

Artificial Cervical Disc Replacement versus Anterior Cervical Discectomy and Fusion in the Management of Single Level Cervical Disc Prolapse: Randomized Control Single Blinded Study

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Abstract

Background: Anterior cervical decompression and interbody fusion can result in the loss of range of motion with accelerated adjacent disc degeneration.

Aim of Study: This study details the analysis of the indications, safety, efficacy and complications of cervical dynamic artificial disc replacement (CDR) for cases of cervical disc diseases compared to PEEK (polyetheretherketone) cage insertion, in addition statistical comparison between both techniques.

Patient and Methods: The study included 30 patients with single level disc disease with radiculopathy both confirmed by clinical and radiological data, with failed medical treatment for 6 weeks at least.

Results: Average age of presentation was 37.7 years (age range 18-50) for both groups, female ratio for the fixed group was 1:1.5, and 1:0.8 for the dynamic group. The average duration of symptoms was 51.4 weeks, 21 cases had left, while 9 had right sided radiculopathy. The most common presenting symptom after neck pain was the brachialgia, most common sign was sensory changes. Most common operated level was C5-6 for both groups. The average follow-up period in our study was 6 months, during which no recurrence, instability or progressive kyphosis occurred.

The neck disability index, in the Anterior Cervical Discectomy and Fixation (ACDF) group (66.7% scored from 5 to 14), (33.3% from 15 to 24), versus in the artificial disc group (53.3% scored from 5 to 14), (46.7% scored from 15 to 24).

The clinical assessment as regard the motor and sensory shows no different out comes where the both study groups give the same final surgical results.

Conclusion: Cervical dynamic implants offer many distinct advantages over the traditional (ACDF) to include preserved segmental motion, decreased adjacent level strain, offers adequate motion to avoid overloading and accelerating adjacent level degeneration.

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Overall, the results provided suggest that CDR although being more expensive, but may be a safe and effective alternative surgical procedure to fusion for the treatment for single level cervical disc.

Key Words: Anterior cervical discectomy and fusion (ACDF) – Cervical dynamic artificial disc replacement (CDR).

Introduction

MANAGEMENT of cervical disc herniation with anterior decompression with interbody fusion using internal fixation device was the classic method of treatment, but this fusion can affect the range of motion of cervical vertebra, which causes acceleration of the process of degeneration in the adjacent cervical disc. It can protrude against the nerve roots or the spinal cord compressing them, making a second operation necessary [1].

Adjacent-level disease in several studies accounts for about 25 to 54% of patients who undergo long term follow-up following Anterior Cervical Discectomy & Fixation (ACDF) [2].

In a single level subaxial fixation, the cervical spine has the ability to compensate and can maintain the overall motion. However, as more levels are included into the construct, cervical motility is adversely affected. Levels adjacent to a cervical fusion can experience extra stresses that contribute to its degeneration [3].

Cervical dynamic implants provide many distinct advantages over the classic anterior cervical discectomy and fusion to include preserved segmental motion, minimizing adjacent level strain, and improving the, outcomes. Although it was initially intended for single-level disease, multilevel cervical dynamic implants revealed to be safe and

effective alternative to fusion in the management of cervical myelopathy and radiculopathy [3].

Cervical inter-body cages have been utilized to provide immediate stability with a high fusion rates, without or with supplemental fixation. In the light of the literature, multilevel anterior cervical discectomy and fixation procedures, augmenting the fixation with plate may seem to be preferred due to the higher fusion and lower incidence of reoperation, and better pain relief [4].

The benefit with using only cage was largely adopted by shorter operative time and less hospital stay. Carbon fiber, titanium, and Polyether ether ketone PEEK have been the most commonly used materials in cage production. The use of a titanium cage can result in vertebral body collapse if over degradation of the endplates was done during discectomy. Moreover, radiological metallic artifacts can complicate imaging. Furthermore, radio transparent carbon fiber although have been used widely, but synovitis and the fiber debris lymphatic spread may be found after the intra-articular procedures have been implanted [5].

One of the main goals of dynamic cervical implants is to reproduce normal kinematics after being implanted. Another studies showed the preserved motion in cervical dynamic implants treated spinal levels, in addition to preserving the Range of Motion (ROM) at the operative level of the cervical dynamic implants [6].

Aim of the work:

The study aims to compare between the outcome of two different modalities of treatment applied for the cervical disc diseases, the first group is the dynamic group, (treated by insertion of the artificial cervical disc, while the second group is the fixed group (treated by insertion of inter vertebral cage).

The post-operative outcome had been evaluated in the terms of symptoms and signs remission, operative time, complications, follow-up and radiological assessment for the two operative techniques.

