its mechanism, thereby improving the finger pinch force performance. However, the percentage and value of the increased pinch force of our device were slightly higher than the results of previous studies. This may be attributed to our triple four-bar linkage design, which helped to easily convert wrist extension into a finger grasping action and hence increase the power performance. Compared with a single four-bar linkage design, the movement of our triple four-bar linkage was more similar to finger movement and thus slightly increased the pinch force. However, the trajectory of this linkage and finger movements remain to be investigated in future studies.

No significant difference was observed in the increase of the pinch force between the posttest and 2-week follow-up assessments. According to the relevant literature on the functional recovery of patients with SCI, the functional recovery rate reaches a plateau 9 months after injury [29]. In addition, the pinch force generated with a linkage mechanism was positively correlated with the wrist extension muscle force [10]. In the present study, the wrist extension muscle strength score of the participants was mostly 5 (MMT). Therefore, the changes observed in the pinch force after 2 weeks were likely due to the patients' familiarity with the device rather than changes in muscle strength. During the pinch test, our participants had a finger muscle strength score of 0 (MMT) because of their abnormal hand tension.

B. Dexterity

During the BBT, a significant increase was observed in hand dexterity between patients wearing the assistive device and patients not wearing the assistive device (baseline), increasing by 37% (posttest) and 78% (follow-up), respectively. As indicated in a previous study, during the BBT, patients wearing a 3D-printed wrist-driven orthosis performed better than those not wearing an orthosis [15]. This was mainly because their grasping action became more uniform and stable after using the assistive device. This confirms that wearing an orthosis can immediately improve the hand dexterity performance. In addition to the considerable improvement observed during the BBT, the number of blocks was also larger than that reported in a previous study [15]. This may be attributed to the use of silicone finger cots, which increased the levels of friction at the fingertips and improved the hand dexterity performance.

During our experiment, we observed that most of the participants tended to perform several trials and adjust their angles to pick up the blocks without using the device. Because of the different hand conditions of the participants, the movements made to grasp the blocks were also different, for example, some participants used the lateral side of their flexed thumb joint to increase the contact area or used tension to clamp, a scenario that has also been reported in a previous study [6]. The assistive device fixed and improved the grasping posture, allowing the participants to pick up the blocks more efficiently, hence indicating that our device increased the stability of grasping objects. Although all of our participants performed wrist extension and elbow flexion, they could not perform elbow extension, which may have affected repeated movements in the BBT. However, we observed that they used shoulder movements or gravity as a compensation mechanism, and all of them successfully completed the BBT.

Compared with the posttest assessment, the improvement in hand dexterity during the 2-week follow-up assessment was significant, indicating that hand dexterity was still improved after they took the device home for 2 weeks. This improvement may have been due to the increasing familiarity of the participants with the assistive device after using for several times at home.

C. Self-Care Abilities

The total score of the SCIM-III self-care subscale was 20 points, but the average at baseline was 5 ± 5.45 points. In both the posttest and 2-week follow-up assessments, a score of 5.25 ± 5.29 points was observed. Not only was the difference between groups not significant, but the scores were also significantly low.

The average scores of the items did not change, except for that of grooming, which is presumably attributed to the participants' usage habits and the characteristics of the assessment items. First, the average injury time of our participants was 11.63 ± 8.98 years, and most of them developed their own compensatory techniques or other assistive devices. Second, bathing and dressing require a sensory function and the ability to change posture. However, these functions are impaired in most patients with C-SCI, which is why they still require caregiver help with such ADLs. This may explain why the eating score was the highest among the four items, because eating mainly involves hand manipulation movements, with decreased posture changes and no other movements. Most participants reported using the device about 1 to 2 times a week. Some of our participants indicated that they attempted to use a toothbrush with a thick handle or an electric toothbrush with the orthosis and achieved some improvements in self-care abilities.

