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Research Article

The beneficial effect of physiotherapy on the cervical spine mobility of ACDF patients and healthy individuals: An original observational cohort comparison research protocol

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ABSTRACT

Purpose: Population aging and certain behaviors associated with modern life are contributing factors for the increasing incidence of degenerative cervical spine conditions (DCSC), and the number of cervical spine surgeries every year is. Our aim was to determine, with an original research protocol, the impact of ACDF and physiotherapy on the range of motion and EMG parameters of patients suffering from DCSC.
Patients and Methods: Two comparable subgroups of 29 patients each were recruited for the present investigation. The first cohort was composed of ACDF patients, whereas the second cohort was composed by healthy subjects. Inclinometry/Range of Motion (RoM) analyses of the neck, and cervical muscles electromyography (EMG) were used to evaluate the neck mobility. We investigated the effects of physiotherapy on ROM and EMG results in order to identify possible significant differences between healthy subjects and ACDF patients.
Results: A total of 58 patients were included in the final cohort. Extensive statistical analysis disclosed that higher NDI values were associated with a reduction of the Extension and Rotation movements, NDI scores, were found to be negatively associated to EMG voltages for Rotation, independently of the physiotherapy performed either. Extension, Lateral Bending, and Rotation showed significant improvement after just one session of physiotherapy, whereas Flexion and Extension proved to be those that contributed most to the overall neck mobility.
Conclusion: The cervical spine fusion contributes to an overall reduction of cervical mobility. This data is confirmed by inclinometer and EMG parameters. Physiotherapy increases neck mobility thus possibly improving the clinical status of patients.

1. Introduction

1.1. Background

Population aging and certain modern behaviors which contribute to bad neck posture, such as excessive use of tablets and cell-phones [1,2], are connected to the increased incidence of degenerative pathologies of the cervical spine, and associated myelopathies and radiculopathies [3–5].

Conservative treatments such as physio-kinesiotherapy have yielded significantly positive results in individuals affected by degenerative pathology of the cervical spine without significant neurological disorders, but not in all patients. Physio-kinesiotherapy has been also proven helpful after surgical intervention. Not surprisingly, an increase in the number of surgical treatments for these pathologies has also been recorded.

Among the available surgical treatments, the most commonly used is the anterior cervical discectomy with fusion (ACDF) [6–9], which ensures good decompression of the spinal cord and roots, halts the degenerative process, and can even lead to an improvement of the

Abbreviations: ACDF, Anterior cervical discectomy and fusion; EMG, Electromyography; RoM, Range of Motion; NDI, Neck Disability Index; AUC, Area Under Curve; CT, Computed Tomography; MRI, Magnetic resonance imaging.

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overall neurological outlook of a patient. This type of surgery, however, entails interbody fusion of one or more spinal levels with consequent mobility reduction.

1.2. Objectives

The majority of studies on cervical mobility after an interbody fusion rely on X-rays, CT and MRI imaging [10–13]. These tools provide useful data on the contribution of the bony component to the cervical spine movement, but provide limited information on the musculoligamentous system. We therefore adopted a new research method based on inclinometry/Range of Motion (RoM) of the neck, and on cervical muscles electromyography (EMG) to evaluate how much ACDF impacts the muscle movements and thus neck mobility and the quality of life of those subjected to surgical treatment. We have also investigated the effects of physiotherapy on RoM and EMG results in order to identify possible differences of clinical significance between a group of surgically-treated patients, who have limited range of movement of the cervical spine, and healthy volunteers. Only a limited number of previously published studies investigate the EMG changes in patients suffering from neck pain [14–16]; most of them focused on side aspects, like the recruitment of thoracic spine muscle, or trapezius muscles in patients suffering from neck pain [15,16], or EMG variations in physiotherapy patients suffering from dystonia [17]. The present investigation could therefore be one of the first focusing on the effects of physiotherapy on fused patients and healthy individuals in respect to their RoM and EMG parameters.

