

Three and Four Levels Anterior Cervical Discectomy and PEEK Cage Fusion Alone in Treatment of Cervical Degenerative Radiculomyelopathy

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Abstract

Background: Anterior Cervical Discectomy and Fusion (ACDF) is the commonest procedure used in treatment of degenerative cervical radiculomyelopathy, and the use of spinal cages with auto graft helps in increasing foraminal height, and regaining the lordotic cervical curvature, besides it gives high rate of fusion with less complications.

Aim of the Study: To evaluate the safety and efficacy of three and four levels ACDF with PEEK cages only without plating, and to assess the clinical and radiologic outcome.

Study Design: This non randomized non controlled clinical trial case series of seventeen patients, their aged 42 to 73 years of age with cervical degenerative radiculomyelopathy who were treated with three or four ACDF with PEEK cage fusion which were done at Neurosurgery Department of Benha University Hospitals during the period from 2011 to 2016, With mean follow-up 18.6 months.

Patients and Methods: Ten males and seven females, of them four cases with cervical spondylotic myelopathy, and thirteen cases with radiculopathy were included. Patients were clinically evaluated using Visual Analogue Score (VAS) for pain and Neck Disability Index (NDI), and radiologically evaluated for neck curvature, fusion rate in lateral radiographs.

Results: Five cases underwent four levels ACDF, and twelve cases underwent 3 levels ACDF with a total of 56 levels operated upon. As regard clinical state there was a statistically significant improvement in VAS in neck and arm pain ($p < 0.001$), and also in NDI ($p < 0.001$). All cases with myelopathy had significant satisfactory improvement in spasticity with improved ability. As regard radiology 82.4% of patients had good fusion, significant improvement in lordotic curve (from mean of 7.6° to 16.2°) and increased disc height.

Conclusion: Three and four levels ACDF with PEEK cage alone without plating in treatment of degenerative cervical radiculomyelopathy is safe and effective and had good clinical outcome with low complication, and good radiologic outcome

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with excellent fusion rate, restoring the lordotic curve and increasing and maintaining disc height.

Key Words: Anterior cervical discectomy – Cage fusion – Cervical degenerative radiculomyelopathy.

Introduction

IN the surgical treatment of cervical radiculopathy and myelopathy a different options were used aiming for neurological decompression, restoring anatomical lordotic curve, increasing disc height and foraminal height for better neural tissue release and promoting permanent position for more stable result [1,2]. Anterior and posterior approach were used guided by cervical curvature, offending compressive element while anterior or posterior, and number of levels affected [1-3].

Anterior approach had been used widely in single and double level affection with different techniques and material used with good result [3-5]. PEEK cages were used in last 2 decades for treatment of cervical degenerative disease CDD aiming for fusion, increasing foraminal and disc height and contributes for restoration of cervical lordosis. The use of PEEK cage in treatment for 3 and 4 levels with and [4-6] without plating were reported [7-11]. Plating provided optimum fusion rate, but carry high incidence of cage subsidence and low rate of plate related complication [8], and

Abbreviation:

ACDF : Anterior Cervical Discectomy and Fusion.
PEEK : Polyetheretherketone.
VAS : Visual Analogue Score.
NDI : Neck Disability Index.
JOA : Japanese Orthopedic Association score.
CT : Computerized Tomography.
MRI : Magnetic Resonance Imaging.
CDD : Cervical Degenerative Disease.

stand use of PEEK cages for 3 and 4 levels CDD had been used with favorable outcome [7,10,11].

The aim of this study is to evaluate the safety, efficacy of 3 and 4 levels ACDF with PEEK cages only without plating, and to assess the clinical and radiological outcome.

Subjects and Methods

This non randomized non controlled clinical trial on seventeen patients presented with clinical sign and symptoms of cervical radiculopathy (13 patients), and radiculomyelopathy (4 patients), with radiological evidence of 3 levels cervical degenerative pathology in 12 cases, and 4 levels in 5 cases, who failed conservative treatment and were subjected for surgery. All patients underwent anterior approach for cervical discectomy and fusion using PEEK cages only without plating at Benha university hospitals through the period from November 2011 to June 2016.