Although the 3D-printed hand orthosis considerably improved the hand dexterity of our participants, it did not significantly improve their self-care abilities. Compared with previous studies employing both assessments simultaneously, in our study, no significant improvement was observed in the self-care abilities of our participants with the 3D-printed myoelectric hand orthosis [35]. This was mainly because ADLs mostly require abilities other than hand function, such as trunk balancing and lower-limb muscle strength. Therefore, an improvement in hand dexterity does not fully represent an improvement in self-care abilities. Our device mainly focused on hand movements, which is why it resulted in improved performance in the BBT with relatively simple movements. However, no considerable improvement was observed in ADLs involving more complex movements, which is consistent with the results of previous studies.

D. Comparison of the 3D-Printed Hand Orthosis

Portnova et al. [15] and Kang et al. [10] created hand orthosis with four-bar linkage to help the SCI subject to grip object. Kang et al. also addressed that joint alignment during movement may affect the performance of assistive devices. Due to this, the study did two modifications based on joint alignment and friction of finger. First, the hand device had triple four-bar linkage mechanism to mimic the natural hand movement and transfer the wrist movement sensitively, and adjustable finger parts and linkages to fit different sizes of hand. Previous studies [10], [15] only had one four-bar linkage and not offer adjustment to fit different hand sizes. Second, the silicone finger cots were used to increase friction while grasping. As a result, we added silicon finger cots in hand device and found the greater improvement in pinch force and hand dexterity for the SCI subjects.

Regarding the advantage of the current device, the subjects were satisfied with the weight and size of the device other than the improvement in pinch force and dexterity. All users did not experience skin redness or other discomfort after wearing the assistive device. Regarding the disadvantage of the current device, some users mentioned that the device in this study had many parts, so they concerned about the durability of longterm use. One subject mentioned that the wrist extensor muscle fatigued after holding heavy object (such as a water bottle) for a long time.

E. Limitations

Because this study mainly aimed to examine the feasibility of using a 3D-printed, wrist-driven orthosis, the sample size was small. The interval between the posttest and follow-up was only 2 weeks, which may have affected the duration of use and level of familiarity with the device. Therefore, future studies with larger sample sizes investigating long-term effects are required. In addition, our device was designed for three-jaw chuck movements, but the other hand movements made on a daily basis are rather complicated. Therefore, future studies should consider in other grasping movements such as spherical grasp, tripod grasp, hook grasp, and palmar pinch [32], [33]. Additionally, the volume of the linkages was still bulky for daily use. The mechanism should be more fit to the shape of the hand to reduce the impact in the future work.

V. CONCLUSION

In this study, we used 3D printing technology to develop a wrist-driven orthosis, the advantages of which included its low cost and customizability. When this 3D-printed wrist-driven orthosis was used for 2 weeks, considerable improvements were observed in the three-jaw chuck pinch force and hand dexterity of patients with C-SCI. However, no considerable improvement was observed in their self-care abilities. This study concluded that 3D-printed wrist-driven orthosis with triple four-bar linkage may help early stage of C-SCI to learn and use tenodesis grip easily. However, the different grasping movements and durability of orthosis could be investigated in future study.