2. Materials and methods

2.1. Participants

For the purpose of this study we recruited 58 subjects (Table 1), divided in two groups:

- o A, ACDF group, which included 29 individuals who underwent ACDF surgery;
- o B, Control group, which included 29 individuals who received no surgical intervention.

2.2. Study design

The resulting design of the study is an observational cohort comparison study in which the data analyzed were collected by a team of independent researchers, who were blinded to the objective and design of the study and recorded the inclinometric and neurophysiological data. Another separate researcher, was aware if patients belonged to Group A or Group B. The selection process included a first phase in which the Group A was selected out of a cohort of previously operated ACDF patients, on the ground of their availability and will to participate to the investigation; we reached a total number of 29 individuals. To achieve the comparability of the two subgroups, we subdivided participants of Group A in age-classes, and the volunteers were selected according to the number of individuals belonging to each age-subgroup in order to increase the age-match of the population thus reducing potential age-specific differences. Out the initial screening to recruit subjects for Group B, we reached the number 29 individuals, who were healthy volunteers available and willing to participate to the study.

Table 1
The final cohort.

Participants		Number of participants	Age, years	Sex, Males	Sex, Females
Patients			52.3 ± 11.5		
	1 level	22		14	8
	2 levels	7		4	3
Control group		29	54.1 ± 10.9	15	14
Total		**58**	**53.2 ± 15.8**	**33**	**25**

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2.3. Eligibility and selection criteria

Inclusion criteria for group A were:

- ACDF surgery one to ten years prior to the beginning of the study.
- No report of permanent damage to bone, muscular or nerve structures after surgery, such as to cause disability.
- Absence of inflammation, infection or trauma to the cervical spine or the spinal cord: all ACDF procedures had been carried out to treat degenerative conditions of the spine.
- Completion of at least one cycle of physiotherapy after surgery according to the Mézières method.

The exclusion criteria for the control group (B) were:

- Any prior surgery to the cervical spine;
- History of vertebral to the cervical spine;
- History of whiplash injury to the cervical spine;
- History of conservatively treated cervical disc herniation;
- Presence of degenerative or inflammatory process of the musculoskeletal system.

2.4. Interventions: experimental protocol

Prior to the beginning of experimental study, each patient underwent the Neck Disability Index test [18–20], a clinical tool for assessing the presence or absence of cervical spine pathologies.

To measure neck mobility in 3D, we placed an inertial 9DOF sensor in a headgear worn by each subject, and utilized a microcontroller with BLE transmission. Particular care was given to position the sensor on the head midline, at the intersection with the biauricular line, between the two external acoustic meatus. Data of the digital inclinometer were recorded via an app compatible with Android 4.3 or superior operating systems. Concurrently to data collection through the digital sensor, a surface electromyography of two sternocleidomastoid muscles was also carried out. The choice of these muscles was determined by two factors: their activity is the most easily measurable with surface electrodes, and their hypo- or hyper- activity can indirectly give information on deeper muscles, like the longus colli muscles [21]. The activity was measured, recorded and subsequently analyzed as Area Under Curve (AUC).

Maximum range of neck mobility was measured in each subject. This included Flexion, Extension, Rotation, Axial Rotation and bilateral Bending, always starting from the most neutral neck-position possible. All movements were executed under the careful guidance and observation of a member of our research team with a degree in physiotherapy. While inclination and rotation movements are usually combined to achieve the largest possible mobility range; for this study, these two aspects were measured separately to ensure maximum precision. If during a rotation test the display showed an inclination $>10^{\circ}$, the test was voided and then repeated. Likewise, if during the inclination test the rotation component exceeded 5° the test was voided and then repeated.

2.5. Outcome variables

The test was divided in four stages:

1. Neck Disability Index measurement;

2. RoM and muscular activation first measurement;
3. Physiotherapy session according to the guidelines on cervical pain in the Classification of Function, Disability and Health (latest version:2014) [22,23]
4. RoM and muscular activation second measurement.

A session of standard cervical physiotherapy was given between first and second RoM-EMG measurements to test its real effectiveness, and secondarily to eliminate any muscular tension that might have arisen in patients undergoing the test for the first time.