Patients and Methods

This study was performed at the Department of Neurosurgery in Cairo University Hospitals in 2016 on 30 patients who were admitted to our department from the outpatient clinic, 15 patients in group A will be operated upon by cervical dynamic artificial disc replacement CDR & 15 patients in group B will be treated by anterior cervical discectomy and fusion ACDF with PEEK cage.

We will follow the patients in both groups for 12 months in terms of their clinical condition and fusion.

The post-operative outcome had been evaluated in the terms of symptoms and signs remission, operative time, complications, follow-up radiological assessment for the two operative techniques.

Inclusion criteria:

- Age: Range 18-50 years.
- No sex predilection.
- Radiologically confirmed cervical disc prolapse (decreased disc height compared to the adjacent level and disc herniation with definite cervical root(s) compression.
- Concordant symptoms and signs of the cervical root related dysfunction.
- Progressive motor deficit.
- Persistence of symptoms despite non surgical treatment for at least 6 weeks except those with initial motor deficit.

Exclusion criteria:

- Age: Less than 18 years or above 50 years.
- Multiple cervical disc prolapse.
- Cervical myelopathy.

Evaluation of the patients:

- Present history cervical pain axial neck pain, cervical radiculopathy, heaviness of the upper limb.
- Neurological examination signs of radiculopathy, decreased range of movement, Spurling's sign, upper limb weakness, parasthesia, dermatomal sensory deficit and reflexes. Signs of myelopathy on examination: To be excluded from the study.
- *Radiological investigations:*

Plain radiograms: Flexion-extension lateral cervical spine radiographs can disclose occult instability, AP views identified osteophytes and fractures. Lateral views assessed stability and spondylosis.

Magnetic resonance imaging: Osteophytes and calcified bulging disc structures were dark on T2-weighted fast spin-echo and T1-weighted spin-echo imaging.

Operative technique:

All patients were operated upon by anterior cervical approach either discectomy with fusion or discectomy with artificial disc placement.

An informed consent was obtained, and unless contraindicated, the patient was asked to extend and flex the neck voluntarily to assess for any clinical symptoms. In this manner, the surgeon and anesthesiologist can limit their manipulations so as not to exceed the patient's own range of motion. The anesthesiologist will use flexible fiber optic intubation when necessary.

The patient is placed in supine position with their limbs padded and protected, with their neck in a mild extension and head resting on a head rest. The desired level is determined by fluoroscopy and a horizontal skin incision is made. Microscopic anterior discectomy is completed after intraoperative fluoroscopic confirmation of the desired level, we insert either a PEEK cage of proper size, while in CDR we use the porous coated motion prosthesis, consisting of two cobalt chrome alloy end plates having a large radius bearing surface.



Fig. (1): Intra-operative artificial cervical disc device.

Post-operative follow-up:

We followed the patients in terms of their pain using the universal pain assessment tools and in terms of cervical fusion using follow-up X-ray flexion and extension.

Pain was assessed in the neck and arm 1 month and 6 months and 1 year post-operatively using the universal pain assessment.

1- *Neck Disability Index (NDI):* The Neck Disability Index (NDI) is a ten-item questionnaire on the basis of the Oswestry Low Back Pain Index that estimates disability associated with neck pain. There are four items that is related to subjective symptomatology of the pain intensity, concentration, headache, sleeping and the other six items related to the activities of daily living, lifting, work, recreation, driving, reading, personal care).

It propose that a score (ranging 0-50) of less than 4 indicates no disability, 5-14 mild disability, 15-24 moderate disability, 25-34 severe disability, while scores greater than 35 indicates complete disability [7].

2- *Visual analogue scale, neck and arm pain scoring:* Using 10 points visual analogue scale with 0=no pain and 10=severe pain; mild moderate in between [8].

3- *Evaluation of successful bone fusion, neurological evaluation:* Group B to assess fusion and in Group A to exclude fusion, was assessed at 6 months and 1 year post-operative.

Results

1- *Age:* Age range from 21 to 50 years with mean age of 37.7 years.

2- *Sex:* Males (75%) and females (25%).

3- *Presenting complaints:* Patients presented with several symptoms, 18 patients (60%) presented with cervical pain 13 patients (43%) presented with radiculopathy, 11 (37%) patients presented with tingling and numbness, 7 patients (6%) presented with partial weakness and 6 patients (20%) presented with hyposthesia.

