

Clinical Outcome Assessment in Patients Treated by Dynamic Cervical Implants (DCI) Versus Fixed Method Using Inter Vertebral Cage in the Treatment of Cervical Disc Diseases

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Abstract

Background: This study details analysis of the indications, safety, efficacy and complications of dynamic cervical replacement for replacement of cervical disc in cases cervical disc diseases compared to PEEK cage insertion.

Aim of the Work: The study aims to compare the outcome of two modalities for the treatment of the cervical disc diseases, the first group is the fixed group (treated by insertion of inter vertebral cages), and the second group is the dynamic one, (treated by insertion of the dynamic cervical implants or DCI).

Patient and Methods: A prospective study conducted on 50 patients with single or double level cervical disc diseases like herniated or degenerative lesions treated with fixed and dynamic prosthesis, confirmed by clinical data.

Results: Average age of presentation was 44.1 years for both groups, female ratio for the fixed group was 1.5:1, and 1:1.08 for the dynamic group, with age ranged between 35 and 53 years for both studies with an average of 44.1 ± 6.345 years. The average duration of symptoms was 51.4 weeks. The average follow-up period in our study was 22.5 months, 21 cases had left sided radiculopathy, 10 cases had right sided affection. The most common presenting symptom after brachialgia (100%) was neck pain, 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 22.5 months.

Conclusion: The DCI implant is the alternative to cage fusion and total disc prosthesis with a wider range of indications. The DCI implant offers stable, controlled (adequate) motion to already significantly degenerated motion segments.

Key Words: Cervical spine – Disc herniation radiculopathy – Neural foramen.

Introduction

TREATMENT of cervical disc herniation with anterior cervical decompression and interbody fusion with internal fixation device has been the classic method, but the fusion can result in the loss of range of motion of cervical vertebra [8].

One of the primary goals of cervical dynamic implants is to reproduce normal kinematics after implantation. Another study showed the preservation of motion in cervical dynamic implants treated spinal segments [4].

Using cage alone for single-level ACDF was the cheapest and therefore most cost-effective. The cost of disc cervical dynamic implants was comparable to cage and plate. The benefit with cage only group was largely driven by shorter operative time and shorter hospital stay [18]. Titanium, carbon fiber, and PEEK are most commonly used material for cage production. The use of a titanium cage may lead to vertebral body collapse if the end plate is over degraded during discectomy [2].

Cervical dynamic implants an exciting new technique in the management of cervical radiculopathy and myelopathy. Cervical dynamic implants offer many distinct advantages over the traditional ACDF to include preserved segmental motion, decreased adjacent level strain, and improved outcomes [9].

Patients and Methods

This is a prospective study conducted 50 patients with single or multiple level cervical disc

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diseases like herniated or degenerative lesions treated either by fixed prosthesis or dynamic prosthesis, the outcome of both methods was confirmed by concordant clinical data.

Patients were operated upon open anterior cervical surgery approach. Admitted and operated at Nasser Institute Hospital and Kasr El-Ainy, Cairo University Hospitals between March 2011 and August 2013.

Inclusion criteria:

Inclusion criteria included single or multiple levels, mobile, cervical segments with cervical disc disease from C3 to C7; including disc herniation, degenerative discopathy and discogenic stenosis. These patients will be selected specifically and divided into two groups, in order to compare them statistically. Specifically selected and divided randomly into two groups: Fixed Group (A) receiving inter body fusion by cage and the dynamic Group (B) will undergo surgical replacement by Dynamic Cervical Implants (DCI).

Exclusion criteria:

Metabolic bone diseases serious osteoporosis, ankylosing spondylitis, rheumatoid arthritis obvious instability of cervical vertebra, cervical trauma, cervical tumors, infection of cervical vertebra or disc spaces and contraindications of anesthesia.

Pre and post assessment of clinical data:

A complete thorough general and neurological examination was performed, including the following: Motor system examination; including wasting, tone, power and reflexes. Motor power assessment was done according to the Medical Research Council (MRC) grading system. Reflexes was assessed and graded according to muscle stretch reflex grading system. Sensory system examination and assessment.