Seventeen patients, ten males, and seven females, with their age ranged from 42 to 73 years (mean age 57.8 ± 7.6 yrs).

Pre-operative assessment:

All patients were assessed clinically with careful history taking, and proper clinical examination, all cases were ambulating except the oldest case (73 years) who was on wheel chair for 1.5 months before surgery. Clinical evaluation was done: Visual Analogue Score (VAS) for pain and Neck Disability Index (NDI) for assessing outcome [12]. All patients were administered a subjective VAS and NDI questionnaire pre-operatively and 2 months after surgery, rated on a scale from 1 to 10. The content validity of the questionnaire was confirmed by a team of three experts of Neurosurgery. The questionnaire was first written in English and translated to Arabic which is then translated back to English in order to ensure that the translated version gives the proper meaning.

All patients had pre-operative cervical X-ray in AP and lateral positions, and Magnetic Resonance Imaging (MRI), but Computerized Tomography (CT) was done in three cases with MRI possibility of ossified posterior longitudinal ligament OPLL, only one case had evidence of C 4,5 to C5,6 continuous ossification that wasn't opposite the most compressed level and it was proceeded for ACDF without corpectomy, the other two cases had advanced osteophytosis only.

Operative notes:

In the supine position, general anesthesia was introduced to patients; in the four cases with myelopathy endotracheal intubation was done while patient wearing the hard collar for controlled extension. A transverse incision was utilized in all cases, and its place was centered at middle of affected levels using fluoroscopy. Then the dissection is continued towards the cervical vertebrae, where longus coli was properly dissected laterally to expose the vertebrae and to provide a site for resting of Cloward retractors. One retractor was used through the procedure and it allowed for a view of two levels at once and it was repositioned for work in other levels. Kaspar retractor was used for vertebral distraction.

At all levels, and under the operating microscope, exposure of anterior osteophyte was done and pieces are taken for filling the cages. Discectomy then was done using sharp curettes advancing to the posterior longitudinal ligament, removal then was continued using the curettes, Kerrison rongeurs number 1 and 2, and blunt hook, posterior osteophytes if presented were removed carefully and thoroughly until a clear posterior wedging is done and foraminotomy also done until a rectangular view of the posterior part is seen.

After finishing discectomy in all levels cages size is tested then the desired cages were filled with pieces of bones obtained during surgery mixed with blood except in two cases where synthetic bone graft was used then placed in the intervertebral place and verified with fluoroscopy.

After surgery all patients wore a hard neck collar and were discharged by the 2nd day except one case with CSF leak during surgery discharged at the 6th day. The hard collar was used for 6 weeks then soft collar for 3-5 weeks.

Post-operative follow-up:

All patients were assessed clinically and radiologically for a period of follow-up ranged from 12 to 27 months (mean 18.6 ± 4.3 months). Clinical evaluation was done by postoperative VAS and NDI. Radiologically, immediate post-operative X-ray AP and lateral views were done as standard for follow-up then at 2 months, 4-6 months and at 10-12 months, two cases had intermittent improvement and underwent MRI, MRI were satisfactory, and these two patients had complementary medical treatment and did fairly good. Also fusion was assessed and was defined by the presence of bone trabeculation through the disc space, crossing

through the cage without lucencies between cages and bony endplate, besides the fixed position of operated levels in dynamic X-ray views. Cervical

lordosis was assessed pre and post-operatively on lateral X-ray, the angle between extended line along anterior border of C 2 and C7 is obtained.

