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TetraGrip – a four channel upper limb FES device for people with C5/C6 tetraplegia: device design and clinical outcome

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Abstract

The TetraGrip is an inertial measurement unit-controlled surface upper limb FES device developed for improving hand functions of people with tetraplegia. The reliability of the control system and the repeatability and reproducibility of the device were assessed by analysing the results obtained when 14 able-bodied volunteers used the device. These volunteers were able to generate the control signals effectively once they had sufficient training. The two tetraplegic volunteers participated in a 12-week long clinical study (exercise, 4 weeks; functional tasks, 8 weeks), where they used the device to perform functional tasks. Outcome measures used were the grasp release test, the grip strength test, and the box and block test. Both tetraplegic volunteers showed improvement in performing the tasks specified in all outcome measures. The TetraGrip performed as intended when the able-bodied volunteers used it, and it improved the hand functions of both volunteers with tetraplegia. However, a larger clinical study is necessary to assess the performance of the device with a wider range of people with tetraplegia such as those with C5 complete/incomplete.

KEYWORDS

Activities of daily living; functional electrical stimulation; inertial measurement unit; outcome measures; spinal cord injuries; tetraplegia

1. Background

Tetraplegia is a condition where a person loses functions of all four limbs as a result of injury to the spinal cord in the cervical region. However, the level and completeness of the injury determines the amount of residual hand and arm function available. If nerves supplying the target muscle are intact below the level of the spinal cord injury (SCI) then functional electrical stimulation (FES) can be used to improve the hand function. FES is the technique of applying electrical current to a group of muscles through the use of electrodes in order to achieve functional movements. It is widely used for the upper limb rehabilitation of people with hemiplegia (stroke) and tetraplegia [1–3].

A detailed literature review has revealed several upper limb FES devices that have been successfully used to improve the hand and arm functions of people with tetraplegia [4–7]. Some of these devices were made commercially available, and two devices, the NeuroControl[®] Freehand System and the NESS H200, were approved by the US food and drug administration

(FDA [3,8]). However, the NeuroControl[®] Freehand system is no longer marketed, and the NESS H200 uses a rigid arm splint to hold the electrodes in position which limits the number of users who can use it to achieve functional movements [3]. Recently, MyndMove (MyndTech, Canada) has been made commercially available [9], but there was not enough clinical evidence to assess if the device improved the hand functions in people with tetraplegia.

Hence, a new four channel upper limb FES device, called the TetraGrip, was developed to improve the hand functions of people with C5/C6 tetraplegia. The device design and the outcome of the clinical study performed using this device is presented in this article.

2. Device design

The TetraGrip is a four-channel surface FES device controlled using an inertial measurement unit (IMU) strapped across the contralateral shoulder. The IMU used here was the NanoWii quadcopter controller, and it was

used to detect the change in shoulder position. The shoulder movements used to control the

Stimulator state control signal	Idle	Locked	Unlocked
Single shoulder elevation	Key grip	Unlock	Lock
Two shoulder Elevations (3 s apart)	Palmar grasp	Stop	Lock
Shoulder protraction	N/A	N/A	Tighten grasp
Shoulder retraction	N/A	N/A	Loosen grasp

Shoulder elevation signal was generated by performing a movement that resembles a quick shoulder shrug. This signal appeared as a spike in the accelerometer and the gyroscope signals. The shoulder protraction and retraction, on the other hand, were gradual forward and backward movement of the shoulder. This movement resulted in a change in the accelerometer z-axis signal that resembled a sinusoidal wave. Table 1 summarises the control signals used to

TetraGrip were elevation, protraction, and retraction.

contraction of the desired upper limb muscles required to perform either key grip or palmar grasp.

The device was programmed to perform key grip and palmar grasp operations. Additionally, an exercise mode was also available which alternated between

operate the TetraGrip, and Figures 1 and 2 presents the change in the IMU signals that were used to identify the generation of the control signals.

The heart of the device was an Arduino Mega, which monitored the change in signals from the IMU and controlled the operation of the output unit. The output unit consisted of four single channel FES devices (Odstock[®] StimEngines) and were named Channel 1, Channel 2, Channel 3, and Channel 4. The Arduino Mega switched on the channels in a particular sequence when it detected a control signal. This sequential switching of the channels resulted in the

Table 1. Control signals used to operate the TetraGrip.