All the surgical procedure of Group A were performed according to the standard anterior cervical approach for a discectomy and fusion, according to the Smith-Robinson technique. The interbody fusion was realized with an interbody cage without anterior plating. As per a routine recommendation, for 30 days, postoperatively, the patients were asked to wear a cervical subaxial rigid orthesis (Schanz collar). At 30 days, a plain X-Ray film of the cervical spine confirmed the proper positioning of the interbody cage.

Before surgical procedure, all patients gave explicit, written, informed consent after appropriate briefing. The informed consent was approved by the Institutional Review Board of the Human Neurosciences Department "La Sapienza" University of Rome. All individuals signed a further written informed consent before enrolling in the experimental protocol. No harm or injury was expected or even predictable based on the experimental methods selected. Data reported in the study have been completely anonymized. No treatment randomization has been performed. This study is consistent with the Helsinki declaration of Human Rights.

2.6. Statistical methods

The sample was analyzed with SPSS version 18. Comparison between nominal variables has been made with Chi^2 test. Means were compared with One Way and Multivariate ANOVA analysis along with Contrast analysis and Post-Hoc Tests. Continuous variables correlations have been investigated with Pearson's Bivariate correlation. Factor analysis was performed to investigate the variance of the sample regarding the neck mobility. Threshold of statistical significance was considered $p < 0.05$.

2.7. Potential source of bias and study size

There are no missing data since incomplete records were an exclusion criterion. A potential source of bias can derive from the small sample size, which, nevertheless, in regards to the endpoints selected, presents a satisfactory estimated post-hoc statistical power ($1 - \beta = 0.87$ for α 0.05 and effect size 0.7).

3. Results

3.1. Participants

In the period between July 2018 and November 2019, a total of 58 individuals underwent the aforementioned experimental protocol as described in the Materials and Methods section.

3.2. Descriptive data

A total of 58 individuals were enrolled. 29 patients, belonging to group A, had undergone an anterior surgical fusion (according to standard ACDF technique) in a period ranging between 2010 and 2016. Among them, 7 were operated on 2-levels, and the remaining 22 were operated on a single level. Group B, the healthy control group, comprised the remaining 29 people.

The average age of the two groups was respectively 52.3 ± 11.5 and 54.1 ± 10.9, with no statistically significant difference ($p = 0.543$); conversely, the average NDI score was significantly higher in the surgically-treated group (group A), as expected according to the inclusion and exclusion criteria ($p = 0.014$). In group A the most common level treated was C5-C6 (19 patients, 65.5% – Fig. 1). Note that in some patients more than one level was involved, for a resulting number of 36 level fused in a total of 29 patients.

3.3. Outcome data and main results

3.3.1. NDI score

The NDI scores proved to be statistically higher in the surgically-treated group ($p = 0.014$), the scores were positively associated with the number of levels treated ($r = 0.262$, $p = 0.043$). Higher NDI scores were also significantly associated with a reduction in Bilateral Extension ($r = -0.393$, $p = 0.015$), Rotation ($r = -0.355$, $p = 0.029$) and Lateral Bending movements ($r = -0.308$, $p = 0.018$). Interestingly, the aforementioned significant associations relate to the measurements *before physiotherapy*, whereas after physiotherapy, similar effects appear to be absent (r between −0.193 and −0.225 with p between 0.174 and 0.245).

In regards to the NDI scores, 15 was considered the cut-off value for impairment linked to neck disturbances, as previously reported in the Literature. A value of $NDI > 15$ was found to be associated with a reduction of the Extension and Rotation degrees ($p = 0.022$ and $p = 0.23$, respectively).

