Acta Biomed 2023; Vol. 94, N. 5 e2023255 DOI: 10.23750/abm.v94i5.14408 ©Mattioli 1885

Using "functional hand" protocol to improve hand function following a spinal cord injury: An explorative study

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Abstract. *Background and aim of the work:* A cervical spinal cord injury often affects hand control, causing ineffective grasping and handling functions, with a negative impact on patient's independence and quality of life. Literature recognises scientific evidence only for surgical or instrumental re-education approaches. The purpose of this study is to present the "functional hand" protocol, a physiotherapy tool that, to date, represents a good clinical practice but has no supporting literature. *Research design and methods:* a longitudinal-single cohort study was conducted at Spinal Unit- Azienda Usl Piacenza. Patients with spinal cord injury at C5-C7 neurologic level, older than 18 years, with correct comprehension of Italian language were recruited. All patients were evaluated with Action Research Arm Test (ARAT) scale to state hand functionality; positive/ negative history of Functional Hand protocol was deducted by physiotherapy discharge letters on first spinal unit hospitalisation. *Results:* six patients were involved in the study; three of them had a positive history of protocol application. ARAT scores differences showed that patients who underwent functional hand protocol had a lower impairment, a better ability to produce cylindrical and cuboid sockets. *Conclusions:* Functional hand protocol reached a preliminary evidence as effective tool to improve hand recovery in tetraplegic patients; future studies should confirm these conclusions on larger samples, and verify protocol effectiveness in addition to other treatment strategies (functional electric stimulation/ transcranial direct current stimulation/ robotic assisted therapy). (www.actabiomedica.it)

Key words: tetraplegia, functional hand protocol, ARAT, inpatient rehabilitation

Introduction

Spinal cord injuries (SCI) affect over 2.5 million people in the world, causing tetraplegia and paraplegia; they're often result of car accidents, falls, gunshot wound, sport injuries (1-2); SCI represents a lifelong condition, with a devastating impact on quality of life, self-efficacy and social participation (3-8). More than half of SCI occurs at cervical level, determining a motor outcome of tetraplegia and impairment of upper limb/hand function (9-10). The loss of hand function is a devastating element in the daily life of a tetraplegic patient, as it entails a high degree of dependence by external caregivers for both simple activities (BADL-basic activities of daily life) and instrumental activities (IADL-instrumental activities of daily life) (11-12).

Physical therapists, so, devote ample space to rehabilitation approaches dedicated to upper limb recovery, often combining exercise treatment with occupational therapy. Nevertheless, to date, less is known about evidence of these rehabilitation approaches on final hand function, due to a general lack of studies about.

A previous systematic review by our group (13) demonstrated that, by existing evidence, four main interventions are known in literature (alone or combined): robotic hand workstation, functional electric

stimulation (FES), transcranial direct current stimulation (TDCS), acute intermittent hypoxia (14-21); examining non-instrumental approaches, however, no clear evidence emerged.

A good clinical practice in Italy, to date, is represented by the "Functional Hand" approach, created and implemented by CNOPUS (Consesso Nazionale Operatori Unità Spinale) in 2000 (22): the protocol, specifically developed for tetraplegic patients, represents a standard in many spinal centres to improve hand function. Its peculiarity is the development of a structured shortening of fingers and thumb's flexor muscles, so to make the patient able to perform light, functional and useful everyday grips; functional hand needs to be supported by the activity of radial extensor of carpus, or by an orthosis to stabilize the wrist (thus permits movement through biceps activation). SCI patients with a lesion level between C5 and C7 are assessed for functional hand, which can be offered in the passive form (without activation of the radial extensor of the carpus- neurologic level C5) or in the active one (with activation of the carpus-neurological level C6); patients with a C7 level are only considered suitable if an imbalance of strength between finger extensors vs flexors muscles occurs.