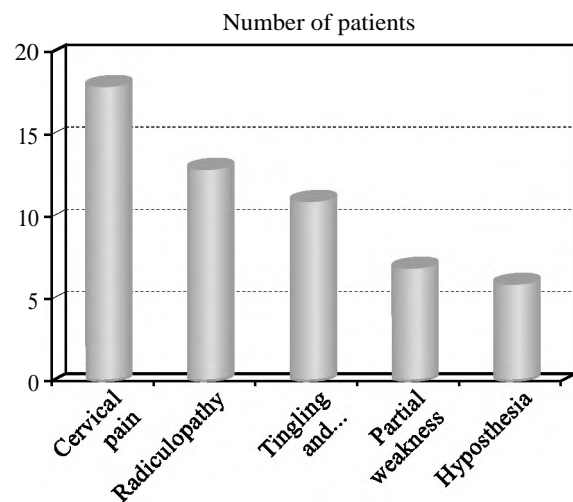


Fig. (2): No of patient and their complaint.

4- *Timing of surgery:* All the thirty patients were treated surgically after failed conservative management except the patients who presented with partial weakness were treated surgically without waiting for conservative treatment.

5- *Complications:* Only 2 (3%) patients presented with superficial wound infection and was treated with antibiotics and resolved, was of group B. Five patients (16%) developed post-operative dysphagia that resolved subsequently after 3 to

4 weeks (3 patient of group A and 2 of group B).

6- *Neck Disability Index (NDI)*: Follow-up after 1 month showed 10 (67%) patients scored from 5 to 14 in the ACDF group while only 8 (53%) patients scored from 5 to 14 in the artificial disc group.

5 (33%) patients scored from 15 to 24 in the ACDF group while 7 (47%) patients scored from 15 to 24 in the artificial disc group.

Table (1): Follow-up of neck disability index 1 month post-operative in ACDF group.

ACDF					
Pre-operative			1 month post-operative		
Mild Neck Disability Index (5-14)	Moderate Neck Disability Index (15-24)	Severe Neck Disability Index (>24)	Mild Neck Disability Index (5-14)	Moderate Neck Disability Index (15-24)	Severe Neck Disability Index (>24)
0	8	7	10	5	0

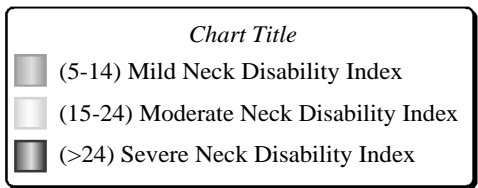
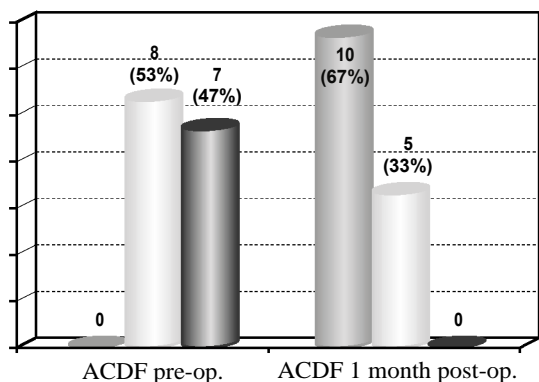


Fig. (3): Follow-up of neck disability index 1 month post-operative in ACDF group.

Table (2): Neck disability index 6 month and 1 year post-operative in ACDF group.

ACDF					
6 months post-operative			1 year post-operative		
Mild Neck Disability Index (5-14)	Moderate Neck Disability Index (15-24)	Severe Neck Disability Index (>24)	Mild Neck Disability Index (5-14)	Moderate Neck Disability Index (15-24)	Severe Neck Disability Index (>24)
10	5	0	11	4	0

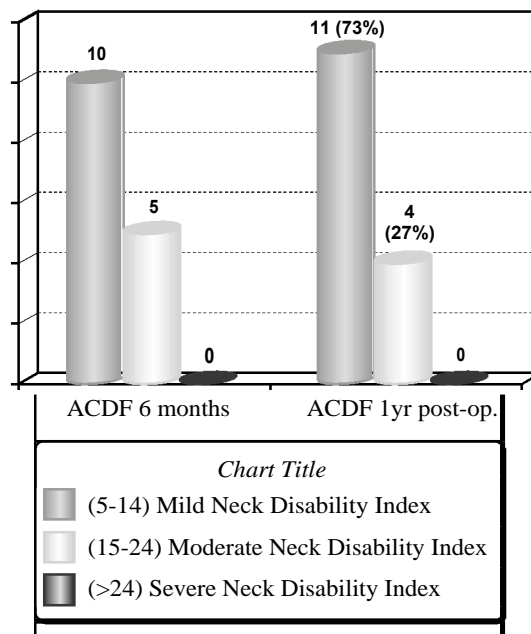


Fig. (4): Neck disability index 6 month and 1 year post-operative in ACDF group.

Table (3): Neck disability index 1 month post-operative in CDR group.