3.3.2. EMG parameters

EMG parameters, measured for each of the investigated neck movements showed a strong positive reciprocal statistical correlation (r between 0.460 and 896 with p between 0.001 and 0.29). In a Multivariate analysis it was possible to relate the impact of the number of levels fused to the EMG parameters: in the subgroups of operated individuals, patients who underwent a 2-level fusion presented higher AUCs in comparison with patients who underwent a single level fusion, independently of the physiotherapy performed; this finding was of statistical significance for the Bending and Rotation movements ($p = 0.020$ and $p = 0.034$ respectively, Fig. 2 A and B). From a clinical perspective, on a Bivariate Analysis, NDI scores were found to be associated to EMG voltages for Rotation, independently of the physiotherapy performed ($p = 0.049$).

3.3.3. Neck excursion

Neck excursion parameters proved to be reciprocally positively correlated ($0.001 < p < .034$) in the pre and post-physiotherapy measurements, showing the tendency of both patients and control subjects to

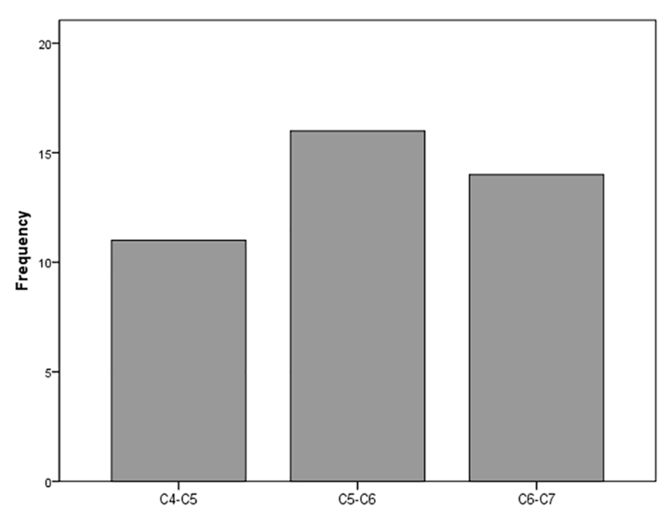

Fig. 1. Frequency of the levels involved.

