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ORIGINAL ARTICLE - SPINE DEGENERATIVE

Effect of external cervical orthoses on clinical and radiological outcome of patients undergoing anterior cervical discectomy and fusion

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Abstract

Background The current use of external cervical orthoses (ECO) after cervical discectomy is still based on a common practice than a solid scientific literature. The aim of this study is to evaluate the impact of ECO on radiological and functional outcomes in patients undergoing anterior cervical discectomy and fusion (ACDF).

Methods We compared two cohorts of consecutive patients who underwent ACDF with and without ECO after surgery. Thirty-six patients operated from January 2015 to June 2016 received an ECO whereas 36 patients, operated from July 2016 to December 2017, did not. Each patient underwent radiological and functional evaluation using plain x-ray at 1, 6, and 12 months after surgery and Neck Disability Index (NDI) at 2 weeks and 3, 6, and 12 months after surgery, respectively.

Results In the ECO group, 5 patients (13.9%) presented an incomplete fusion and 31 patients (86.1%) presented a complete fusion (CI 0.705–0.953). In the non-ECO group, 8 patients (22.2%) presented an incomplete fusion and 28 patients (77.8% [CI 0.608–0.899]) had a complete fusion, with no statistically significant differences between two groups. No statistically significant differences were also observed regarding the NDI neither at 2 weeks nor at 3-, 6-, and 12-month follow-up. At multivariate analysis, patients who underwent two-level ACDF showed a five-fold increased risk of worse NDI at 3-, 6-, 12-month ($p = 0.003$, CI 1.770–14.584) follow-up.

Conclusions We advise against the routine use of ECO after single- or two-level ACDF as we did not find out any significant statistical differences between the two groups.

Keywords Anterior cervical discectomy · Cervical disc herniation · Cervical external orthoses · Cervical myelopathy · Neck disability index

Introduction

Although the underling pathophysiological mechanisms are poorly understood [12], the cervical radiculopathy represents one of the leading causes demanding spine surgery worldwide [4].

First described by Robertson and Cloward in the 1950s [3], ACDF has been widely used to treat cervical myelopathy and radiculopathy. In experienced hands, ACDF represents a relatively straightforward operation with high rate of clinical success [2]. Following ACDF, cervical collars have been used with the aim of preventing further spinal cord injuries [10–14] promoting vertebral ossification and relieving pain and finally providing patients with an increased sense of security [5]. Despite these theoretical advantages, the routine use of postoperative ECO is still based on a common practice and surgeon's preference than solid evidence-based literature. Moreover, their use is not without complications, including skin breakdown and damage [8, 9], difficulty in swallowing, coughing, breathing, and vomiting [8].

Furthermore, the type of cervical orthoses and the duration of its use are debated [6–11]. From a theoretical point of view, since ossification of adjacent levels rarely occurs before

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3 months after surgery, the cervical collar should be worn for at least 3 months. Instead, it is common practice to wear the collar only for 20–30 days after surgery. Therefore, we present a case series comparing two different cohorts of consecutive patients in order to evaluate the impact of postoperative ECO on both fusion rate and functional outcome in patients with cervical myelopathy or radiculopathy undergoing ACDF at our institution.

Materials and methods

This is a case series comparing functional and radiological outcome of two different cohorts of patients up to 12 months after surgery.

Indications for surgery were the following: patients with cervical radiculopathy due to cervical disc herniation that had failed conservative treatment of at least 6 weeks or patients with cervical cord compression or myelopathy secondary to cervical disk herniation. In all cases, diagnosis was confirmed by magnetic resonance. Patients with radiographic signs of cervical spine instability, with severe facet joint arthritis as well patients with traumatic or neoplastic diseases involving the spine were excluded from the study. Participation was voluntary and all participants signed a written informed consent; patients were thereafter free to interrupt their participation at any time and without explanation. We enrolled 72 patients (age range 18–77). From January 2015 to June 2016 (control group, 36 cases), patients received an ECO (Schanz model) after surgery. From July 2016 to December 2017 (cases, 36 patients), patients did not receive any cervical collar (ECO) after surgery. Patients were operated by the same senior surgeon using the standard ACDF microsurgical technique and the same type of PEEK cage (Spine Vision ACIF, 92160 Antony FRANCE).

Following surgery, x-rays were performed on the first postoperative day.