REFERENCES

- Y. Kang et al., "Epidemiology of worldwide spinal cord injury: A literature review," *J. Neurorestoratol.*, vol. 6, no. 1, pp. 1–9, 2017.
- [2] J.-C. Wu et al., "Effects of age, gender, and socio-economic status on the incidence of spinal cord injury: An assessment using the elevenyear comprehensive nationwide database of Taiwan," *J. Neurotrauma*, vol. 29, no. 5, pp. 889–897, Mar. 2012.
- [3] Facts and Figures at a Glance, Nat. Spinal Cord Injury Stat. Center, Univ. Alabama at Birmingham, 2020.
- [4] G.-Z. Ning, Q. Wu, Y.-L. Li, and S.-Q. Feng, "Epidemiology of traumatic spinal cord injury in Asia: A systematic review," *J. Spinal Cord Med.*, vol. 35, no. 4, pp. 229–239, Jul. 2012.
- [5] S. C. Kirshblum et al., "International standards for neurological classification of spinal cord injury (revised 2011)," J. Spinal Cord Med., vol. 34, no. 6, pp. 535–546, Nov. 2011.
- [6] L. A. Harvey, J. Batty, R. Jones, and J. Crosbie, "Hand function of C6 and C7 tetraplegics 1–16 years following injury," *Spinal Cord*, vol. 39, no. 1, pp. 37–43, Jan. 2001.
- [7] K. D. Anderson, "Targeting recovery: Priorities of the spinal cordinjured population," *J Neurotrauma*, vol. 21, no. 10, pp. 1371–1383, Oct. 2004.
- [8] G. J. Snoek, M. J. IJzerman, H. J. Hermens, D. Maxwell, and F. Biering-Sorensen, "Survey of the needs of patients with spinal cord injury: Impact and priority for improvement in hand function in tetraplegics," *Spinal Cord*, vol. 42, no. 9, pp. 526–532, Sep. 2004.
- [9] R. L. Waters, R. H. Adkins, J. S. Yakura, and I. Sie, "Motor and sensory recovery following incomplete tetraplegia," *Arch. Phys. Med. Rehabil.*, vol. 75, no. 3, pp. 306–311, Mar. 1994.
- [10] Y.-S. Kang, Y.-G. Park, B.-S. Lee, and H.-S. Park, "Biomechanical evaluation of wrist-driven flexor Hinge orthosis in persons with spinal cord injury," *J. Rehabil. Res. Develop.*, vol. 50, no. 8, pp. 1129–1138, 2013.
- [11] L. Harvey, "Principles of conservative management for a non-orthotic tenodesis grip in tetraplegics," *J. Hand Therapy*, vol. 9, no. 3, pp. 238–242, Jul. 1996.
- [12] H. Y. Jung, J. Lee, and H. I. Shin, "The natural course of passive tenodesis grip in individuals with spinal cord injury with preserved wrist extension power but paralyzed fingers and thumbs," *Spinal Cord*, vol. 56, no. 9, pp. 900–906, Sep. 2018.
- [13] M. Mekki, A. D. Delgado, A. Fry, D. Putrino, and V. Huang, "Robotic rehabilitation and spinal cord injury: A narrative review," *Neurotherapeutics*, vol. 15, no. 3, pp. 604–617, Jul. 2018.
- [14] L. Cappello et al., "Assisting hand function after spinal cord injury with a fabric-based soft robotic glove," *J. NeuroEng. Rehabil.*, vol. 15, no. 1, p. 59, Dec. 2018.
- [15] A. A. Portnova, G. Mukherjee, K. M. Peters, A. Yamane, and K. M. Steele, "Design of a 3D-printed, open-source wrist-driven orthosis for individuals with spinal cord injury," *PLoS ONE*, vol. 13, no. 2, Feb. 2018, Art. no. e0193106.
- [16] N. Lotti et al., "Adaptive model-based myoelectric control for a soft wearable arm exosuit: A new generation of wearable robot control," *IEEE Robot. Autom. Mag.*, vol. 27, no. 1, pp. 43–53, Mar. 2020.
- [17] T. Bützer, O. Lambercy, J. Arata, and R. Gassert, "Fully wearable actuated soft exoskeleton for grasping assistance in everyday activities," *Soft Robot.*, vol. 8, no. 2, pp. 128–143, Apr. 2021.
- [18] R. A. Bos, K. Nizamis, B. F. J. M. Koopman, J. L. Herder, M. Sartori, and D. H. Plettenburg, "A case study with symbihand: An sEMGcontrolled electrohydraulic hand orthosis for individuals with Duchenne muscular dystrophy," *IEEE Trans. Neural Syst. Rehabil. Eng.*, vol. 28, no. 1, pp. 258–266, Jan. 2020.
- [19] H. Xiong and X. Diao, "A review of cable-driven rehabilitation devices," *Disab. Rehabil.*, Assistive Technol., vol. 15, no. 8, pp. 885–897, Nov. 2020.
- [20] A. Mohammadi, J. Lavranos, P. Choong, and D. Oetomo, "Flexoglove: A 3D printed soft exoskeleton robotic glove for impaired hand rehabilitation and assistance," in *Proc. 40th Annu. Int. Conf. IEEE Eng. Med. Biol. Soc.*, Jul. 2018, pp. 2120–2123.
- [21] B. B. Kang, H. Choi, H. Lee, and K.-J. Cho, "Exo-glove poly II: A polymer-based soft wearable robot for the hand with a tendondriven actuation system," *Soft Robot.*, vol. 6, no. 2, pp. 214–227, Apr. 2019.