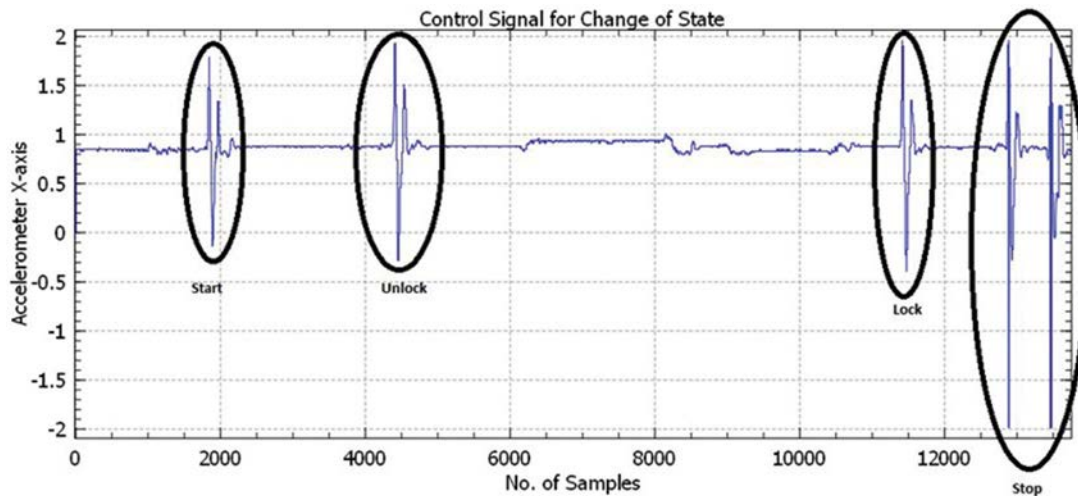


Figure 1. Change in the IMU when shoulder elevations were performed.

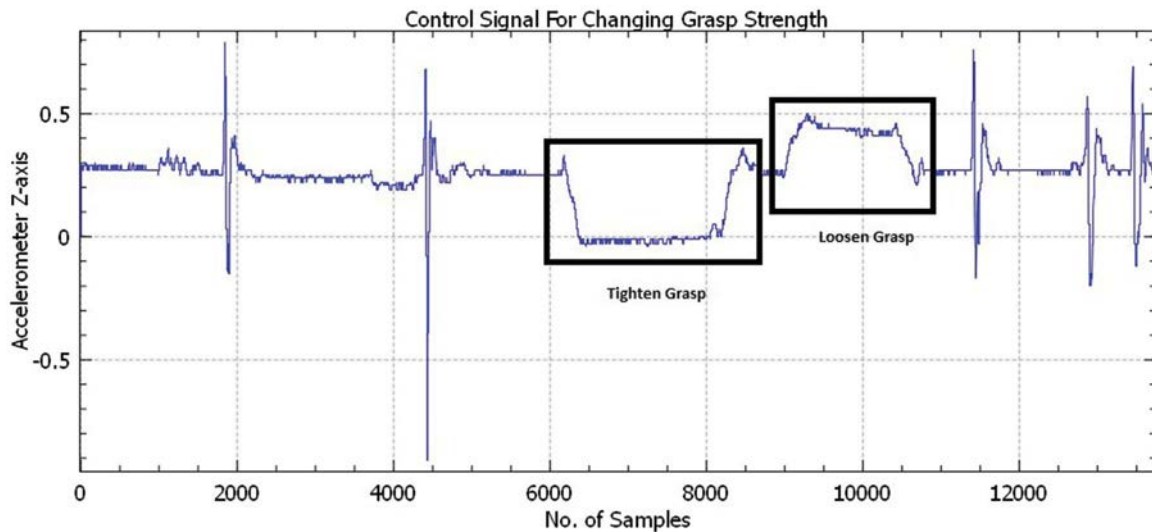


Figure 2. Change in the IMU signal when shoulder protraction and retraction was performed.

the key grip and palmar grasp movements. For key grip, Channel 1, Channel 2 and Channel 4 delivered the stimulation. Channel 1 was connected to the extensor digitorum communis (EDC), Channel 2 was connected to flexor digitorum superficialis/profundus (FDS/FDP), and Channel 4 was connected to adductor pollicis brevis (APB). For palmar grasp, the connections for Channel 1 and Channel 2 remained unchanged, and Channel 3 was connected to opponens pollicis (OP).