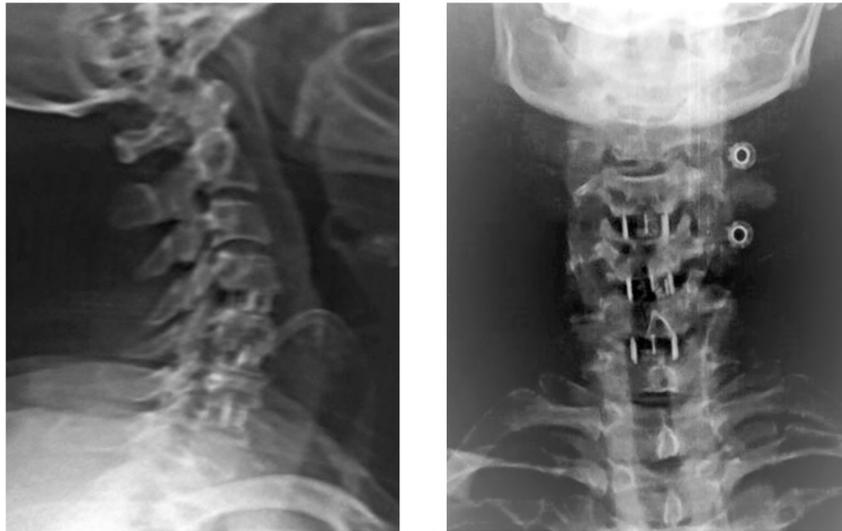


Fig. (1): A case with C4-5 to C6-7 3 levels PEEK cage alone fusion at 9 months follow-up showing good fusion.



Fig. (2): A case with C4-5 to C6-7 3 levels ACDF with cages alone showing cage subsidence at level C6-7. This female patient had mild intermittent axial neck pain resolving on medical treatment.

Results

This study was conducted on 17 patients, 10 males (58.8%), and 7 females (41.2%). Thirteen patients (76.5%) presented with radiculopathy, and

4 patients (23.5%) with radiculomyelopathy, their ages ranged from 42 to 73 years (mean age 57.8 ± 7.6 years). Three levels ACDF with PEEK cage was done in 12 cases (70.6%), and 4 levels was done in 5 cases (29.4%).