In its passive form (neurologic C5 level), the functional hand is packaged through a brace that stabilises the wrist at 30 degrees of extension, while metacarpophalangeal and proximal interphalangeal joints are held in 90-degree flexion through patches; distal interphalangeal joints are held in extension. For active (neurologic C6 level) form, the patch is placed longitudinally on the fingers to hold the flexion of the metacarpophalangeal and proximal interphalangeal joints. The functional hand is held for several hours a day (up to 23 hours), freeing it for hygiene and mobilisation, and in the first days a strategy for monitoring the hand, the appearance of redness or allergic skin reactions is structured.

Despite the extensive clinical use of Functional Hand protocol, to date, there is no supporting literature validating its efficacy; the aim of the present study is to provide, by means of a longitudinal investigation, the long-term functional outcome in patients who have experienced functional hand protocol following SCI. The secondary aim of this study is to make a comparison treated vs not treated patients, in order to verify if functional hand protocol was more effective than usual exercise.

Patients and methods

A longitudinal- single cohort study has been conducted at Fiorenzuola d'Arda Spinal Unit- Azienda USL Piacenza; the study was approved by Aven Ethics Committee with protocol n. 2022/0108225 -07/03/2022. Azienda Usl Piacenza gave final approval on 04/04/2022.

The target population for inclusion in our study was represented by patients with C5-C7 complete tetraplegia, in whom the involvement of hand function induced a specific treatment for grip and manipulation functions.

Incomplete lesions (AIS B at Spinal Unit admission, only sensitivity below neurological level) were also included. To this goal, a convenience sampling was carried out from the historical dataset of patients treated at the Spinal Unit of Villanova sull'Arda (now Fiorenzuola d'Arda) over the last thirty years, as to include patients admitted before 2000 (the year in which the functional hand protocol was introduced) as well as after that date.

Specific inclusion criteria were as follows: more than 18 years old; complete/incomplete SCI diagnosis according to ISCOS criteria (23) by more than a year; neurologic level between C5 and C7 (cut-off neurological levels to evaluate the introduction of Functional hand protocol); Italian language comprehension.

Exclusion criteria were: neurologic level lower than C8 (innervated hand); tendon transposition surgery; orthopaedic hand disease; psychiatric disorders; severe spasticity (Ashworth scale score more than 3); neurodegenerative disorders; muscular retraction. All exclusion criteria were drawn in order to eliminating all conditions that could affect hand functions in addition to the primary diagnosis (spinal cord injury).

By the initial historical dataset patients' name, diagnosis and contact were retrieved; they were so contacted by phone, then a follow up visit was scheduled; after the visit, participation to the study was proposed.

If the patient gave his written consent, a researcher started the following operations:

- Retrieval of information with respect to the execution of "functional hand" protocol from the patient's physiotherapy discharge letters related to the first post-injury hospitalisation
- Filling case report form (CRF) with patient's general data
- Patients evaluation by Action Research Arm Test (ARAT) scale (24)

Initially introduced by Lyle et al (24) the ARAT scale was developed to assess arm function for neurologic patients; the scale was historically applied to stroke patients, but in 2012 was involved among SCI-Edge tools (25); previous existing RCTS about arm function in quadriplegia used ARAT as main outcome (14-15-19). ARAT scale is composed by 19 tests and four sub-scales: Grasp, Grip, Pinch, Gross-movements (final score 0-56 points); in the present study pinch sub-scale results were not considered for analysis, as the principle of muscular shortening of functional hand does not allow a fine grip (as required by ARAT testing). The test was conducted on the limb where functional hand was applied, if both limbs had been treated the worst performance was recorded. For untreated patients, both limbs were analysed and the worst performance was recorded. ARAT test kit was purchased by Amsterdam University Medical Centers (UMC); no permission was needed to use the tool.

For each patient following general data were acquired: sex, age, neurologic level and AIS grading, years by the injury, work, sport (if applicable).