The stimulation parameters such as the current, pulse width, frequency, and the duration of stimulation were entered for each user with the help of RealTerm serial monitor. Once all parameters were entered, the system entered the “idle” state; where, it continuously monitored the generation of the control signal. If the system detected a start signal (refer to Table 1), the device entered the functional mode (key grip or palmar grasp depending upon the start signal detected). The system entered the “locked” state once all stimulation parameters reached their target values. In this state, it delivered the stimulation based on the entered value of parameters. The system entered the “unlocked” state when the corresponding control signal (refer to Table 1) was generated. Grip strength could be altered by either protracting or retracting the shoulder when the system was unlocked. This allowed the user to dynamically modify their grasp while the system was still in a functional mode. In order to stop stimulation, corresponding control signal was recognised by the system only when it was locked. If the user had unlocked the

system to modify the grasp then they were required to lock the system first and then generate the control signal to terminate the stimulation. Figures 3 and 4 illustrate the stimulation envelopes used to generate functional key grip and palmar grasp movements.

3. Methodology

To evaluate if the device was working as intended, 14 able-bodied volunteers donned the device and generated the required control signals to operate it. The device tracked the number of successful attempts, and the researcher tracked the actual number of attempts by the volunteer manually. The volunteers performed these tests on three different days (Day 1, Day 2, and Day 3), and the percentage error between the total number of attempts and the number of successful attempts was calculated for the results obtained on each day. A comparison between the percentage errors on Day 1 and Day 3 provided information on false triggers and learning effect.

Once the device was satisfactorily working, 10 tetraplegic volunteers were invited to participate in a 12week long clinical study and 2 agreed to participate. The volunteers used an Odstock Microstim 2v2 [10] for the first 4 weeks in order to exercise the required muscles. For the next eight weeks, they came once a week to the National Clinical FES Centre, Salisbury, UK and used the TetraGrip functionally to perform the tasks specified in the outcome measures. They

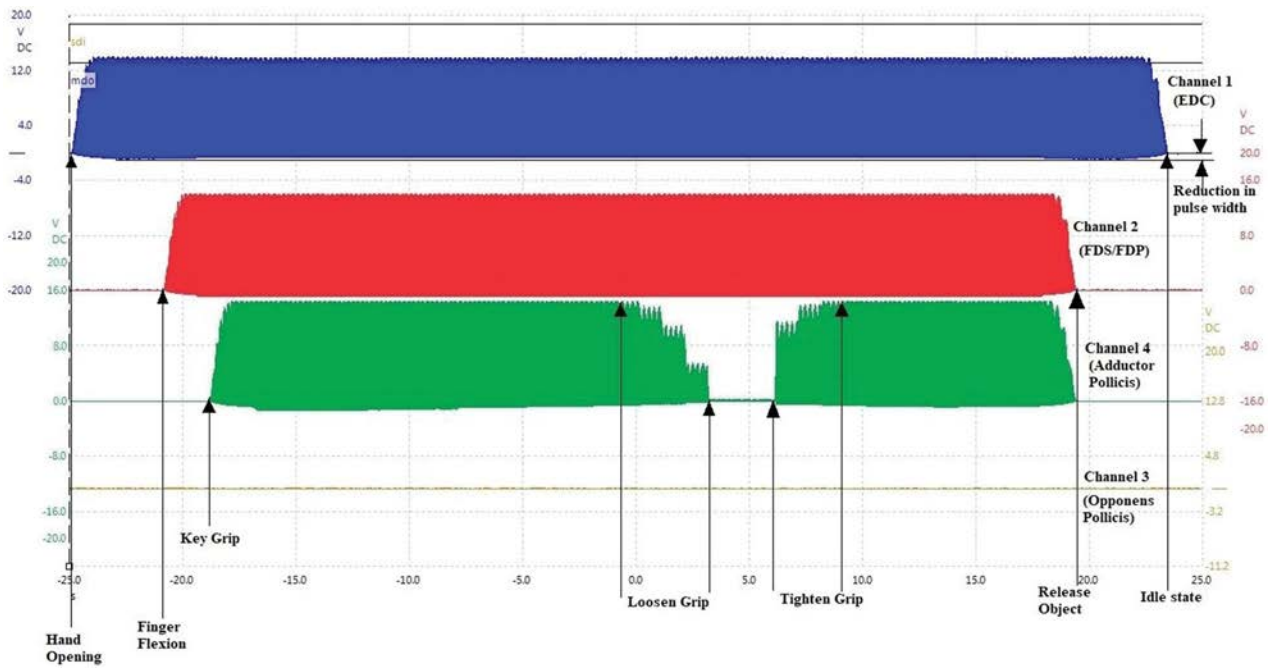


Figure 3. Stimulation Envelope for generating the key grip movement.