Before discharge, the patients with collar were instructed to wear it at daytime, both in and outdoors over a 4-week period after which the collar could be removed. All patients were restricted form activities such as contact sports, running, heavy lifting, driving, and outer-range cervical spine movements during the first 3 months after the operation. Before surgery and after 1, 3, 6, and 12 months, NDI was administered to all patients. Cervical range of motion (CROM) was tested as well.

Radiographs, performed at 1, 6, and 12 months after surgery, included upright anterior-posterior, lateral and flexion-extension radiographs. Fusion was defined as the presence of bridging trabecular bone as evidenced by continuous bony connection of the vertebral bodies above and below in at least one of the following areas: lateral, anterior, posterior, and/or through the allograft ring implant. Incomplete fusion was defined by the presence of bony remodeling resembling fusion without the presence of continuous bony connection.

The statistical analyses were carried out using the Statistical Package for the Social Sciences software package for Windows

Table 1 Baseline demographic variables (*n.s.* not significant difference)

Variables	With ECO ($n = 36$)			Without ECO ($n = 36$)		
	n (%)	Median	Range	*n* (%)	Median	Range
Male (n.s.)	17 (47.2%)			18(50%)		
Female	19 (52.8%)			18 (50%)		
Age (years) (n.s.)		48	31–77		48	33–77
BMI (n.s.)		26.6	19–40.5		25.2	17.2–41.2
Myelopathy (n.s.)	14 (39%)			9 (25%)		
Without myelopathy	22 (61%)			27 (75%)		
Complication (n.s.)	0%			0%		
Single level (n.s.)	16 (44.4%)			20 (55.6%)		
Two-level	20 (55.6%)			16 (44.4%)		
NDI at 2 weeks (n.s.)		16.5%	0–78%		11.5%	10–68%
NDI at 3–6-12 months (n.s.)		3%	0–48%		2.1%	0–35.5%
CROM (n.s.)		80%	40–100%		80%	30–100%
Fusion at 1 month (n.s.)	No fusion = 29 (80.6%)			No fusion = 32 (88.9%)		
	Incomplete = 6 (16.7%)			Incomplete = 4 (11.1%)		
	Complete = 1 (2.8%)			Complete = 0 (0%)		
Fusion at 6 and 12 months (n.s.)	No fusion = 0%			No fusion = 0(0%)		
	Incomplete = 5 (13.9%)			Incomplete = 8 (22.2%)		
	Complete = 31 (86.1%)			Complete = 28 (77.8%)		

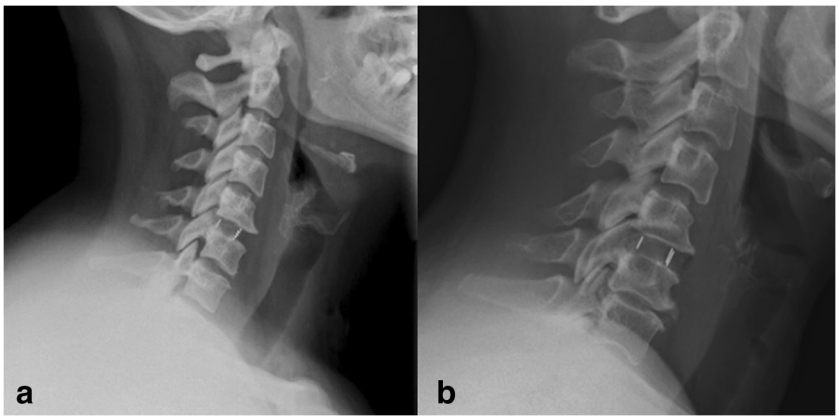

Fig. 1 Lateral cervical x-rays at 12 months without cervical vertebrae fusion. **a** A patient with no cervical fusion. **b** A partial bony fusion

(version 11.0.1; SPSS, Inc. Microsoft Corporation, One Microsoft Way Redmond, WA 98052-7329, USA).

The sample size was calculated on the basis of the primary hypothesis of the study. We considered the incidence of fusion after ACDF with collar reported in the literature and hypothesized that percentage would decrease without the collar, due to absence of immobilization. Target sample size was 76 (38 in each group). The sample size was calculated assuming an incidence of fusion of 80% in the control group and 50% fusion rate (38 vs 38 patients) or 45% fusion rate (29 vs 29 patients) in patients without collar, with 5% significance ($a = 0.005$) and 80% power ($b = 0.80$). The sample size was calculated using web-based sample size calculator (https://clincalc.com/stats/samplesize.aspx).