Artificial disc					
Pre-operative			1 month post-operative		
Mild Neck Disability Index (5-14)	Moderate Neck Disability Index (15-24)	Severe Neck Disability Index (>24)	Mild Neck Disability Index (5-14)	Moderate Neck Disability Index (15-24)	Severe Neck Disability Index (>24)
1	8	6	8	7	0

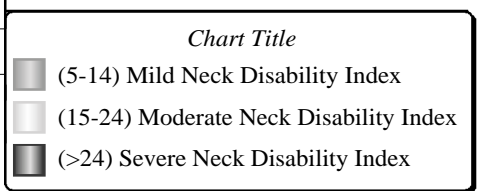
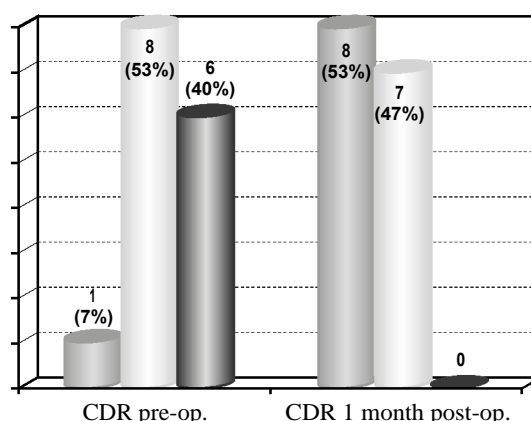
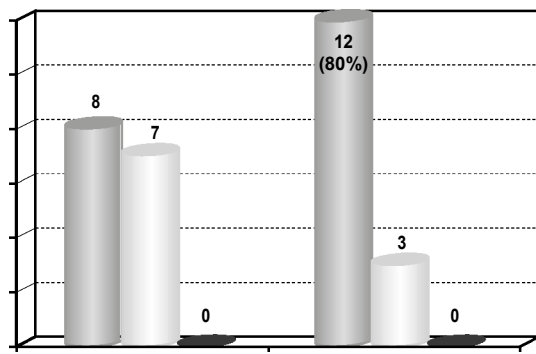


Fig. (5): Neck disability index 1 month post-operative in CDR.

Table (4): Neck disability index 6 month and 1 year post-operative in CDR group.

Artificial disc					
6 months post-operative			1 year post-operative		
Mild Neck Disability Index (5-14)	Moderate Neck Disability Index (15-24)	Severe Neck Disability Index (>24)	Mild Neck Disability Index (5-14)	Moderate Neck Disability Index (15-24)	Severe Neck Disability Index (>24)
8	7	0	12	3	0



CDR 6 months post-op. CDR 1 year post-op.

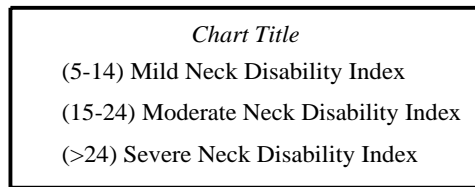
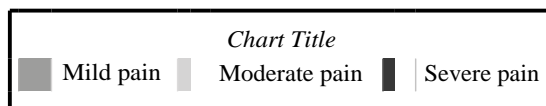
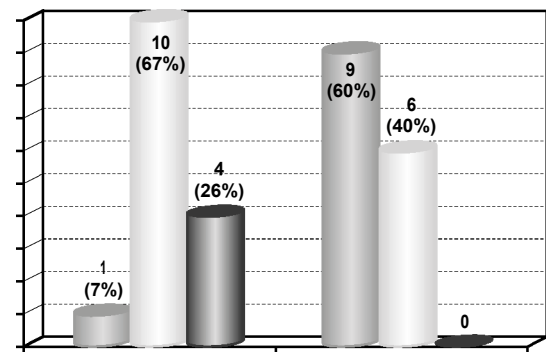


Fig. (6): Neck disability index 6 month and 1 year post-operative in CDR group.

Follow-up of the patients after about 12 months concerning neck disability index, about 11 (67%) patients scored from 5 to 14 in the ACDF group versus 12 (80%) in the artificial disc group. 4



(27%) patients scored from 15 to 24 in the ACDF versus three (20%) in the artificial disc group.

5- Neck pain assessment: For the patients who were operated by ACDF at follow-up 1 month post-operative, 9 patients (60%) with mild pain, and 6 patients (40%) with moderate pain.

At 6 months follow-up the pain improved to mild in 10 (67%) patients and 4 patients to moderate (26%).

At 1 year follow-up the pain improved to mild in 13 (86%) patients and 2 patient to moderate (14%).

For those patients who were operated by cervical disc replacement CDR pain was assessed using the universal pain scale after one month post operative, 12 patients (80%) showed mild pain, and three patients (20%) showed moderate pain.

After six months post-operative, still same result that of one month, 12 (80%) showed mild pain, and 3 (20%) showed moderate pain.