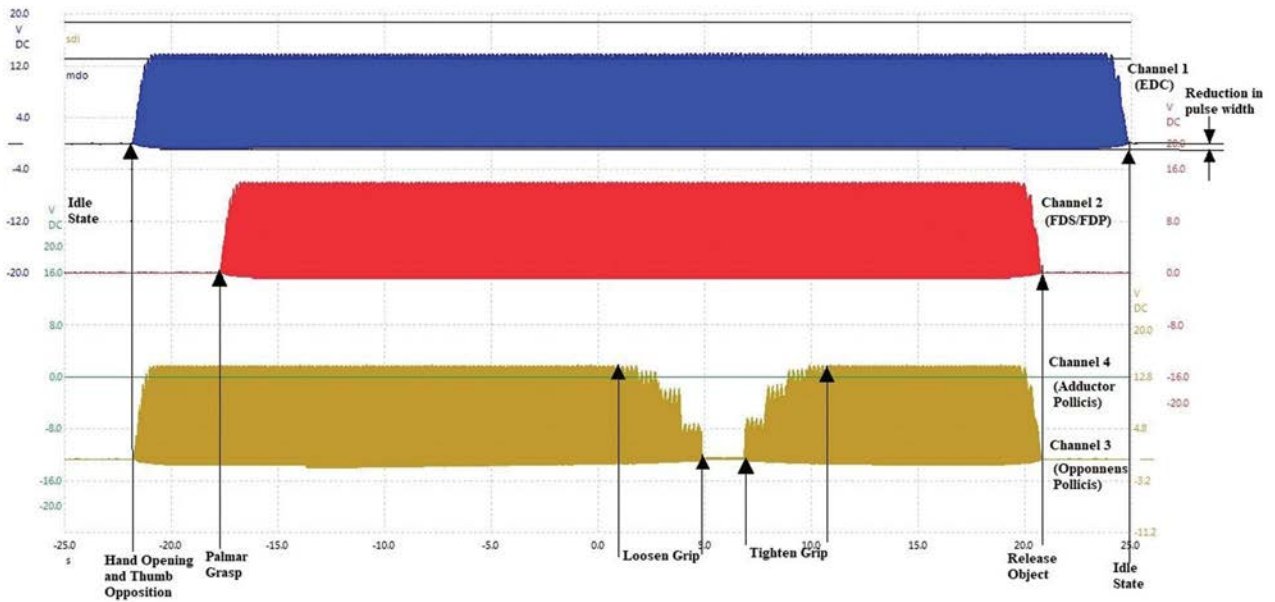


Figure 4. Stimulation Envelope for generating the palmar grasp movement.

Table 2. GRT Scores for both volunteers.

Tasks	Week 7				Week 8				Week 9				Week 10				Week 11				Week 12			
	V1		V2		V1		V2		V1		V2		V1		V2		V1		V2		V1		V2	
	FES	NS	FES	NS	FES	NS	FES	NS	FES	NS	FES	NS	FES	NS	FES	NS	FES	NS	FES	NS	FES	NS	FES	NS
Pegs			12	14			12	17	5	15	14	20	6	16	13	20	8	15	12	23	9	20	13	22
Weight			4	0			2	0	2	0	8	0	2	1	8	0	0	0	8	0	2	0	13	0
Fork			0	0			0	0	1	0	3	0	0	0	5	0	3	0	9	0	0	0	14	0
Blocks			8	11			11	14	4	14	7	14	11	5	12	20	6	11	13	21	11	10	15	22
Cans			7	15			9	4	5	10	8	13	4	3	10	18	5	8	13	20	10	8	11	23
Video tapes			0	0			5	2	3	2	5	4	2	3	7	9	8	4	10	9	4	3	9	6

continued their exercise regime for the rest of the week using Odstock Microstim 2v2. The outcome measures used for this study were the grip strength test, the box and block test, and the grasp release test.