Radiological assessment:

Plain X-rays cervical spine for all cases, including antero-posterior view, dynamic views to assess stability, oblique views for foraminal and facet details and the standard lateral view to assess curvature, sagittal rotation and alignment. Thin slice computerized tomography with coronal and sagittal reconstruction. MRI of the cervical spine as well as dynamic views are systematically performed. Electrophysiological studies: Nerve conduction studies and electromyography were performed.

Operative technique of anterior cervical discectomy for both fixed and dynamic methods:

After identification of the target level by fluoroscopy, the operation is performed in the supine position under general anesthesia with the extremities padded and protected. The neck is moderately hyperextended with the head placed in a headrest. A roll can be placed under the inter scapular area to obtain greater extension. Fig. (1) [5].

For simple one or two level discectomies, a transverse incision is made along a skin crease. When multilevel discectomies are being considered, the border of the sternocleidomastoid is incised obliquely. The platysma muscle is divided sharply either along its fibers or along the axis of the transverse incision [1,2].

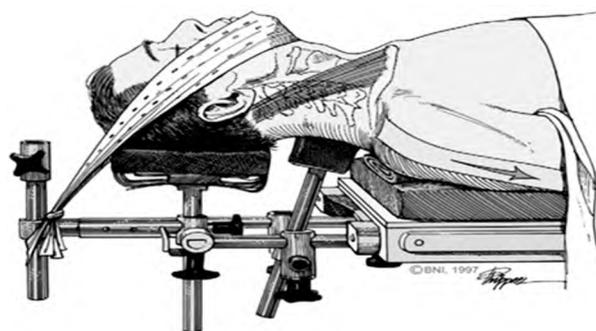


Fig. (1): Positioning for anterior discectomy patient positioning with the Caspar head holder.

Deep to the platysma muscle lays the anterior jugular plexus. The veins can be ligated or mobilized. Underneath the platysma muscle the medial border of the sternocleidomastoid is identified. The muscle may be mobilized with blunt dissection and retracted laterally. The laryngeal strap muscles are also identified and carefully mobilized medially [3].

Once the sternocleidomastoid muscle is mobilized, the surgeon can feel the pulsations of the carotid artery with digital palpation. The carotid sheath is retracted laterally with cloward retractors, and the trachea and esophagus are retracted medially. Once the correct level is identified, the longus coli muscle is dissected laterally off the anterior vertebral body with bipolar cauterization and periosteal elevators. Once the muscle is mobilized, self-retaining retractors are placed with the teeth of the retractor underneath the muscle [1].

Disc removal is done with alternatively, Caspar distracting pins can be placed at the midlevel of the vertebral body to obtain adequate exposure and provide distraction to facilitate identification of the intervertebral space [2].

Insertion of the intervertebral device:

1- The fixed method:

Discectomy:

The discectomy begins by removing the anterior aspect of the annulus fibrosis circumferentially with a sharp knife. The superficial disc is resected with curettes. The Luschka joints are excellent anatomic landmarks that help the surgeon avoid inadvertent injury to the vertebral artery, which lies immediately lateral to the joint. Once the PLL is identified, we remove it to determine whether any sub ligamentous disc material is present. It can be resected safely with upgoing curettes or small Kerrison punches [4].

Fusion:

Once the discectomy, the end plates are prepared to enhance bony fusion. After discectomy, the surgeon prepares the discectomy site by drilling a circular hole 10 to 14mm deep and 12 to 16mm in diameter [5].

Polyetheretherketone (PEEK) cage is a semi-crystalline aromatic polymer that is used as a structural spacer to maintain the disc and foraminal height. Recombinant human bone morphogenetic protein-2 (rhBMP-2) has been used in conjunction with synthetic materials such as PEEK to increase the rate of fusion with good results [1].

Careful preparation of the end plate ensures successful incorporation of the graft and prevents it from being dislodged. Meticulous attention is needed to measure the height of the graft accurately and to modify it to preserve normal cervical lordosis. After the graft is placed, the distraction is removed slowly to provide compression along the cage. Post-operative orthosis is dictated by the patient's underlying condition and bone integrity. Patients undergoing one-level discectomies seldom require a hard cervical collar after surgery. Patients with multilevel discectomies are usually maintained in a hard collar for approximately 6 weeks [3].