At 1 year follow-up the pain improved to mild in 14 (93%) patients and 1 patient to moderate (7%).

6- Arm pain: Radiculopathy improved after 6 month in 6 (40%) patients from severe to mild, in 8 (54%) patient from moderate to mild and 1 patient no difference in group A (CDR).

In group B (ACDF) radiculopathy improved after 6 month in 7 (47%) patient from severe to mild and in 7 (47%) patients from moderate to mild and 1 patient no difference.

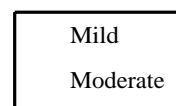
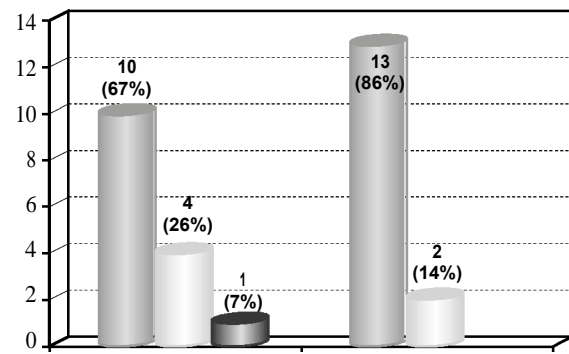


Fig. (7): Neck pain in ACDF group.

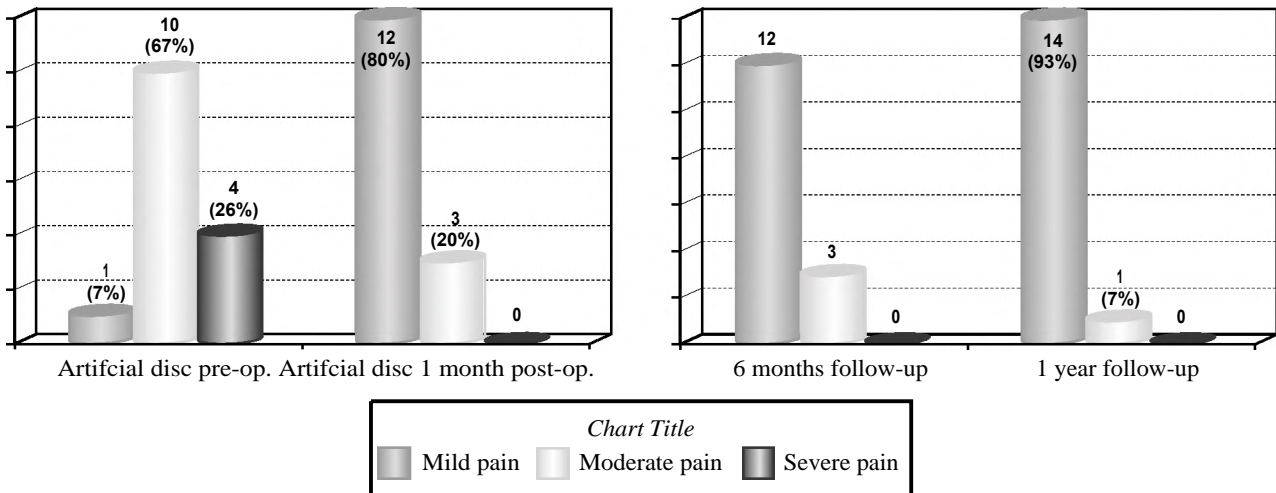


Fig. (8): Neck pain in CDR group at 1, 6, 12 months post-operative.

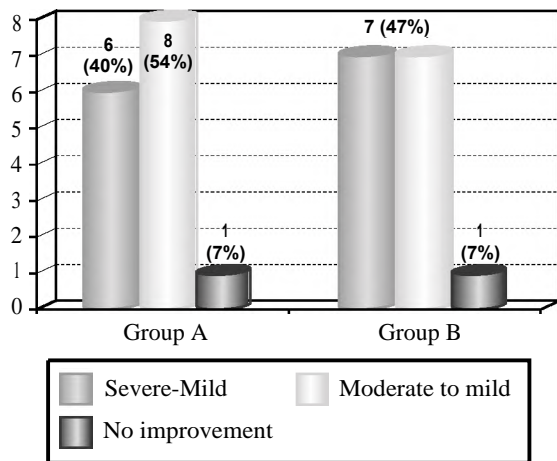


Fig. (9): Arm pain in CDR (A) & ACDF (B) at 6 months.