3.1. The grip strength test

This test was used to record the change in the grasp strength in Newtons both with and without the use of FES. A modified Jamar pinch metre was used for recording the force exerted by the volunteer. This outcome measure was used to monitor any improvement in the user's ability to grasp after regular use of FES [4].

3.2. The box and block test

This test was used to assess improvement (if any) in the manual dexterity of the volunteer [11]. In this study, it was used to assess if there was any improvement in the volunteer's ability, after receiving FES therapy, in performing tasks that requires picking and releasing objects. The box and block test kit were used for this outcome measure. This test required the user to move maximum number of blocks from one compartment to another within 60s. The user allowed a trial for 15s before beginning the actual test. The box is placed length-wise in front of the user's midline with the compartment holding the blocks towards the hand being tested. This test requires the user's fingertips to cross the partition while transferring the blocks, and they are not required to pick up the blocks that fall outside the box.

3.3. The grasp release test

The Grasp Release Test (GRT) is an outcome measure consisting of six tasks, three requiring key grip and three requiring palmar grasp [4]. The tasks using key grip included pegs, weights, and forks, and the tasks using palmar grasp involved blocks, cans, and video tapes. These tasks were performed both with and without FES, and the total number of times each task was repeated in 30s were recorded. This outcome measure was used to monitor any improvement in the user's ability in performing tasks using key grip and palmar grasp after receiving FES.

4. Results

4.1. Ethics

This research work was reviewed and approved by the research ethics committee, the faculty of science and technology, Bournemouth University. The reference number for this application was 6690, and it was approved on April 14, 2015.

4.2. Study involving able-bodied volunteers

Of the 14 able-bodied volunteers who participated in the study, nine volunteers completed the study; and, five volunteers were unable to complete the study due to their work commitments.

4.3. Study involving tetraplegic volunteers

The volunteers used the device for the first time on Day 1, and the percentage errors ranged between 2.5% and 23.6% for the key grip control signals and between 7.7% and 24.2% for the palmar grasp control signals. The

percentage error on Day 3 ranged between 1.4% and 10.9% for the key grip control signals and between 2.1% and 15.1% for the palmar grasp control signals. One volunteer had difficulty in performing the slow shoulder protraction on Day 3, and the connector connecting the IMU to the device had a breakdown issue on Day 3 which was detected after the user attempted a few unlock signals. This increased the percentage error on Day 3. Overall, the system performed as indicated, and no adverse events were observed during this study.

When the tetraplegic volunteers used the device, it was observed that the grip strength for both key grip and palmar grasp for both volunteers improved. For Volunteer 1, the key grip strength ranged between 1.91 N and 3.21 N without FES, and it ranged between 6.54 N and 8.16 N while using the TetraGrip in the key grip mode. The palmar grasp strength for Volunteer 1 between 0.21 N and 1.91 N without FES, and it ranged between 4.09 N and 9.59 N when the TetraGrip was used in the palmar grasp mode. For Volunteer 2, the key grip strength ranged between 0.65 N and 3.27 N without FES and between 3.54 N and 13.08 N when the TetraGrip was used in the key grip mode. The palmar grasp strength for Volunteer 2 ranged between 0.11 N and 1.74 N without FES and between 4.63 N and 16.62 N when the TetraGrip was used in the palmar grasp mode.

The box and block score for Volunteer 1 ranged between 9 and 20 and that for Volunteer 2 ranged between 25 and 33.

Both volunteers attempted all tasks specified in the grasp release test (GRT). Volunteer 1 attempted these tasks from Week 9 of the clinical study till Week 12. This was because he required additional exercise sessions to strengthen the muscles in order to achieve functional key grip and rasp movements. The overall GRT score with FES, which was the summation of scores achieved in the

individual tasks performed in one clinical session, improved from 20 on Week 9 to 36 on Week 12. Volunteer 2 attempted the tasks specified in GRT from Week 7 till Week 12 of the study, The overall GRT score with FES for Volunteer 2 improved from 31 on Week 7 to 75 on Week 12. The scores obtained by both volunteers while performing the tasks specified in the GRT are summarised in Table 2 and Figure 5 summarises the GRT score for both volunteers.