At that time, cervical radiographs in flexion and extension views are obtained to assess incorporation of the graft [6].

2- The dynamic method:

History of the device:

The DCI implant was originally developed in 2002 by Dr. Guy Matgé, Luxembourg. A total of 12 patients were implant with the original device (first generation). Initially, the device was marketed by Fixano SAS (Péronnas, France) and the transfer of ownership to Paradigm Spine was finalized in

early 2005. The DCITM was CE-marked by Paradigm Spine and the design was further optimized to better accommodate the implant to the anatomy. In this second generation the footprint was changed from square to rectangular and more sizes were added Fig. (2).

The DCI implant used in this study has a unique design. The omega shape was designed to fit to the lateral anatomical view of the disc and the adjacent endplates. It is a one-piece anatomical-shaped, self-fixing dynamic spacer made of titanium, easy to implant like a cage. Being a single-piece implant, it has excellent fatigue strength with no wear debris. The implant auto-stabilize itself by engaging the anteriorly placed teeth of the implant in the endplates of the vertebra above & below. The dynamic cervical implant stabilizes the cervical spine while providing controlled motion in flexion-extension, which is the main motion in sub axial cervical spine. Shock absorption, a main advantage compared to most existing prostheses, prevents adjacent accelerated degeneration [7].

Surgical technique:

Microdiscectomy was performed, leaving a clean disc space. Endplate cleaning is careful to respect cartilage and avoid bony bleeding [5,8].

It is recommended not to remove anterior osteophytes preventing heterotopic ossification. Internal foraminotomy is an important step in radiculopathy cases together with Posterior Longitudinal Ligament (PLL) resection for optimal decompression in myelopathy cases. Trial implants are then utilized to define the appropriate implant size. Exact size selection is most important to avoid migration. The general guideline for optimal implant sizing is selecting the implant with the maximum width and a proper height as needed for appropriate restoration of the segment [7,9].

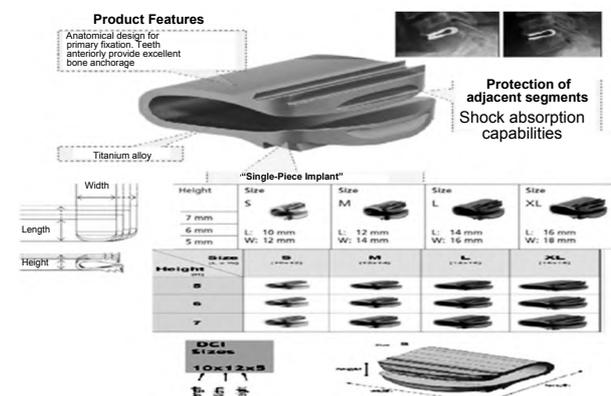


Fig. (2): Sizes of the DCI device.

The trial is centered at the midline of the medial-lateral diameter of the vertebral body. Implant positioning is centered at midline with maximum endplate coverage for optimal stress distribution [10,11].

The implant is inserted utilizing the DCI inserter for protection of endplate surface due to reduced implant height during insertion and the use of depth stop for accurate positioning. By the use of the depth stop an optimal insertion depth of 2-3mm inside the anterior and posterior border can be measured. This is verified under fluoroscopic control [7].

It is important to place the implant as far as posterior to fit the concavity of the inferior endplate of the superior vertebral body. The trials with depth control facilitate ideal positioning. Slight compression on CASPAR distractor stabilizes further the implant by engaging teeth in the endplates [5,8].

The post-operative follow-up:

Clinical and radiological follow-up: Patients can normally be mobilized the next day, avoiding excessive cervical motion. Post-operative NSAID's for ten days may have an impact on heterotopic ossification. An AP and lateral view of the cervical spine is taken before discharge [5,12].