- [22] T. D. Ngo, A. Kashani, G. Imbalzano, K. T. Q. Nguyen, and D. Hui, "Additive manufacturing (3D printing): A review of materials, methods, applications and challenges," *Compos. B, Eng.*, vol. 143, pp. 172–196, Jun. 2018.
- [23] T. Campbell, C. Williams, O. Ivanova, and B. Garrett, "Could 3D printing change the world? Technologies, potential, and implications of additive manufacturing," Atlantic Council, Washington, DC, USA, Oct. 2011, pp. 1–15.
- [24] K. H. Lee, S. J. Kim, Y. H. Cha, J. L. Kim, D. K. Kim, and S. J. Kim, "Three-dimensional printed prosthesis demonstrates functional improvement in a patient with an amputated thumb: A technical note," *Prosthetics, Orthotics Int.*, vol. 42, no. 1, pp. 107–111, 2018.
- [25] G. Xu et al., "Three-dimensional-printed upper limb prosthesis for a child with traumatic amputation of right wrist: A case report," *Medicine*, vol. 96, no. 52, Dec. 2017, Art. no. e9426.
- [26] T.-Y. Huang, L.-L. H. Pan, W.-W. Yang, L.-Y. Huang, P.-C. Sun, and C.-S. Chen, "Biomechanical evaluation of three-dimensional printed dynamic hand device for patients with chronic stroke," *IEEE Trans. Neural Syst. Rehabil. Eng.*, vol. 27, no. 6, pp. 1246–1252, Jun. 2019.
- [27] A. I. W. McPherson, V. V. Patel, P. R. Downey, A. A. Alvi, M. E. Abbott, and H. S. Stuart, "Motor-augmented wrist-driven orthosis: Flexible grasp assistance for people with spinal cord injury," in *Proc. 42nd Annu. Int. Conf. IEEE Eng. Med. Biol. Soc. (EMBC)*, Jul. 2020, pp. 4936–4940.
- [28] R. H. Brumfield and J. A. Champoux, "A biomechanical study of normal functional wrist motion," *Clin. Orthop. Relat. Res.*, vol. 187, pp. 23–25, Jul./Aug. 1984.

- [29] M. S. V. Mathiowetz, B. S. K. Weber, B. S. G. Volland, and B. S. N. Kashman, "Reliability and validity of grip and pinch strength evaluations," *J. Hand Surg.*, vol. 9, no. 2, pp. 222–226, Mar. 1984.
- [30] M. Franceschini et al., "Predictors of activities of daily living outcomes after upper limb robot-assisted therapy in subacute stroke patients," *PLoS ONE*, vol. 13, no. 2, Feb. 2018, Art. no. e0193235.
- [31] T. Platz, C. Pinkowski, F. van Wijck, I.-H. Kim, P. di Bella, and G. Johnson, "Reliability and validity of arm function assessment with standardized guidelines for the Fugl–Meyer test, action research arm test and box and block test: A multicentre study," *Clin. Rehabil.*, vol. 19, no. 4, pp. 404–411, Jun. 2005.
- [32] V. Mathiowetz, G. Volland, N. Kashman, and K. Weber, "Adult norms for the box and block test of manual dexterity," *Amer. J. Occupat. Therapy*, vol. 39, no. 6, pp. 386–391, Jun. 1985.
- [33] M. Itzkovich et al., "SCIM III (spinal cord independence measure version III): Reliability of assessment by interview and comparison with assessment by observation," *Spinal Cord*, vol. 56, no. 1, pp. 46–51, Jan. 2018.
- [34] T. Feix, J. Romero, H.-B. Schmiedmayer, A. M. Dollar, and D. Kragic, "The GRASP taxonomy of human grasp types," *IEEE Trans. Human-Mach. Syst.*, vol. 46, no. 1, pp. 66–77, Feb. 2016.
- [35] K.-S. Lee and M.-C. Jung, "Common patterns of voluntary grasp types according to object shape, size, and direction," *Int. J. Ind. Ergonom.*, vol. 44, no. 5, pp. 761–768, Sep. 2014.