ARAT performing was conducted with a standard positioning: the patient was seated comfortably on his/her wheelchair, ensuring the correct biomechanical alignment of the lower limbs (hip and knee positioned at 90° of flexion, ankles in neutral position and in support of the ground or the wheelchair footplates). If supports for stabilising the trunk were present, they were allowed. ARAT testing kit was placed in front of the patient on a table adjusted to the height of the wheelchair. The following tests were performed:

- Grasp sub-area: the patient had to carry a block 10 cm from the horizontal plane to the top of the kit box; if this task succeeded immediately, the grip test was performed, otherwise intermediate tests were carried out with cubes of increasing diameter (2.5 cm, 5 cm, 7.5 cm, sphere, rectangular stone)
- Grip sub-area: the patient had to pour water from one glass to another; if the test was successful immediately, the gross movement section was carried out, otherwise intermediate tests were performed (insert a 2.25 cm cylindrical tube in one chamber, then 1 cm, then insert a washer over a bolt)
- Gross motor sub-area: the patient had to perform three movements, bring the hand behind the head, then above the head, then to the mouth.

Each task was performed for a maximum of 3 trials, with the best attempt being recorded; the score awarded was 3 if the patient performed the movement correctly (maximum subarea score if he could perform the first task on the first attempt), 2 if the task was completed with difficulty or in a longer time of 60 seconds, 1 if the task was only partially performed in the allotted 60 seconds, 0 if the patient failed to perform the task.

All data were organized by excel worksheet, and then re-elaborated in graphic form: mean and individual differences for ARAT total scores and subscales were considered as primary outcome.

Results

In Figure 1 the study flowchart has been presented: by 15 patients contacted for follow up visit 9 refused to participate, while the other six were assessed for eligibility to the study. They were all eligible and recruited.

Demographic data of the sample

In Table 1 all collected general data were resumed; our sample was composed by 5 men (84% of the

sample) and 1 woman (16%); mean age at study time was 54 years old, with a standard deviation of 17.5 years. All patients had a traumatic SCI, with neurological level comprised between C5 and C7. Four patients had a complete SCI (AIS grading A) while two had incomplete injury (AIS grading B). One only patient, at study time, worked as employee, while only another one practiced sport (wheelchair tennis). By discharge letter three patients (pt. 1-level C5, pt. 4-level C5, pt. 6-level C5) have been treated with functional hand protocol during the first hospitalisation.

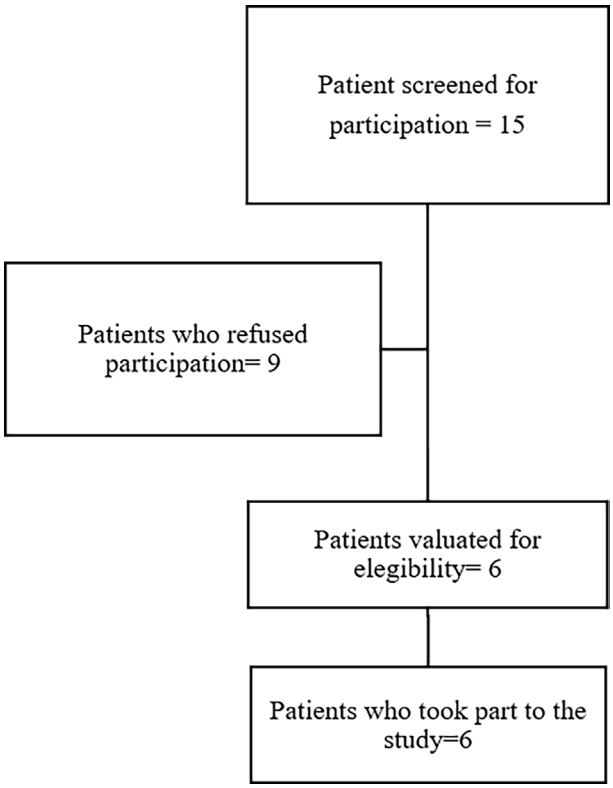

Figure 1. Flowchart of study inclusion and eligibility. Alt text: a four-step flow diagram showing the patient inclusion process: from an initial number of 15 screened patients, six ones took part at the study.