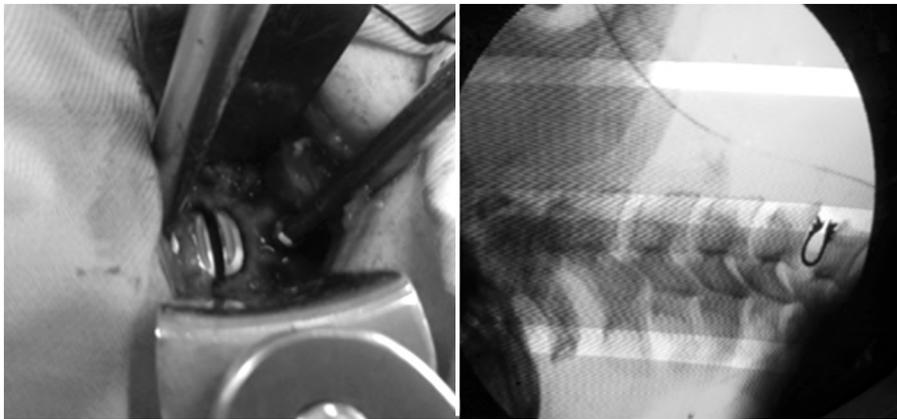


Fig. (3): Intra-operative view for C5-6 cervical disc herniation.

Results

Statistical analysis:

Collected data were presented as mean (SD), numbers and percentages as appropriate. Categorical variables were analyzed using Chi-square (χ^2) test. Continuous variables were tested using unpaired student's *t*-test. Statistical analysis was performed using *r* Package (Version 3.0.2). *p*-value <0.05 is considered statistically significant.

Patient data:

The series included 50 cases suffering from cervical disc diseases divided into two groups, fixed Group (A), were they are 15 males and 10 females. In addition, the dynamic Group (B) were they are 12 males and 13 females, their age ranged from 35 to 53 years with a mean of 44.1 and median of 44.5 years with standard deviation of ± 6.345 years, for both group, within the group study, the levels of the surgery are distributed from the cervical vertebra C3 to C7, levels that are more common are C 4-5 and C5-6. In addition, the double level surgery is the same for both groups of study groups. Table (1).

Clinical data:

The operation time:

The operative work was ranging about from 90 to 120 for both tow groups.

Frequency of symptoms and signs:

The duration of symptoms and signs ranged from 12 weeks to 2 years with average and median of 51.4 weeks. Between the both groups of the study, the arm pain (brachialgia) and the neck pain were the common symptoms, where the all study groups were complaining of both complains, involving different brachial plexus distribution according to the involved cervical level, and different degrees of axial neck pain, Table (2).

The urological complaint was in the form of precipitancy, post voiding dribbling, incontinence, (28%, 7/25) within the fixed group and (32%, 8/25) within the dynamic group. The motor deficit was found (36%, 9/25) at within the fixed group, and was (44%, 11/25) at the dynamic group. The spurling test was positive within (28%, 7/25) within the fixed group, and (32%, 8/25) of the dynamic group. The hyper reflexia with different degrees was

detected in the upper and lower limbs affecting (44%, 11/25) within the fixed group, and (48%, 12/25) within the dynamic group.

Outcome:

Post-operative follow-up varied from 12 to 36 months (mean, 22 months).

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The sensory and the neck pain outcome:

Data collected included VAS pain scores, pain medication intake, and functional abilities, including changes in performance levels of activities of daily living. At each evaluation, patients were asked to quantify their overall pain using a VAS pain score ranging from zero to 10. Patients were also surveyed in regards to their use of pain killers.

Within the dynamic group, satisfactory results for neck and radicular pain were achieved by the first post-operative day and deficits had almost cleared by 3 months. Most patients (84%, 21/25) lost their neck pain, (VAS 2 or less) and most of those presenting with radiculopathy (72%, 18/25) showed dramatic improvement by the first day after surgery, (VAS 2 or less) within the fixed group patients lost their neck pain were (60%, 15/25), and brachialgia (64%, 16/25), there was significant result as regard the resolvment of the axial neck pain could be seen in dynamic group as compared to the fixed group. With no significant

different results as regard the brachialgia and radicular pain, Table (3).