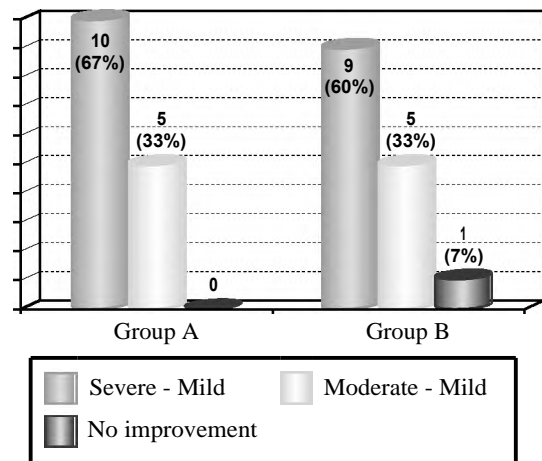


Fig. (10): Arm pain in CDR (A) & ACDF (B) at 1 year.

At follow-up after 1 year arm pain radiculopathy improved in 10 (67%) patients from severe to mild and in 5 (33%) patients from severe to moderate in group A.

In group B radiculopathy improved in 9 (40%) patient from severe to mild and in 5 (33%) patients from moderate to mild and 1 (7%) patient no difference.

6- *Fusion rate*: We assessed the range of motion ROM indicating fusion among both groups using X-ray cervical spine flexion and extension.

	ACDF Group B	Artificial disc Group A
6 months follow-up	73%	0
12 months follow-up	100%	0

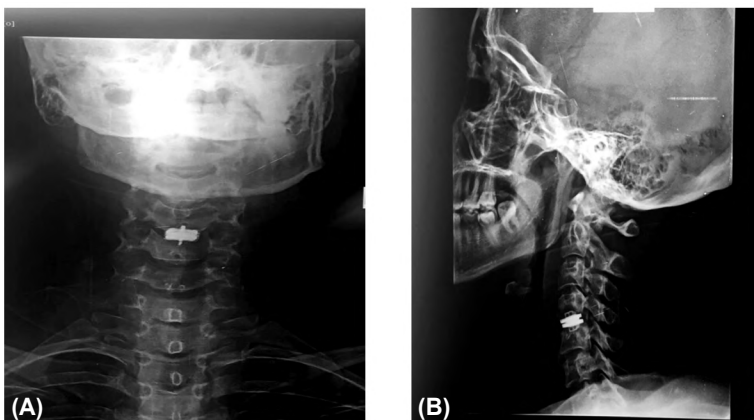


Fig. (11): Post-operative plain X-ray A/P and lateral showing artificial disc in proper place.



Fig. (12): Follow-up X-ray dynamic flexion and extension showed preserved motion in the artificial disc versus.

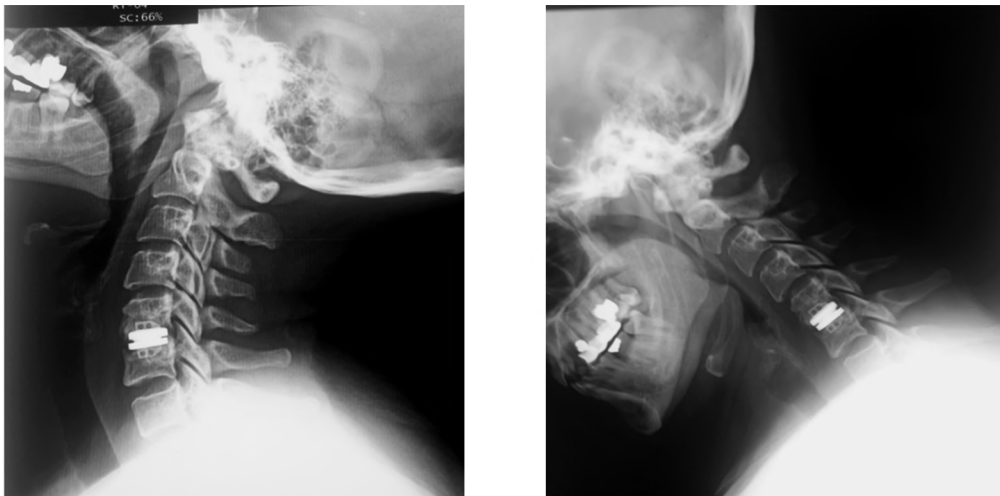


Fig. (13): Follow-up X-ray dynamic flexion and extension showed preserved motion in the artificial disc versus.



Fig. (14): The PEEK cage which performs additional stresses on adjacent levels in flexion and extension.

Discussion

Management of cervical disc herniation with anterior cervical decompression and interbody fusion with fixation has been the traditional method, but it can reduce the range of motion of operated cervical level, while accelerating the adjacent cervical discs degeneration. The problem had caught the attention of many surgeons.