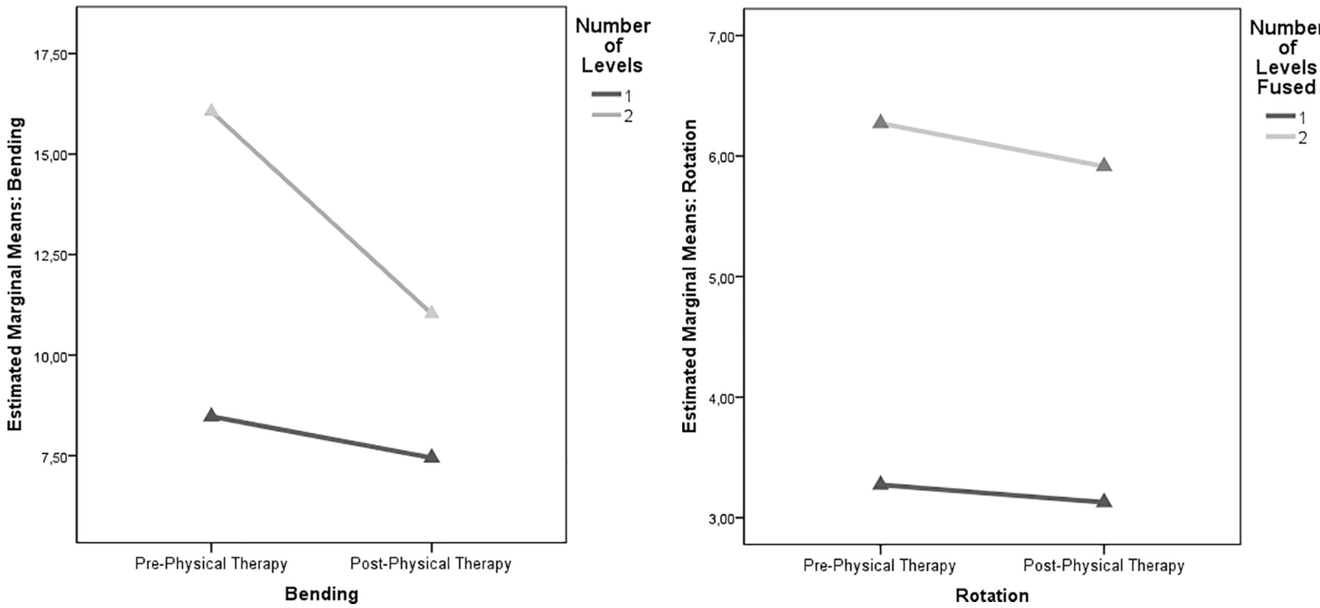

Fig. 2. Repeated Measures analysis concerning the impact of ACDF on A. Bending and B. Rotation movements prior and after physiotherapy. The Y axis contains Area Under Curve values of EMG.

have an overall co-working effectiveness or limitation in the neck movements. The Flexion and Extension proved to be those that contributed most to the overall effectiveness of neck mobility (r = 543 and 0.569 both p = 0.001).

4. Other analyses

4.1. Factor analysis

Each neck movement was investigated to assess how it affected the overall mobility range. Flexion and Extension significantly influence the variability of neck excursion, more than other directional movements, independently of physiotherapy (p = 0.011 and p = 0.020, Fig. 3A and B).

Factor analysis was chosen to disclose and retrieve underlying statistical interactions between the movement variable, explaining the variance of such parameters: an explorative factor analysis could in this case highlight which of the movement was more directly involved in determining the overall neck mobility, in search of possible statistically significant difference between the surgical and non surgical subgroup and before and after the physiotherapy treatment.

Factor analysis showed that Flexion and Extension cumulatively influence variance of the total neck excursion by 49.1% and 20.5% respectively before physiotherapy, and by 45.2% and 22.5% after physiotherapy in the surgically-treated group; and by 47.7% and 25.5% respectively before physiotherapy, and by 40.0% and 26.1% after physiotherapy in the healthy control group. An ANOVA Repeated Measures analysis revealed that the total mobility range of the neck was significantly wider in the control group compared to the surgically-treated group (p = 001 Fig. 4), independently of the physiotherapy performed, the age of the patients, and the number of levels fused.

4.2. Retest T-Test

A T-Test pre/post was performed to investigate possible variation in EMG and neck excursion parameters in relation to physiotherapy treatment, for both groups. Flexion was the only movement displaying no statistically significant variation after physiotherapy (p = 0.148), the remaining: namely Extension, Lateral Bending, and Rotation showed significant improvement after just one session (on average $+ 3.9^\circ \pm 8.1^\circ$, respectively p = 0.001, 0.006 and 0.003). Overall, for the surgically-treated group, EMG parameters (AUCs), displayed significant variations when physiotherapy was applied, with statistical differences in Flexion and Bending (respectively p = 0.043 and p = 0.046).