ARAT scores

The overall analysis of total ARAT score demonstrated a general trend of higher performances of treated patients; the mean total ARAT score was of 37/39 points for patient with a positive history of Functional hand protocol, while not treated patient had a mean total score of 25.6. See Table 2 for further details.

The same difference was observed for sub-scales scores: grasp mean was 17/18 points for treated patient, 10 for not treated patient, so underlying a better ability to perform a cuboid grasp to manipulate different size blocks. Grip sub scores showed a mean of 11/12 points for treated patients, and of 6 points for not-treated ones; this value reflects a better ability to manipulate cylindrical objects. Finally, gross movement sub scores mean was 9/9 for treated patients and 7/9 for not treated ones, thus indicating a lower difference. Tasks in this area, however, depend also by shoulder activation. Figures 2, 3 and 4 reflect single patient's results.

Conclusions

The present study was conducted in conformity to Strobe statement (26). To date, this is the first attempt to describe a wide used rehabilitative approach to tetraplegic hand dysfunction. By present single cohort

Table 1. General data of the sample. Pt: patient; SCI: spinal cord injury.

	Age (range)	Diagnosis	Neurologic level	AIS Grading	Work	Sport	Years by injury
PT 1	80-90 years	Traumatic SCI	C5-C6	B	NO	NO	13
PT 2	50-60 years	Traumatic SCI	C6	A	NO	NO	35
PT 3	30-40 years	Traumatic SCI	C5	A	NO	NO	22
PT 4	50-60 years	Traumatic SCI	C5	B	YES	NO	2
PT 5	50-60 years	Traumatic SCI	C6-C7	A	NO	YES	29
PT 6	40-50 years	Traumatic SCI	C5	A	NO	NO	1

Table 2. Results of ARAT testing. Pt: patient; RS: right side. All not treated patients were evaluated on both sides, but the worst performance (right) was analysed; all treated patients had one only side to test, except for PT 6 (both side treated), who had the same scoring for both arms. In this case right side was involved for data analysis.

	FUCNTIONAL HAND	GRASP SCORE	GRIP SCORE	GROSS MOVEMENT SCORE	TOTAL
PT 1	YES (RS)	16/18	10/12	9/9	35/39
PT 2	NO (RS ANALYSED)	0/18	0/12	3/9	3/39
PT 3	NO (RS ANALYSED)	18/18	6/12	9/9	33/39
PT 4	YES (RS)	16/18	11/12	9/9	36/39
PT 5	NO (RS ANALYSED)	12/18	12/12	9/9	33/39
PT 6	YES (BOTH SIDES- RS ANALYSED)	18/18	12/12	9/9	39/39