The motor outcome:

The patients who had motor problems were complaining of upper and/or muscle weakness with different degrees, spastic gait. They were 16 patients in the fixed group (64%) and 19 patients (76%) in the dynamic group. Table (4):

The result of the surgery through the next two years was variant, as the results are classified to:

- 1- Good recovery, with complete recovery of the motor problem and restore of the full motor power (grade 5) and function, it was (50%, 8/16) for fixed group and (52.9%, 9/17), for the dynamic group.
- 2- Moderate improvement, here the muscle power of one or more muscle group was regained to some extend to improve the quality of life, and the residual muscle weakness don't interfere with daily work and activity (reaching grade 4), (37.5%, 6/16) for fixed group and (35.3%, 6/17), for the dynamic group.
- 3- Little or no improvement, where the muscle power don't show any change, (the same pre-operative muscle power grading). (12.5%, 2/16) for fixed group and (11.7%, 2/17), for the dynamic group.

As regard the motor outcome, the motor outcome shows no significant results within the dynamic group compared to the fixed group.

Table (1): The patient's data.

	Fixed n=25	Dynamic n=25	p- value
<i>Demographic data:</i>			
• Male/female ratio	15:10	12:13	0.57
• Age, in years:			
Range	35-53	35-53	
Mean (SD)	44 (4.6)	43 (5.1)	0.47
<i>Age distribution:</i>			
• 30-40 years	10	11	0.884
• 40-50 years	12	12	
• >50 years	3	2	
<i>Disc level:</i>			
• C3, 4	4	5	0.932
• C4, 5	6	7	
• C5, 6	9	8	
• C6, 7	3	2	
• Double level	3	3	

Table (2): Frequency of symptoms and signs among the study group.

	Cases of Group A	Cases of Group B
<i>Symptoms:</i>		
Arm pain (brachialgia)	25	25
Neck pain	25	25
Urological symptoms	7	8
<i>Signs:</i>		
Motor weakness	9	11
Positive spurling test	7	8
Hyper reflexia	11	12

Table (3): The brachialgia and neck pain outcome within the two groups.

	Fixed n=25	Dynamic n=25	p-value
<i>Sensory outcome:</i>			
Excellent (VAS 2 or less)	16	18	0.055
Fair or poor (VAS more than 2)	9	7	
<i>Neck pain outcome:</i>			
Good or excellent (VAS 2 or less)	15	21	0.023
Fair or poor (VAS more than 2)	10	4	

Table (4): The motor results among the two groups.

Motor improvement	Fixed n=16	Dynamic n=17	p-value
• Good recovery (G.5)	8	9	0.065
• Moderate improvement (G.4)	6	6	
• Little or no improvement (G.3 or less)	2	2	

Discussion

With respect the sensory outcome, in our study there were large heterogeneous groups of pathological entities, ranging from unilateral radiculopathies to bilateral brachialgia, affecting single or multiple cervical root levels.

Within the dynamic group, satisfactory results for neck and radicular pain were achieved by the first post-operative day and deficits had almost cleared by 3 months. Most patients (84%, 21/25) lost their neck pain, (VAS 2 or less) and most of those presenting with radiculopathy (72%, 18/25) showed dramatic improvement by the first day after surgery, (VAS 2 or less) within the fixed group patients lost their neck pain were (60%, 15/25), and brachialgia (64%, 16/25), there was significant result as regard the resolvment of the axial neck pain could be seen in dynamic group as

compared to the fixed group. With no significant different results as regard the brachialgia and radicular pain [13].

The patients who had motor problems were complaining of upper and/or muscle weakness with different degrees, spastic gait. They were 16 patients in the fixed group (64%) and 19 patients (76%) in the dynamic group, Table (3).

The result of the surgery through the next two years was variant, as the results are classified to:

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As regard the motor outcome, the motor outcome shows no significant results within the dynamic group compared to the fixed group. Matsumoto M, Okada E, Ichihara D, et al., proved that the DCI implant is a clinically effective and safe solution for treating neck and arm pain in cases of cervical disc herniation, canal stenosis and DDD.

Conclusion:

This prospective study was conducted to determine the indications, safety, efficacy and complications associated with performing anterior microscopic cervical discectomy and prosthesis insertion (fixed and dynamic) for treatment of cervical disc diseases. In addition, statistical comparison between both techniques [9].