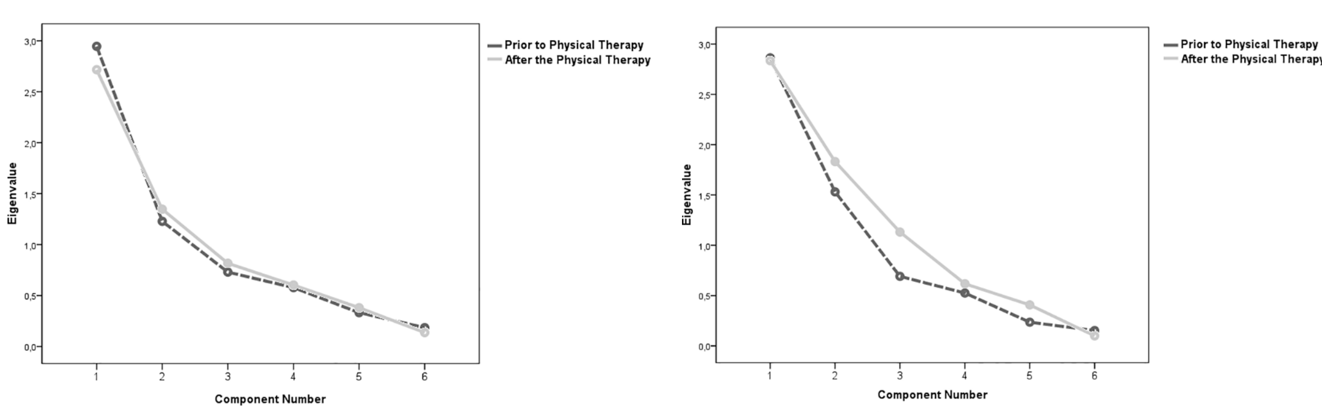

Fig. 3. Factor Analysis disclosing the effect of component 1 and 2, namely Flexion and Extension, A- Surgical subgroup, B. Healthy control group.

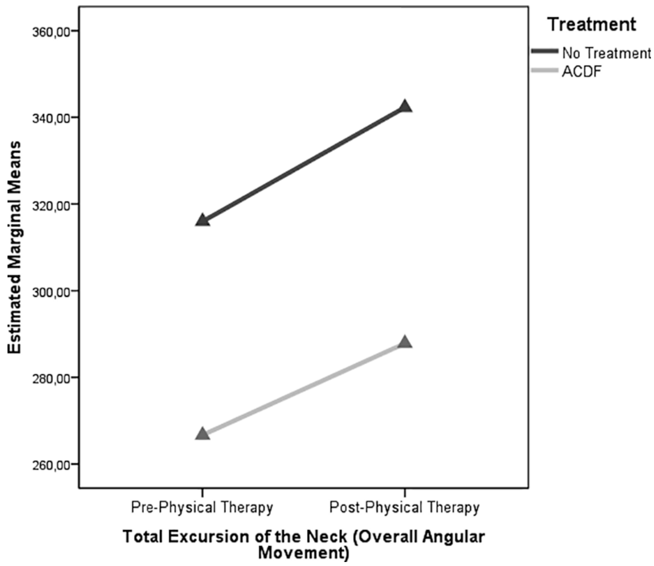

Fig. 4. Repeated Measures analysis concerning the impact of ACDF on overall neck mobility prior and after physiotherapy. Overall neck mobility is reported in degrees, on Y axis, and derived from the sum of all the movement of the neck, according to the inclinometric findings.

5. Discussion

The first outcome of this study is rather obvious: the overall mobility of the neck – which is obtained by adding the degrees of excursion of Flexion-Extension movements and the Rotation and Lateral Bending movements – was statistically superior in the control group compared to the surgically-treated group. This did not change across the two measurements of RoM taken before and after physiotherapy. In order to halt the degeneration of one's neurological status with surgery by ACDF in the presence of cervical spondylotic myeloradiculopathy, and even to affect significant improvement, it seems that the price a patient has to pay is a degree of neck mobility.

It was interesting to observe, through the multivariate statistical analysis on the surface EMG and simultaneously on the RoM, that in the group of surgically treated patients (A) there was clearly more activation of the sternocleidomastoids, equally on both sides, compared to the control group. The activation of the sternocleidomastoids was more pronounced in patients who had been operated on two levels, compared to those who had undergone surgery on one level. One possible interpretation is that in the presence of arthrodesis, the muscles need to exert a greater effort to obtain satisfactory cervical movements, moreover the sternocleidomastoid muscles take in part on the function of the longus colli muscles, since the latter are usually more damaged by ACDF surgical procedure.

The NDI score was significantly higher in surgically treated patients compared to healthy people. Even within the surgically treated group there were differences: a significant disparity in index between those with one fusion, and those two fusions was observed. In fact, a higher NDI is associated with a greater reduction of Extension, Rotation and Lateral Bending, measured in the second stage of the test.

When, in the fourth stage of the study, cervical RoM was measured again, post physiotherapy, the association that had been observed between NDI and movement reduction disappeared because almost all surgically-treated patients showed improved cervical movement. This phenomenon was even more pronounced in those who had less mobility.