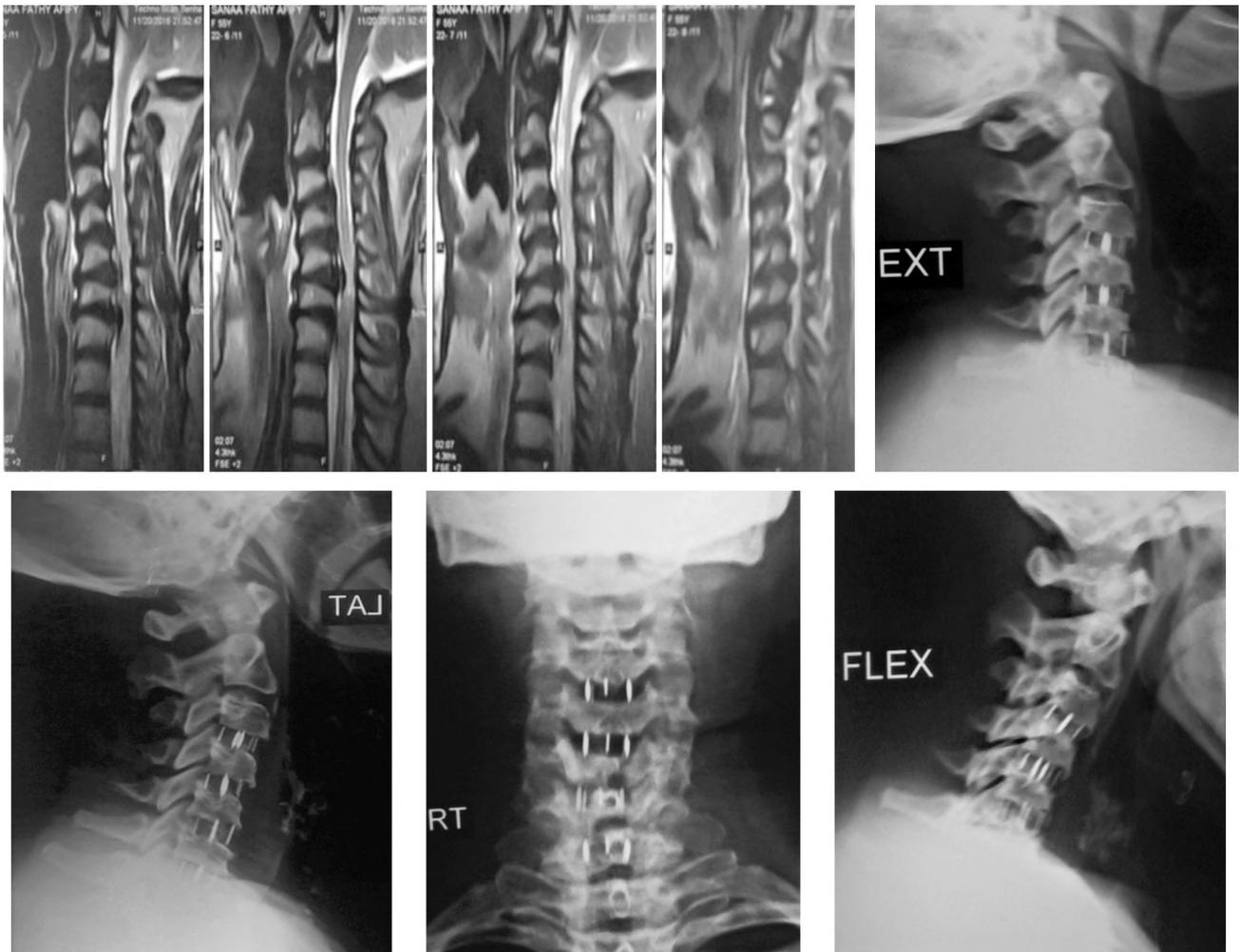


Fig. (3): This female patient presented with radiculomyelopathy and quadriplegia more on the left side MRI pre-operative showed C_{3-4} to C_{6-7} cervical disc lesion with cord compression mainly opposite C_{5-6} . Plain X-ray AP and lateral of early post-operative period and to the right flexion and extension radiograph at 12 months after surgery showing good fusion and stability during flexion and extension. Patient clinically showed excellent improvement.

Clinical outcome:

The mean follow-up time was (18.6 ± 4.2 months) ranged from 12 to 27 month, no operative related mortality or morbidity occurred in the early post-operative period. The mean of Visual Analogue Score VAS for neck and arm pain before surgery was (6.79 ± 1.13), and it improved to (2.05 ± 1.08) at 2 months after surgery, and the mean of neck disability index NDI before surgery was (40.2 ± 15), and it improved to (14.88 ± 5.48) at 2 months after surgery. The difference between means of VAS and NDI before and after surgery was statistically significant (Table 2).

Radiologic outcome:

Regarding fusion, final follow-up X-ray was done at least 12 months after surgery, and according to defined criteria, 3 cases (17.6%) had unfused levels (1 level in each case). This represented 3 out of 56 levels (5.4%) with good fusion rate in 53 levels (94.6%). The mean cervical lordotic angle improved from 7.6° to 16.2° at final follow-up radiograph.

Complications:

No mortality had occurred related to surgery, nor significant morbidity. One patient (5.9%) had

dural tear and CSF leak, the non suction drain was kept for 10 days and then removed at <20ml. per day for 3 days and patient was given acetazolamide and potassium supplement for 2 weeks. The 3 patients with unfused levels were asymptomatic and they would be followed for any related symptoms. Cage subsidence occurred in one patient (5.9%) who had a 3 level surgery at the distal level at C6,7 representing (1.8%) of the operated levels, this was observed on X-ray follow-up at 2 months after surgery, and no further subsidence occurred later on and patient was asymptomatic. No other surgical complication occurred such as infection, swelling, swallowing difficulties, cage extrusion, or worsening neurological condition.

Table (1): Epidemiology of the studied group.