The Fisher exact test was used for comparing clinical variables of patients. ANOVA analysis was used to compare means. Logistic regression analysis was used for defining the impact of the aforementioned variables on dichotomized functional outcome measures (NDI at 2 weeks and NDI at 3, 6, and12 months). Results presenting $p \leq 0.05$ were considered statistically significant.

Results

The ECO group was composed of 17 males and 19 females and the non-ECO group of 18 males and 18 females. In the ECO group, 32 patients wore the cervical collar for 4 weeks and 4 for more than 4 weeks.

The baseline demographic characteristics of population are shown in Table 1.

None of all 72 patients had postoperative complications and none was lost at the final follow-up.

The 1 month follow-up cervical x-ray showed that 61 (84.7%) patients had no cervical fusion, 10 (13.9%) had an incomplete fusion, and 1 (1.4%) had a complete fusion. In the ECO group, 29 (80.6%) patients had no cervical fusion, 6 (16.7%) had an incomplete fusion, and 1 (2.8%) had a complete fusion. In the non-ECO group, 32 (88.9%) patients had no cervical fusion, 4 (11.1%) had an incomplete fusion, and no patient had a complete fusion (Fig. 1).

The x-rays at 6- and at 12-month follow-up were the same. Particularly, 59 patients (81.9%) presented fusion and 13 patients (18.1%) presented incomplete fusion. In the ECO group, 5 patients (13.9%) presented an incomplete fusion and 31

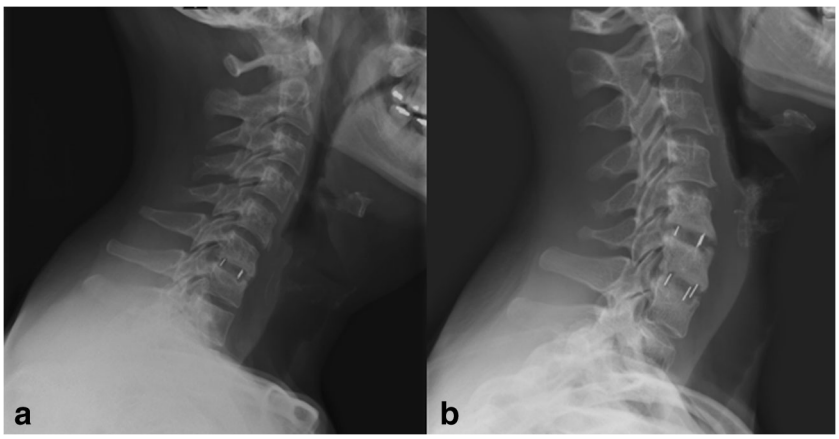

Fig. 2 Lateral cervical x-rays at 12 months with complete cervical vertebrae fusion after one-level (**a**) and 2-level (**b**) ACDF

Table 2 Contingency tables showing none of the variables had an impact on fusion rate

	Uncompleted fusion *n* (%) at 6 and 12 months	Completed fusion *n* at 6 and 12 months	*p* (χ^2) unilateral	*p* (χ^2) bilateral
Male/female	7/6	28/31	0.76	0.45
Median age population (year) < 48/≥ 48	4/9	31/28	0.22	0.13
Median BMI population < 25,615/≥ 25,-615	4/9	29/30	0.36	0.18
ICD-9-CM 721.1/722.0	5/8	18/41	0.74	0.40
Cervical level single/two	6/7	30/29	1	0.50
ECO without/with	8/5	28/31	0.54	0.27

patients (86.1%) presented a complete fusion (0.861 [CI 0.705–0.953]). In the non-ECO group, 8 patients (22.2%) presented an incomplete fusion and 28 patients (77.8%) had a complete fusion (0.778 [CI 0.608–0.899]) -Fig. 2.

At univariate analysis, none of the aforementioned demographic variables had a significant impact on the fusion rate at 6 and 12 months (Table 2).