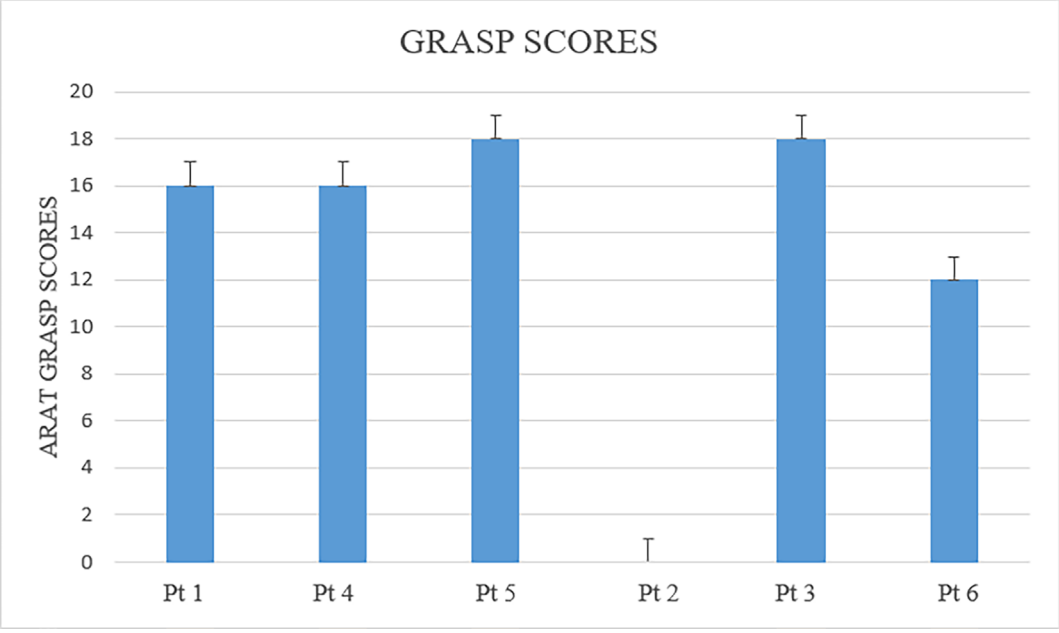

Figure 2. Comparison of Grasp subscale scores between treated/not treated patients. A histogram with individual patients on abscissas and ARAT –Grasp scores on ordinates. Patients treated with functional hand protocol achieve a higher score.

study results, Functional hand protocol seems to be an effective tool to restore and preserve hand function even after many years by SCI occurrence: ARAT scores, in fact, demonstrated a general trend of better performance in treated patients, even in total scores than in subscales' ones. In general terms this indicates that the procedure is effective to restore hand ability in confront to exercise only; this could be a first step to overcome the gap in scientific literature about conservative treatment of tetraplegic hand. A recent literature review, in fact, shows that, commonly, physiotherapists have not a clear concept about pathophysiology and treatment strategies for tetraplegic hand, deriving their approaches by stroke patients (27). So, due to this evidence lack, research mainly dedicates to surgical approaches: to date, the use of tendon transposition is the most validated proposal for stable (more than a year by SCI) tetraplegic patients (28-31). Very little is known about conservative treatments: even in published experiences (32-35) manual intervention is mainly

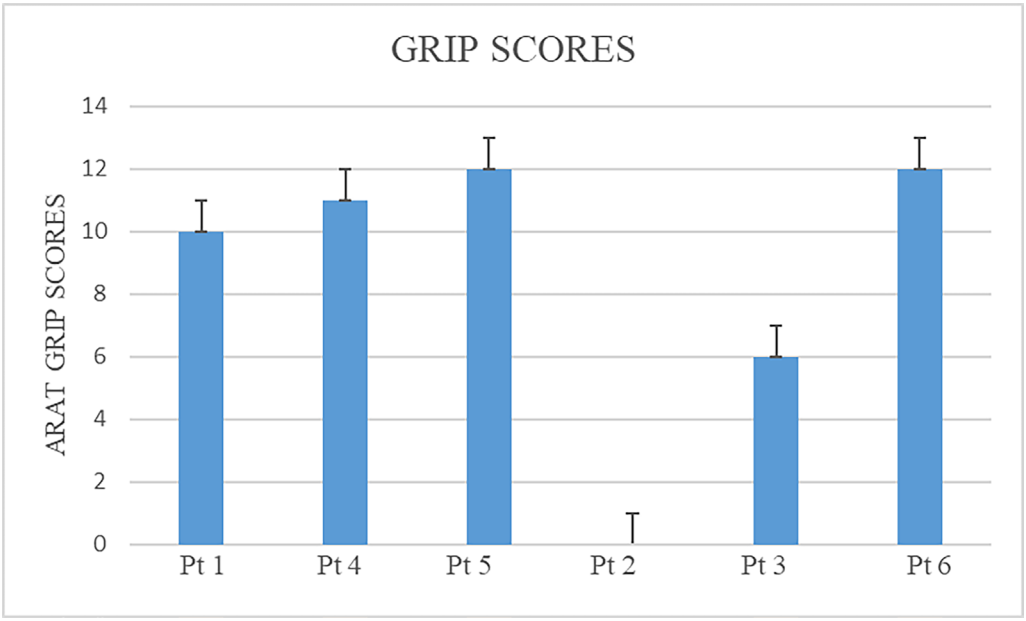

Figure 3. Comparison of Grip subscale scores between treated/not treated patients. A histogram with individual patients on abscissas and ARAT –Grip scores on ordinates. Patients treated with functional hand protocol achieve a higher score.