Variable	Value (17)
<i>Age/y:</i>	
mean ± SD	57.8±7.6
Range	42-73
<i>Sex n (%):</i>	
Male	10 (58.8%)
Female	7 (41.2%)
<i>Clinical presentation n (%):</i>	
Arm pain	17 (100%)
Neck pain	10 (58.8%)
Myelopathy	4 (23.5%)
Sphincteric troubles	1 (5.9%)
<i>Operated levels n (%):</i>	
3 levels	12 (70.6%)
4 levels	5 (29.4%)
<i>Follow-up period (months):</i>	
mean ± SD	18.6±4.3
Range	12-27

Table (2): Comparison between pre-operative and post-operative VAS and NDI.

	VAS	NDI
Pre-operative	6.79±1.13	40.2±15
Post-operative	2.05±1.08	14.88±5.48
<i>p</i> -value	<0.001 (significant)	<0.001 (significant)

Discussion

Since the introduction of the anterior cervical approach for treatment of cervical degenerative disease CDD with anterior discectomy and fusion, [1,2] this approach was and still gaining popularity and trust. Posterior approach for cervical diseases had limited indication now, as it had many complications as progressive kyphosis, loss of sagittal balance, and axial neck pain. It is also clear that most offending pathology in CDD as soft disc, osteophytes, ossified posterior ligament that com-

promise the neural structure are located anteriorly [1-3,13].

In surgical treatment of CDD, it is important to fulfill all surgical goals; removal of degenerated disc material, decompression of compromised neural structures, increasing the neural foraminal height, ensure fusion to maintain this favorable goals [3,4,12,14,15].

Fusion with autologus bone graft-usually from the iliac crest-was used at first for long time with success [3]. This graft could early increase disc height, and foraminal height, and also improve cervical lordotic curve, but the high rate of complication as pseudoarthrosis, collapse, subsidence, and resorption gradually decreased its use [16].

Using PEEK cages in treatment of CDD is increasing and gaining trust, because of the physical characters of it as a good implant [3,17,18]. And also its radiolucency that offer good chance for assessment of fusion status on X-ray and CT scan [3,17,18]. Although PEEK cage assisted ACDF had been proven to be safe and effective for treatment of CDD, [10] its use in multilevel CDD showed increased incidence of cage subsidence [19]. But it is to be considered that this high rate was related more to the metal cages, metal cages had high rate of subsidence, [3,20] and its elasticity differed from the bone, besides over distraction of the disc space or cage over sizing that could cause cage subsidence whether metal or PEEK [10,21].

Cage subsidence in this study occurred in one patient (5.9%), this is comparable to other studies with 8.89%, 3.3% and 4%, [7,10,11] other studies with stand alone PEEK cage assisted ACDF showed higher incidence 16.7%, and 16.6% [21,22]. A higher incidence 23.8% occurred in a study using both PEEK cages and plates, but this study was conducted on elderly patients (mean age 71.7yrs), these patients usually had osteoporosis and are vulnerable for this complication [8]. One study suggested the use of bone mineral density measurement before surgery to decrease cage subsidence and predict its occurrence in osteoporotic patients [11].

Many studies showed that good results were obtained in treatment of one or two levels CDD with PEEK cage assisted ACDF [3,4,24], and recently especially the last decade many studies were conducted for the assessment of the use of PEEK cage alone in 3 and 4 levels and they all had excellent results [7,10,11,22,23,25]. On the other side other studies in the same time assessed combined use of PEEK cage and plating and they had also

excellent results with very low incidence of mild complication [8,9]. In all of these studies no major complication were encountered and only few patients needed reoperation suggesting similar results in both techniques.

The use of plate augmentation appeared to had better fusion rate in the early follow-up, and decreased incidence of pseudoarthrosis, maintenance of foraminal height. This aims were obtained with low rate of complication such as plate and screw loosening, respiratory discomfort, dysphagia, and hoarseness, [8,9] this complication were temporary and did not affect improved clinical state of the patients.