One-way ANOVA to compare the NDI at 2 weeks and at 3, 6, and 12 months with the demographic variables showed no difference at various follow-ups between groups (Table 3). Nonetheless, we found that patients who underwent two-level ACDF had a worse clinical outcome than for the single-level at 2 weeks ($p = 0.03$) and at 3, 6, and 12 months ($p = 0.007$). These data were confirmed by multivariate logistic regression analysis, showing patients undergoing two-level ACDF had an increased risk of worse NDI at 3, 6, 12 months (OR = 5081, CI 1770-14,584; $p = 0.003$) (Table 4).

Discussion

Cervical collar is routinely used following ACDF surgery to theoretically improve the clinical and radiological outcome and avoiding surgical postoperative complications. However, this precaution is based more on a common practice than on a solid clinical evidence. The highest level of evidence available so far comes from the review by Camara R. et al. [3] advising against routine use of ECO after ACDF because of a lack of fusion improvement, with no mention regarding functional outcomes.

In our study, we analyzed both radiological and functional outcomes after ACDF in 72 patients. They belonged to two groups that differed solely for the use of ECO after surgery; even if this is not a randomized control study, *sensu stictu*, the temporal line itself represents a randomization factor.

We did not find out any significant difference regarding fusion rate between the two groups at 1, 6, and 12-month follow-up. This evidence is in line with the conclusion of the study by Jagannathan et al. [7], although the evidence of that study is limited, since fusion rates were only investigated in patients without ECO. Abbott et al. [1] studied the impact of ECO in two different groups of patients and noted no qualitative differences in postoperative fusion rates between the group with ECO and the group without it at 3 months after surgery. Despite this evidence, we cannot yet conclude that the radiological outcome is similar between groups, since our power calculation only addressed a ≥ 30% difference between the groups (80% in ECO group vs 50% in non-ECO group). Thus, our primary conclusion is not really justified: a smaller benefit could still be identified with al larger patients' sample. Nonetheless, the number of patients with radiological fusion in the non-ECO-group was higher than expected (0.778 [CI 0.608–0.899]), with a value very close to that reported in the literature for patients with collar. Finally, from a clinical point of view, both complete and partial fusion can be considered as a good result and in both groups we observed a 100% fusion at 12-month follow-up (both complete and partial).

Table 3 Analysis of variance (ANOVA) comparing NDI values in patients with and without ECO. The difference between the two groups are not statistically significant

	ECO					
	N	Mean %	SD %	Minimum %	Maximum %	*p* value
NDI at 2 weeks						
Without ECO	36	16.2	15.2	0.00	68.00	
With ECO	36	21.3	22.2	0.00	78.00	
Total	72	18.8	19.1	0.00	78.00	0.26
NDI at 12 months						
Without ECO	36	5.3	8.5	0.00	35.50	
With ECO	36	9.4	13.3	0.00	48.00	
Total	72	8.1	13.7	0.00	48.00	0.12

Table 4 Multivariate logistic regression analysis. Patients with two level surgery have a higher risk of worse NDI

	Median NDI at 6–12 months			
	***p* (significance: *p* < 0,05)**	OR	95% C.I. for OR	
			Inferior	Superior
Sex	0.525	0.713	0.251	2.023
Median age population (year)	0.475	1.457	0.519	4.092
Cervical level	**0.003**	**5.081**	**1.770**	**14.584**
Cervical collar	0.553	1.366	0.487	3.837

p (significance: $p < 0,05$)

Our results suggest that the use of postoperative ECO is ineffective either on radiological and clinical outcome at 2 weeks, and at 3, 6, and 12 months. The data about NDI are in contrast with the study of Abbot et al. [1], suggesting that the use of ECO after ACDF is associated with significantly lower levels of NDI, although the same authors did not find any statistical differences at 6 months after surgery.

We observed that patients who underwent two-level ACDF had a worse clinical outcome than those who underwent surgery for single-level, with an increased risk of worse NDI (OR = 5081; $p = 0.003$). These findings were already outlined by another paper [15].

The main limitations of our study are the relatively low sample size, with consequent decrease of statistical power, and the inclusion of patients who underwent ACDF for both single-level and two-level disc herniation; moreover, due to the absence of a standardized randomization process, some bias could have occurred since patients could have been positively influenced by our expectations, leading to better outcomes at early follow-ups. Finally, the fact that only one surgeon has been involved could affect the generalizability of these results. Nonetheless, it presents different important strength aspects: it was specifically designed as a prospective case-control study to evaluate fusion rates and clinical outcome in patients who underwent ACDF with and without ECO. All patients were selected and operated by the same senior surgeon using standard ACDF, using the same type of cage in all cases. Finally, all patients were followed up prospectively with a standardized protocol, all patients complied with using ECO, and no patients were lost at follow-up.