In 1999, Hilibrand, et al. [9] reported on a consecutive cervical dynamic implants aiming to restore normal spinal motion after anterior cervical discectomy and to prevent the abnormal kinematic stresses produced by anterior cervical discectomy and fixation. Cervical dynamic implants an exciting recent technique in the management of cervical radiculopathy and myelopathy. Cervical dynamic implants had the advantage to include the preserved segmental motion, reducing adjacent level strains, and improving the outcomes.

Neck disability index:

In our study, we studied 15 patients operated upon by CDR and 15 patients operated upon by ACDF.

Concerning neck disability index in the follow-up after about one month scored from 5 to 14 in the ACDF group versus CDR (67%) vs. (53%). While patients scored from 15 to 24 in the ACDF group versus CDR was (33%) vs. (47%).

Follow-up of the patients post-operative for about 12 months concerning neck disability index was (67%) versus (80%) of the patients scored from 5 to 14 in the ACDF & CDR artificial disc group respectively.

While (26.6%) versus (20%) patients scored from 15 to 24 in the ACDF & CDR.

We noticed intial more improvement in the neck pain in the ACDF group due to decreased motion obtained by PEEK cage, but longer term follow-up after 1 year showed better improvement in the CDR group.

Sasso et al., [10] who studied 136 patients operated upon by CDR and 133 patients operated upon by ACDF in 2011; their study showed that the NDI was significantly better in CDR group at 1.5, 3, 6, 12, 24, 48-month relative to ACDF ($p<0.05$).

Cheng et al., [11] who studied 41 patients operated upon by CDR and 43 patients operated upon by ACDF in 2011; their study showed that the NDI score was significantly better in CDR group than

fusion patients at 24 months and 36-month follow-ups ($p<0.05$).

Zigler et al., [12], who studied 103 patients operated upon by CDR and 106 patients operated upon by ACDF in 2013; their study showed that there were no significant differences between the two treatment groups for percent change of NDI from baseline scores or absolute NDI score at 2 or 5 years following the procedure.

Zhang et al., [13] studied 53 patients operated upon by CDR and 56 patients operated upon by ACDF in 2012; followed the patients at 12 and 24 months following the procedure.

Our results go with Zigler et al., [12] but lower than the results obtained by Cheng et al., [11].

Radiculopathy (arm pain):

In our study, the post-operative radiculopathy improved in follow-up after 1 year arm pain radiculopathy in 67% of patients from severe to mild and in 33% patients from severe to moderate in CDR group.

In ACDF group, radiculopathy improved 60% of patients from severe to mild and in 33% of patients from severe to moderate and 7% no difference.

Sasso et al., [10] their study showed that the improvement in arm pain score significantly favored CDR over fusion group at 12 and 48-month ($p<0.05$).

Cheng et al., [11], arm pain VAS before surgery was 7.2 (control group) and 7.1 (Bryan group). At the 12-month follow-up it was 2.4 (control group) and 1.8 (Bryan group). At the two year follow-up it was 2.7 (control group) and 1.4 (Bryan group) ($p=0.013$).

Zigler et al., [12] their study showed that the VAS arm pain intensity and frequency scores were similar between the two treatment groups at 2 and 5 years.

Our results regarding arm pain is going with Sasso & Cheng studies but better than what obtained in Zigler study.

Neck pain:

In our study, for those patients who were operated by ACDF, at follow-up 1 month post-operative (60%) with mild pain, and (40%) with moderate pain. At 6 months follow-up the pain improved to mild in (67%) of patients and (26%) to moderate & (7%) no improvement.

At 1 year follow-up the pain improved to mild in (86%) of patients and (14%) of patients to moderate.

For those patients who were operated by CDR after one month post-operative, (80%) of patients showed mild pain, and (20%) of patients showed moderate pain.

After six months post-operative, still same result that of one month.

At 1 year follow-up the pain improved to mild in (93%) patients and (7%) of patients to moderate.

Sasso et al., [10], their study showed that the neck pain scores was significantly better in CDR than fusion group at 1.5, 3, 6, 12, 24, 48-month follow-up ($p < 0.05$).

Zigler et al., [12] their study showed that the neck pain scores was significantly lower for pain intensity ($p = 0.0122$) and frequency ($p = 0.0263$) in the CDR than fusion group at the 5-year follow-up.

Zhang et al., [12] their study showed that the VAS neck pain score was significantly better in CDR group relative to fusion group at 24 months follow-ups ($p = 0.013$).

Our results is going with the previous studies.

Range of movement (ROM):

In our study, we assessed the ROM by using X-ray cervical spine flexion and extension in the 6 months follow-up and we found that there was limited ROM in the ACDF group in 73% patients, at 1 year follow-up X-ray showed limited ROM on 100% of patients indicating fusion at operated level, while there was no limitation in the ROM in the CDR group.