Clinically, all patients in this study showed satisfactory t excellent outcome. As regard pain in the neck and upper limb VAS decreased from 6.7 ± 101 to 2.05 ± 1.08 , this was statistically significant, similar results were obtained in other studies the used VAS to assess pain [10,22]. Disability in this study was evaluated with NDI that showed significant difference from 40.2 ± 15 to 14.88 ± 5.48 , this was comparable to studies using this index, [8,9] although this studies were on combined use of cages and plate. Other studies on cage alone use in 3 and 4 levels used JOA for assessment of clinical outcome and all of them showed significant improvement [10,22,23].

Fusion rate in plated 3 and 4 levels ACDF was optimum (100%) (Song 2011), the studies using cages only had a very good fusion rate ranged from 76% to 100% [7,10,11,22,23,25]. In our study fusion

was achieved in 82.4% of cases, this was comparable to other similar studies. All studies and also our study claimed that non fusion segment mostly did not show related clinical symptoms or worsening except very few cases.

As regard changes in cervical lordotic curve, this study showed improved mean of cervical angle from 7.6° to 16.2° , this coincides with other studies [10,11]. One study using combined cages and plates showed no significant improvement in cervical angle despite the use of rigid fixation [9].

Adjacent level disease could be due to the fact that patients with 3 and 4 levels CDD could have also other levels problems rather than it would occur due to surgical fusion, but also fused segment transmitted motion biomechanically place more strain over adjacent levels [22]. In this study we have no incidence of adjacent segment disease during the period of follow-up, other studies with stand alone cages reported 6.6% in two series, [11,22] and one study of combined use of cages and plates had incidence of 14.3% [8].

Generally, the use of PEEK cage alone in 3 and 4 levels ACDF had good to excellent overall results, these results are comparable to that of combined use of PEEK cages and plates. Stand alone cages in ACDF had less operative time and morbidity and would be better. In all studies, including this study the period of follow-up is not long enough to assess long term efficacy of this technique and further work on longer follow-up period is needed for complete assessment.

Table (3): Demographic data from this study and the recent studies in literature review reporting 3 and/or 4 level ACDF, 2 studies of combined use of cages and plates are included for comparison.

Study	Number of patients			Mean age	Gender		Follow-up period
	Total	3 levels	4 levels		M	F	
<i>PEEK Cage stand alone:</i>							
Zhou et al., 2011	15	15		57.2	10	5	19.8
Liu et al., 2012	25	25		52.6	14	11	25.6
Pereira et al., 2013	30	23	7	56.7	16	14	47.2
Abdelwahab and Hoyedy 2014	18	12	6	55	12	6	9
Saoud et al., 2016	30	28	2	52.23	27	3	At least 12
Hakan 2017	58	38	20	64.2	32	26	35.6
Current study	17	12	5	57.8	10	7	18.6
<i>PEEK cage and plating:</i>							
Song et al., 2011	21	21	–	71.7	10	11	34.1
Song et al., 2012	43	39	4	61.3	24	19	>24

Table (4): Results of the current study in comparison to similar recent studies regarding stand alone cages in 3 and/or 4 level ACDF, and combined cages and plates.

Study	Results								
	VAS		Disability improvement		Fusion	Cage subsidence	Cervical lordosis		Adjacent segment disease
	Preop.	Postop.	Preop.	Postop.			Preop.	Postop.	
<i>PEEK Cage stand alone:</i>									
Zhou et al., 2011	NA	NA	JOA 7.3	14.1	93.3%	8.89%	NA	NA	NA
Liu et al., 2012	8.2	1.9	JOA 10.7	14.1	76%	4%	1.3	7	NA
Pereira et al., 2013	5.8	2.2	JOA 12.3	14	90%	16.7%	NA	NA	6.6%
Abdelwahab and Hoyedy 2014	NA	NA	mJOA 10.4	14.7	100%	16.6%	NA	NA	NA
Saoud et al., 2016	Significant improvement		Nurick significant improvement		96.7	3.3%	11.2	28.6	6.6%
Hakan 2017	NA	NA	JOA 13.3	15.5	89.2%	NA	NA	NA	NA
Current study	6.79	2.05	NDI 40.2	14.88	82.4%	5.9%	7.6	16.2	0%
<i>PEEK cage and plating:</i>									
Song et al., 2011	NA	NA	NDI 55.3	15.9	NA	23.8%	5	16.5	14.3 %
Song et al., 2012	6.74	3.93	NDI 29.52	12.34	100%	NA	12.2	14.1	NA

