Comparative Study between Anterior Cervical Discectomy with Fusion and Dynamic Cervical Disc Implant in Management of Single Level Cervical Disc Prolapse: A Prospective Randomized Controlled Trail

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Abstract

Background: As a consequence of direct compression of nerve roots and associated inflammatory processes, cervical disc herniation is a prevalent cause of arm and neck painful (brachialgia) in cases. **Objectives:** To assess the surgical treatment of single-level cervical disc prolapse utilizing fixed and dynamic cervical implants, calculate the difference in clinical outcome between fixed and dynamic cervical implants and estimate the difference in radiological and biomechanical outcome between fixed and dynamic cervical implants. **Patients and methods:** Thirty cases with single-level cervical disc herniation have participated in this prospective investigation. An open anterior cervical surgery approach was utilized to operate on the cases. Admission and operation at Mansoura University Hospitals from 2018 to 2023. **Results:** In terms of postoperative neurological examination, there had been statistically insignificant distinction among the 2 groups, postoperative ODI, Postoperative visual pain analogue scale and postoperative neurological findings $p>0.05$. There was no degenerative cervical disease among patients in MRI postoperative and no osteophytes among patients in CT cervical postoperative, 12 patients (80%) had cervical curve in x-ray in control group and 11 patients (73.3%) in cases group. **Conclusion:** A safe and simple technique is using of DCI implant to treat multiple or single level cervical disc disease. No implant-related morbidity or complications, immediate dynamic stability, and a positive clinical response are its main benefits.

Key words: Dynamic cervical disc implant, Management, Single level cervical disc prolapse, Anterior cervical discectomy.

Introduction

As a consequence of direct compression of nerve roots and associated inflammatory processes, cervical disc herniation is a prevalent cause of arm and neck painful (brachialgia) in cases. In general, cervical disc prolapse can be categorized into four types: sequestration, disc bulge, protrusion, and extrusion [1].

Posterolateral cervical disc herniation symptoms include ipsilateral neck pain or pain that radiates down the ipsilateral arm to the fingers. The pain may be either dull or sharp. Pain may also be replaced by numbness or tingling as the primary presentation. Due to foraminal encroachment, the symptoms mentioned above are exacerbated by neck flexion and arm abduction over the top of the head. Additionally, the ipsilateral arm may exhibit reduced sensation to vibration, touch, or pain [2].

An operation therapy option that is widely accepted for the management of cervical radiculopathy that has failed conservative therapy is anterior cervical discectomy and fusion (ACDF). The process has been initially introduced in 1958 and is regarded as both safe and cost-effective. Nevertheless, one of the concerns with ACDF is that it affects the natural biomechanics of the cervical spine, resulting in the transfer of additional stress to adjacent levels, which lead to degeneration at those levels [3].

In an effort to reduce disease at the adjacent level, the dynamic cervical cage was created to preserve natural biomechanics. The intra-disc pressures in adjacent levels are significantly elevated in ACDF, but there is no distinction in intra-disc pressure and kinematics in adjacent levels following the utilization of a dynamic cage [4].

The objectives of this research were to compare the surgical management of single-level cervical disc prolapse with dynamic and fixed cervical implants, calculate the difference in clinical outcome between fixed and dynamic cervical implants and estimate the difference in radiological and biomechanical outcome between fixed and dynamic cervical implants.

Patients and methods

A prospective investigation has been conducted on thirty cases that had a single-level cervical disc herniation. The open anterior cervical surgery technique has been used to operate on the cases from 2018 to 2023. Cases were admitted and operated on at Mansoura University Hospitals. Cases were grouped into a control group that consisted of 15 patients and a study group consisted of the remaining 15 patients. Patients of the study group performed classic ACDF using dynamic cage while the control group performed ACDF using traditional cage.

Inclusion criteria: Single level cervical disc, age from 30 to 50 years and radiculopathy only.

Exclusion criteria: Extremes of age, other degenerative pathology e.g. cx stenosis, mylopathy or radiculomylopathy, malalignment on radiology, other neurological disorder e.g. ALS and recurrent pathology.

Methods

All cases have been subjected to the following:

1. Pre-operative assessment:

-Detailed history taking.

-Clinical examination:

A comprehensive neurological and general examination was conducted, which involved the following: examination of the motor system, reflexes, Sensory system examination and Special tests; Spurling, shoulder abduction, ROM, etc.

-Radiological assessment:

Cervical spine was thoroughly examined using plain x-rays, dynamic views, oblique views, and standard lateral views. Thin-slice computerized tomography and MRI are also used, along with coronal and sagittal reconstruction, to ensure stability and alignment.

-Electrophysiological investigations:

Nerve conduction investigations and electromyography were conducted only when necessary.