Sasso et al., [10] their study showed that the ROM in CDR patients was significantly higher than baseline measures at all time points after post-operative 3 months. ACDF patients had a mean reduction in ROM at the four year follow-up.

Cheng et al., [11], their study showed that the ROM in ACDF group significantly decreased relative to pre-operative levels while ROM in the CDR group was not significantly different from pre-operative measurements. ROM of operated segments of the CDR group was significantly higher than that for ACDF at the three year follow-up.

Zigler et al., [12], their study showed that the ROM is preserved in CDR at the 2 and 5 year

follow-up while the ROM in ACDF patients was significantly reduced at 2 and 5 years relative to pre-operative values.

Zhang et al., [13] their study showed that the ROM is significantly greater in the CDR than ACDF group at 12 and 24 months following the procedure. Reduction in the ROM from pre-operative baseline was significantly larger in ACDF than CDR at post-operative 24 months.

Complications:

In our study, only 2 (3.3%) patients of the ACDF group presented with superficial wound infection and was treated with antibiotics and resolved.

Five patients (8.3%) (3 patient of the CDR group and 2 of the ACDF group) developed post-operative dysphagia that resolved subsequently after 3 to 4 weeks.

So there is no difference in complications between the 2 groups.

Sasso et al., [10] their study showed that there is no significant differences in rate of adverse events adjacent level surgeries between the two treatment groups.

Cheng et al., [11] studied 41 patients operated upon by CDR and 43 patients operated upon by ACDF in 2011; the study showed that there is significantly less post-operative dysphagia in CDR patients. No secondary surgeries in either treatment groups. 1 spontaneous fusion, 1 deep vein thrombosis and 1 heterotopic ossification in CDR group. Three cases of pseudarthrosis in ACDF group.

Zigler et al., [12], their study showed that the rate of implant-related and surgery-related adverse events are similar between the two groups. At 5 years, the rate of secondary surgery for ProDisc-C patients was significantly lower than that for ACDF patients. More patients in the ACDF group had reoperations involving adjacent level(s) than ProDisc-C patients.

Our study showed no significant difference in the outcome where both study groups yielded nearly the same final surgical results.

Comparing single level cervical disc surgery with ACDF, the CDR has similar or superior clinical and radiographic outcomes, potentially reducing the rate of adjacent segment disease and eliminates adverse events.

The CDR although being more expensive than ACDF but reduction of adjacent segment disease-

and preserving the range of motion outweighs the extra cost and possibly reducing the need of future operation for adjacent segment level.

Overall, the results provided suggest that CDR to be a safe and effective alternative surgical procedure to fusion for the treatment of for single level cervical disc.

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دراسة مقارنة بين التثبيت الإستاتيكي بأقفاص كربونية والتثبيت الديناميكي باستخدام غضروف صناعي في العلاج الجراحي لحالات الإنزلاق الغضروفي العنقي أحادي المستوى

تناولت هذه الدراسة ثلاثون حالة تعاني من أعراض الإنزلاق الغضروفي العنقي نتيجة الضغط على جذور الأعصاب العنقية على مستوى واحد. تم علاج الحالات عن طريق إستئصال الغضروف العنقي من الأمام وإجراء تثبيت إستاتيكي باستخدام الأقفاص الكربونية للنصف الأول من المرضى، كذلك إجراء تثبيت ديناميكي للنصف الآخر باستخدام الغضاريف الصناعية والمقارنة بين المجموعتين، وقد خلصنا إلى ما يلي: تؤدي الجراحات التقليدية بالتثبيت لل فقرات العنقية إلى زيادة بحركة الفقرات بجانب المستوى الذي تم تثبيته كذلك زيادة بضغط الغضروف بالمستويات الأعلى والأسفل للجراحة مما ينتج عنه حدوث تآكل بالغضاريف العنقية المجاورة. مما قد يستلزم التدخل الجراحي لاحقاً.

تظهر أعراض الضغط على الأعصاب أو الحبل الشوكي بالمستوى الموازي لمكان التدخل بالتثبيت الإستاتيكي بمرور الوقت، حيث تحدث بمعدل يستدعي التدخل الجراحي لحوالي ٢٠.٩٪ سنوياً. أظهرت النتائج ما بعد إجراء الجراحات بالطريقتين الإستاتيكية والديناميكية تحسن أعلى بمستوى الإحساس والحركة للحالات المستخدم فيها التثبيت الديناميكي، كذا معدل أقل لحدوث التيبس وتكلس الغضاريف والأربطة لحالات التثبيت الديناميكي على المدى البعيد.

يعد التثبيت الديناميكي باستخدام الغضاريف الصناعية بديلاً آمناً وبسيطاً للتثبيت الإستاتيكي، حيث يعمل على حفظ حركة الفقرات وإمتصاص الصدمات بشكل آمن وفعال.