The study included 50 patients with unilateral single or double level cervical disc diseases associated with radiculopathy, myelopathy or both confirmed by concordant clinical data, refractory to non-surgical measures for 3 months at least. This study indicates that the tested disc replacement device achieves 2-year results ranging from equivalent to superior in comparison to ACDF in the treatment of symptomatic cervical disc disease.

Long-term maintenance of these results has not yet been determined [11].

Disc replacement with DCI is a new strategy. It is an intermediate solution in the spectrum of management strategies of cervical disc diseases. The changes made in the new larger food print shape of the new generation of DCI is said to decrease the rate of fusion. Delay fusion as long as possible is expected to prevent of ALD, the DCI implant stabilizes the cervical spine while still providing stable, controlled motion allowing the spine to be functionally dynamic [14].

The DCI implant is a clinically effective and safe solution for treating neck pain in cases of cervical disc herniation, canal stenosis and DDD. The DCI implant is the alternative to cage fusion as regard safety and efficacy that shown in clinical follow-up and low complication rates and so treating single or multiple levels cervical disc disease with the DCI implant is a safe and easy procedure [15].

In summary, treating single or multiple level cervical disc disease with the DCI implant is a safe and easy procedure. Immediate dynamic stability with good clinical response and no implant-related morbidity or complications are the main advantages of this implant [9].

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المقارنة الإكلينيكية لحالات جراحة الغضروف العنقى عن طريق التثبيت الإستاتيكي باستخدام الأقفاص العنقية والتثبيت الديناميكي باستخدام المزروعات المتحركة

قدم البحث شرح لطرق التشخيص الإكلينيكية وقد تضمن البحث تحليل لتاريخ وأعراض أمراض الغضروف العنقى. بعد ذلك قدم البحث طرق التشخيص المختلفة باستخدام الأشعة التشخيصية العادية والأشعة المقطعية والتصوير بالرنين المغناطيسى كما قدم بعض الإختبارات الكهروفيسيولوجية.

تناولت هذه الدراسة خمسين حالة تعاني من أعراض الإنزلاق الغضروفي العنقى أو ضيق الثقبة الفقرية العنقية نتيجة ضغط على جذور الأعصاب العنقية على مستوى واحد أو مستويين. تم علاج الحالات عن طريق إستئصال الغضروف العنقى من الأمام وإجراء تثبيت إستاتيكي باستخدام الأقفاص الكربونية، للنصف الأول من المرضى، كذا إجراء تثبيت ديناميكي للنصف الآخر باستخدام المزروعات المتحركة والمقارنة بين المجموعتين، بعد تدوين التاريخ المرضى كاملاً وبعد إجراء الإشاعات والأبحاث اللازمة لكل المرضى. أجريت الجراحات بمستشفيات معهد ناصر وجامعة القاهرة فى الفترة ما بين مارس ٢٠١١ وأغسطس ٢٠١٢.

وقد كان متوسط فترة المتابعة للحالات إثنا وعشرين ونصف شهراً ولم تحدث أية مضاعفات أثناء فترة المتابعة وقد تم إستنباط النتائج النهائية للحالات بعد إثني عشر شهراً من إجراء الجراحة.

وتم تقييم الحالات تبعاً للإستجابة من الناحية الإكلينيكية والحركية للفقرات العنقية، كذا حدوث مضاعفات ما بعد جراحة الفقرات العنقية على المستويات الأخرى للجراحة والمقارنة ما بين المجموعتين: ويمكن إستخلاص ما يلى من الدراسة:

- ١- تؤدي الجراحات التقليدية بالتثبيت للفقرات العنقية إلى زيادة بحركة الفقرات بجانب المستوى الذى تم تثبيته كذا زيادة بضغط الغضروف بالمستويات الأعلى والأسفل للجراحة مما ينتج عنه حدوث تيبس بالفقرات والغضاريف العنقية. مما قد يؤدي إلى التدخل الجراحي لاحقاً.
- ٢- أظهرت النتائج لما 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.
- ٣- لم يتم حدوث مضاعفات خاصة بالمزروعات المتحركة مثل فقدان الحركة، الخروج من مكان التثبيت، أو تفاعل للجسم مع مكون المزروعات المعدنية.