In terms of inclinometry, as far as the factor analysis is concerned, it's possible to see how the movements of Flexion-Extension have a major role in the total excursion of the cervical spine, independently of the myorelaxant effects of physiotherapy, which nonetheless significantly improves Extension, Rotation and Bilateral Bending of the spine. The positive effects of conservative or postoperative treatments with physio-kinesiotherapy could be potentially connected to the reduction of muscular hypertonia [14,17,24], which may determine an overall increased mobility of the cervical spine.

Similar results, regarding a beneficial effect of the physiotherapy, were already reported in patients suffering from neck pain [14], but, to the best of our knowledge, not yet reported in the context of a comparison between operated patients and healthy volunteers and before and a after a physiotherapy treatment.

The aging spine becomes naturally stiffer [25], as it becomes stiffer after a surgical fusion. It acquires an increasing amount of degenerative alterations involving the intervertebral discs, the posterior ligamentous complex, the articular processes and the posterior longitudinal ligament [25-28], eventually impairing the global cervical spine mobility and resulting in a increased muscular effort, possibly influencing the EMG tracks of neck muscles. Physiotherapy, apparently increasing the neck mobility through a reduction of the muscular hypertonia, could be cause/effect related to the reduction in the EMG voltages.

The beneficial effects of physiotherapy, could be intrinsically connected with the reduction of the focal cervical muscle hypertonia, leading to a impaired neck mobility and thus to pain symptoms. Our results confirm an increased mobility of the cervical spine, as measured with an inclinometer, after just one physiotherapy treatment. This finding widely confirms our clinical experience: physiotherapy could be a key factor associated to a short-to-mid term amelioration of the clinical results and possibly in an overall improvement of the quality of life of patients suffering from cervical spine disorders.

Physiotherapy could be therefore a critical and possibly unavoidable step in the postoperative cervical spine healing process: it could improve the surgical results of complex as well as simple cervical spine procedures by enhancing the neck mobility, reducing the cervical muscular hypertonia and thus eventually prevent the onset of chronic post-operative pain and even decrease the postoperative pain drug intake.

6. Limitations and generasilability of this study

The sample has a good statistical power for a comparative study, even though potential bias could arise from sample size. Patients' age was standardized so as to minimize this source of bias. The remaining conceivable sources of bias are potential differences in the overall alignment of the cervical spine, the condition of the disks next to the fused levels in group A, and the presence of hypertrophy of the facet joints, of the posterior ligaments and of the cervical spinous processes. However the impact of such bias appears limited and homogenous when considering the method used to measure cervical mobility and the associated EMG effects.

7. Conclusions

The surgical fusion of one or more levels in the cervical spine contributes to an overall reduction of cervical mobility. This data is confirmed by inclinometer parameters. The AUC of the EMG increases because the muscles work harder to execute valid cervical movements. Physio-kinesiotherapy, practiced according to current guidelines, increases mobility of the cervical spine, possibly improving the clinical status of patients. Altogether, this study clearly indicates that all surgically treated patients, especially those with a high NDI score, ought to undergo various cycles of cervical physiotherapy to improve mobility and ultimately their quality of life.

Funding

The present investigation is independent, no funding was received to conduct the investigation.

9. Ethics approval

Before surgical procedure, all patients gave explicit, written, informed consent after appropriate briefing. The informed consent was approved by the Institutional Review Board of the Human Neuroscience Department "La Sapienza" University, Rome. No harm or injury was expected or even predictable based on the experimental methods selected. Data reported in the study have been completely anonymized. No treatment randomization has been performed. This study is consistent with the Helsinki declaration of Human Rights.

The corresponding author and senior author of the present paper had full access to all of the data in the study.

10. Consent to participate and Consent for publication

All patients signed a further written informed consent before enrolling in the experimental protocol and for the subsequent publication.

11. Disclosure of Interest

The authors have no interest to disclose

12. The EQUATOR Network

The structure of the present study is organized following the CONSORT protocol and guidelines.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

The authors certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript. The authors confirm their adherence to ethical standards and have NO financial disclosures that would be a potential conflict of interest with this publication.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.inat.2020.101058.

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