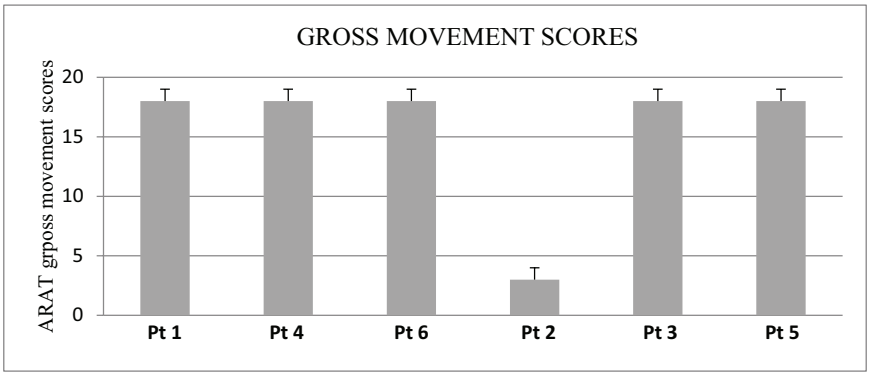

Figure 4. Comparison of Gross movement scores between treated/not treated patients. A histogram with individual patients on abscissas and ARAT – Gross movement scores on ordinates. Patients achieve similar scores, except for patient 2 (not treated with functional hand protocol) who had a lower score.

used as shame/additional modality, with a low success rate (35). Proposed exercises, moreover, are often oriented towards repetitiveness and time-exposition; physiology of a SCI-inducted damage, instead, leads to confronting with clinical pictures in which motor outcome is not only the result of neuroplasticity, but also of root functionality and strength of supra lesional musculature.

The first novelty we introduce with the present study is considering tetraplegic hand management a multidisciplinary task, which requires a close collaboration between doctors, physiotherapists, occupational therapists, nurses and patients. This pathway starts with a rigorous multimodal evaluation, in which general medical conditions, motor abilities and self-efficacy are taken into account. In this perspective

MRC (medical research council) scale plays a central role to assess upper limb muscle strength, in order to verify if functional hand could be active or passive. Moreover, skin observation helps to identify frailty due to vascular/dermatological comorbidity, that could contraindicate protocol application. Once the hand is closed, the patient accepts this condition for the most part of the day and within several months, with high implications for daily life (reduced autonomy, pain). Determination and devotion are so needed to employ this tool in an intensive rehabilitation path; our clinical observation indicates that, on the medium long period, functional hand restore grasping and handling skills essential for performing many ADLs (feeding, personal hygiene, self-propulsion in a wheelchair, trunk management during bed-chair transfers and vice versa).

Despite this some criticalities emerged. At first, our sample is very small, so we can only hypothesise preliminary evidence of the protocol, which should further be investigated on larger populations. In addition, ARAT scale seems not completely suitable to explore functional hand principle, since pinch subscale is not applicable: the protocol is not intended to produce an interdigital fine-grip capability, but only coarse cylindrical or handheld typing sockets. Our study, in conclusion, represents a first step to produce evidence of functional hand efficacy; future research would better verify this hypothesis on larger samples, and further test it in intensive rehabilitation setting and with different combination of treatments (i.e. functional hand + FES/TDCS/Robotic workstation).

Ethic Committee: The study was approved by Aven Ethics Committee with protocol n. 2022/0108225 -07/03/2022. Azienda Usl Piacenza gave final approval on 04/04/2022.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

Authors Contribution: Conceptualization, GC and GL; methodology, GC; investigation, GL, MA and GC; writing—original draft preparation, GC; writing—review and editing, GL and MA. All authors have read and agreed to the published version of the manuscript.

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Received: 6 June 2023
Accepted: 22 September 2023
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