Conclusion:

Three and four levels ACDF with PEEK cage alone without plating in treatment of degenerative cervical radiculomyelopathy is safe and effective and had good clinical outcome with low complication, and good radiologic outcome with excellent fusion rate, restoring the lordotic curve and increasing and maintaining disc height.

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This study had no funding from any resource.

Competing interests:

The authors declare that they have no conflict of interest.

Ethical approval:

This research accepted by Research Ethics Committee (REC) of Faculty of Medicine, Benha University (chairman: Prof/Ibrahim El-Gendy).

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or National Research Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. A written informed consent was obtained from each patient after explaining all steps of this study.

Authors' contributions:

Ahmed Arab and Mohammed El-Tantawy performed the clinical part of the study, Ahmed Arab

and Mohamed El-Maghrabi analyzed the data and wrote with meticulous revision of the paper.

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إستئصال الغضروف العنقى الأمامى مع الإلتئام العظمى بإستخدام الأقفاص الكربونية فقط فى علاج إعتلال الجذور والنخاع العنقى التنكسى بإستخدام الأقفاص الكربونية فقط

الخلفية: إستئصال الغضروف العنقى الأمامى مع الإلتئام العظمى هو الأكثر شيوعا فى علاج إعتلال الجذور والنخاع العنقى التنكسى ويساعد إستخدام الأقفاص الكربونية فى تحسين منحنى الفقرات العنقية وتوسيع مخارج الأعصاب وسرعة الإلتئام العظمى مع مضاعفات أقل.

الهدف: تهدف الدراسة إلى تقييم سلامة وفعالية إستئصال الغضروف العنقى الأمامى مع إستخدام الأقفاص الكربونية للإلتئام العظمى على ثلاث وأربع مستويات بدون إستخدام الشرائح العنقية وتقييم النتائج الإكلينيكية ونتائج الفحص الإشعاعى.

الدراسة: دراسة غير عشوائية على ١٧ مريض تراوحت أعمارهم بين ٤٢ و٧٣ سنة تم علاجهم جراحيا فى الفترة من ٢٠١١ إلى ٢٠١٦ وتم متابعتهم لفترة ١٨.٦ شهر فى المتوسط.

المرضى والطرق: شملت الدراسة ١٠ ذكور و٧ إناث من بينهم ٤ مرضى يعانون من إعتلال الجذور والنخاع العنقى و١٣ مريض يعانون من إعتلال الجذور فقط وتم تقييم المرضى إكلينيكا بواسطة تقييم الألم والإعاقة وإشعاعيا لمنحنى العنق ودرجة الإلتئام العظمى.

النتائج: أجريت الجراحة على أربعة مستويات فى ٥ مرضى وثلاثة مستويات فى ١٢ مريض. كان التحسن الإكلينيكى للكلم والإعاقة كبيرا وهاما إحصائيا، وحدث إلتئام عظمى فى ٨٢.٤٪ من المرضى، وتحسن متوسط منحنى الفقرات العنقية من ٧.٦ درجة إلى ١٦.٢ درجة.

الإستنتاج: يعتبر إستئصال الغضروف العنقى الأمامى مع الإلتئام العظمى بإستخدام الأقفاص الكربونية فقط على ثلاثة وأربعة مستويات آمن وفعال جراحيا مع مضاعفات بسيطة وتحسن إكلينيكى جيد وتحسن جيد فى الإلتئام العظمى ومنحنى الفقرات العنقية.