Conclusion

In line with other authors [15], we advise against the routine use of ECO after single-level or two-level ACDF. The use of postoperative ECO can be proposed for few accurately selected cases.

However, based on the limitations of this study, especially for the low number of patients enrolled, we suggest performing further prospective case-control studies in order to achieve a better and improved comprehension of the effects of postoperative use of ECO after ACDF.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the Ethical Committee of Ferrara University and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by Ethical Committee of Ferrara University Hospital (Ethics CE-AVEC number 55/2019/Oss/AOUFe).

Informed consent Informed consent was obtained from all individual participants included in the study.

References

1. Abbott A, Halvorsen M, Dedering Å (2013) (2013) Is there a need for cervical collar usage post anterior cervical decompression and fusion using interbody cages? A randomized controlled pilot trial. Physiother Theory Pract 29(4):290–300. https://doi.org/10.3109/09593985.2012.731627
2. Bohlman HH, Emery SE, Goodfellow DB, Jones PK (1993) Anterior cervical discectomy and arthrodesis for cervical radiculopathy. Long-term follow-up of one hundred and twenty-two patients. J Bone Joint Surg Am 75(9):1298–1307
3. Camara R, Ajayi OO, Asgarzadie F (2016) Are external cervical orthoses necessary after anterior cervical discectomy and fusion: a review of the literature. Cureus. 2016:8(7). https://doi.org/10.7759/cureus.688
4. Carette S, Fehlings MG (2005) (2005) Clinical practice. Cervical radiculopathy. N Engl J Med 353(4):392–399. https://doi.org/10.1056/NEJMcp043887
5. Connolly PJ, Grob D (1998) Bracing of patients after fusion for degenerative problems of the lumbar spine–yes or no? Spine (Phila Pa 1976) 23(12):1426–1428. https://doi.org/10.1097/00007632-199806150-00024
6. Elliott RE, Tanweer O, Boah A, et al. (2013) Is external cervical orthotic bracing necessary after posterior atlantoaxial fusion with modern instrumentation: meta-analysis and review of literature. World Neurosurg. 79(2):369–374.e12. doi:https://doi.org/10.1016/j.wneu.2012.03.022
7. Jagannathan J, Shaffrey CI, Oskouian RJ et al (2008) Radiographic and clinical outcomes following single-level anterior cervical discectomy and allograft fusion without plate placement or cervical collar. J Neurosurg Spine 8(5):420–428. https://doi.org/10.3171/SPI/2008/8/5/420

8. Krock N (1997) Immobilizing the cervical spine using a collar. Complications Nurs Manag Axone 18(3):52–55
9. Lunsford TR, Davidson M, Lunsford BR. (1994) The effectiveness of four contemporary cervical orthoses in restricting cervical motion. JPO J Prosthetics Orthot 1994;6(4)
10. Miller CP, Bible JE, Jegede KA et al (2010) The effect of rigid cervical collar height on full, active, and functional range of motion during fifteen activities of daily living. Spine (Phila Pa 1976) 35(26):E1546–E1552. https://doi.org/10.1097/BRS.0b013e3181cf6f73
11. Naylor JR, Mulley GP (1991) Surgical collars: a survey of their prescription and use. Br J Rheumatol 30(4):282–284
12. Penolazzi L, Lambertini E, Bergamin LS, et al. (2018) MicroRNA-221 silencing attenuates the degenerated phenotype of intervertebral disc cells. Aging (Albany NY). 10(8):2001–2015. doi: https://doi.org/10.18632/aging.101525
13. Robinson RA (1959) Fusions of the cervical spine. J Bone Joint Surg Am 41-A(1):1–6
14. Webber-Jones JE, Thomas CA, Bordeaux RE Jr (2002) The management and prevention of rigid cervical collar complications. Orthop Nurs 21(4):19–25
15. Zigler JE, Rogers RW, Ohnmeiss DD (2016) comparison of 1-level versus 2-level anterior cervical discectomy and fusion: clinical and radiographic follow-up at 60 months. Spine (Phila Pa 1976) 41(6):463–469. https://doi.org/10.1097/BRS.0000000000000126