5. Discussion

The TetraGrip is a four-channel upper limb FES device programmed to generate waveforms in a sequence that imitates the natural key grip and palmar grasp patterns. These two movements allowed the user to perform majority of ADL [3]. Once developed, the device was used in two studies, one involving volunteers who were able-bodied and the other involving volunteers with tetraplegia. The able-bodied volunteers used this device to test if it performed as intended, and the results were also used to analyse the repeatability and reproducibility of the control system. While analysing the results, it was observed that, with practice, the able-bodied volunteers were able to generate the control signals and operate the device better.

The two volunteers with tetraplegia who participated in this study used the device to perform functional tasks similar to the ones that they would do on a day-to-day basis using key grip and palmar grasp movements. When the grip strength results for both volunteers were compared, it was observed that the grasp was stronger when FES was used when compared with without FES.

The GRT scores also improved for both volunteers. The scores obtained by Volunteer 1 indicated some improvement in his ability to perform the tasks

GRT Scores for both volunteers

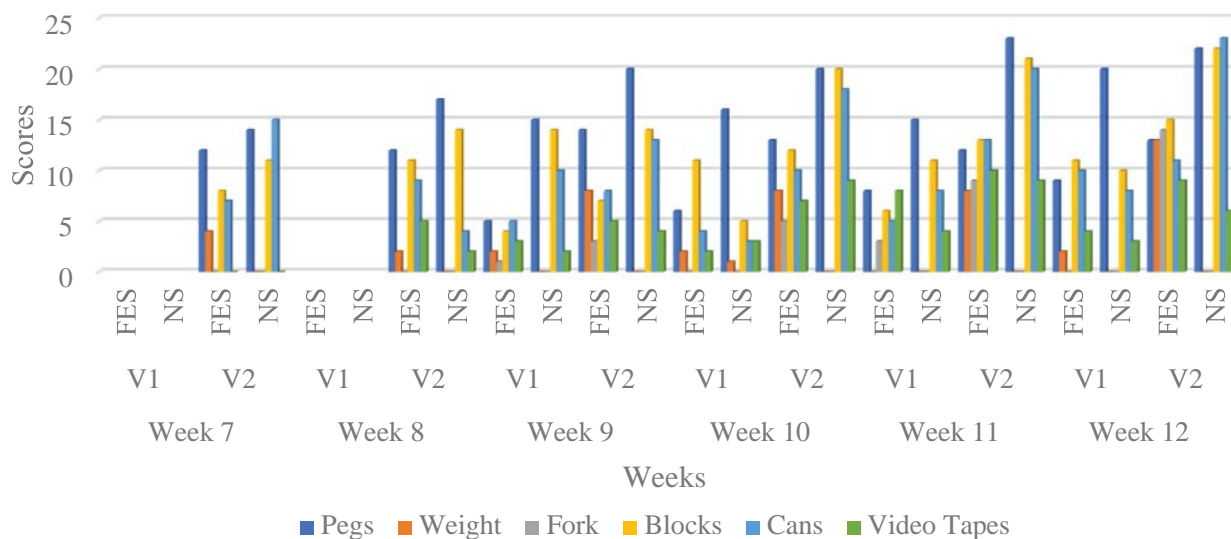


Figure 5. Graph representing the GRT scores of both volunteers.

specified in GRT. However, these improvements were not consistent, and hence it was not possible to identify a training effect. However, the scores obtained by Volunteer 2 indicated a possible training effect. The GRT scores also indicated that the volunteers required FES for performing tasks involving heavier objects and the ones that require them to use more force, such as lifting of the 250 g weight or using the fork setup. However, they were more efficient in performing light tasks such as the pegs or the blocks without FES. This concurs with the results obtained by Taylor et al. in a similar study using the NeuroControl[®]Freehand System [4]. On the last day of the clinical study, Volunteer 1 used the TetraGrip to hold a fork and eat his dinner, and Volunteer 2 used the device to hold a pen and write. Both volunteers were not able to perform these tasks without the use of FES.

6. Conclusion

The initial results obtained from the clinical study summarised in this article suggest that the TetraGrip can be helpful in improving the hand and arm function of people with C6 ASIA A complete tetraplegia. If the device is further developed into a CE marked, take-home device then its performance when the users use it during their day to day life can be assessed. A larger clinical study with a wider group of patients is also required to explore the usefulness of the device for other levels of injury both complete and incomplete.

The protocol for this clinical study should be defined for a longer duration as it will help in obtaining more meaningful data; thereby, enabling the researchers to assess the performance in a detailed manner and improve the device for the user.

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