2. Anterior cervical discectomy operative technique

The case is requested to voluntarily extend and flex the neck to evaluate for any clinical symptoms, unless contraindicated, on the morning of the surgery. Informed consent is obtained. This allows the surgeon and anesthesiologist to restrict their manipulations and ensure that the patient's range of motion is not exceeded. The anesthesiologist has the ability to establish whether flexible fiber optic intubation is required.

Anesthetic considerations and patient's positioning

Technique

The case's extremities were padded and protected during the cervical discectomy, which was conducted under general anesthesia. The head is positioned in a headrest, and the neck is moderately hyperextended. If the case has an L'hermitte's sign or severe canal stenosis, the surgeon should restrict the extent of extension until compressive pathology is removed via surgery. Increased extension can be achieved by applying cervical traction or wrapping 1 inch of tape around the chin. Surgery may be conducted with the aid of an operative microscope or under loupe magnification. Anatomic landmarks or preoperative localizing radiographs may be utilized to center the incision. Surface landmarks, including the cricothyroid membrane, thyroid cartilage, and jaw angle, serve as general reference points for the cervical spine. Additionally, C-arm fluoroscopy may be utilized to evaluate

the precise location of the skin incision. An extended horizontal incision with extensive dissection above the platysma might be utilized for exposure. However, some authors prefer an oblique exposure along the ventral border of the sternocleidomastoid muscle for greater than two-level discectomy. The border of the sternocleidomastoid is incised obliquely for multilevel discectomies, while transverse incisions are made along a skin crease for simple one- or two-level discectomies. The platysma muscle separates sharply to ensure that the deeper surgical field is accessible and to reduce superficial tension that can cause retractors to rotate. The medial border of the sternocleidomastoid is identified, and the anterior jugular plexus is situated deep to the platysma muscle. The area of interest is fully exposed by placing self-retaining retractors.

Insertion of the intervertebral devices which may be:

The fixed type of discectomy involves utilizing a microscope to remove the anterior aspect of the spine. Curettes are used to respect the superficial disc, and a high-speed bur is utilized to approach the posterior ligament (PLL) in the presence of osteophytic ridges. The Luschka joints were used as anatomic landmarks to avoid injury to the vertebral artery. The PLL was then removed to establish if any sub- ligamentous disc material has been present. The PLL was elevated using a blunt hook near the nerve root exit, and safely resected with curettes or small Kerrison punches. Thin-plated Kerrison punches can be utilized for removing central disc-osteophyte complexes. Decompression of the foramen is essential in cases with radiculopathy.

The dynamic type**:** The DCI implant, established in 2002 by Dr. Guy Matgé, was implanted in 12 patients. Initially marketed by Fixano SAS, it was transferred to Paradigm Spine in 2005. The implant was CE-marked and optimized for better anatomy fit. The second generation featured a rectangular footprint and more sizes, which Paradigm Spine tested and validated.

Closure and Postoperative Management:

Three days following the operation, all cases have been to be discharged and were to resume their regular daily routines four weeks later.

3. Postoperative monitoring

-Radiological and clinical monitoring:

Before discharge, it is necessary to avoid excessive cervical motion and obtain lateral view and an AP of the cervical spine following cervical surgery. One month following surgery, cases are permitted to continue their work. Monitoring x-rays are conducted on the first postoperative day, and results are evaluated annually. The data collected involves functional abilities, pain medication

intake, and VAS pain scores. The utilization of painkillers is surveyed, and patients' pain scores range from 0 to 10. Cases that reported a daily reduction of ≥ 50% or complete cessation of pain medication intake had a decrease in their medication intake. The ability of cases to take part in daily activities is used to quantify their functional status.

Statistical analysis

The data that was entered into the computer has been analyzed using the IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Qualitative information has been described using percentages and numbers. The Kolmogorov-Smirnov test has been applied for confirming the distribution's normality. Quantitative data have been described using the following metrics: mean, standard deviation, median, range (minimum and maximum), and interquartile range (IQR). The results were evaluated at a significance level of 5%. Fisher's Exact or Monte Carlo correction and the Chi-square test were used.

Ethical approval:

This study was approved by the Institutional Research Board (IRB) of the faculty of medicine, Mansoura university (Code Number: MD. 18.10.96).

Results

Regarding age group, age ranged from 30-50 years old. The most of our patients 7 (53.3%) in control group was from 41-50 years old and 7 patients (46.7%) between 30 – 40, while in cases group 9 patients (60%) was from 41 – 50, and 6 patients (40%) from 30 – 40, with statistically insignificant distinction among 2 groups (Table 1).

Regarding postoperative neurological examination, most of our patients 12 (80%) in control group were not deficit and 66% of our patients had no pain, while in cases group 11 patients (73.3%) were not deficit and (73.3%) had no pain. There has been statistically insignificant distinction among 2 groups according to motor and sensory as radiculopathy (Table 2).

Regarding postoperative neurological findings, no degenerative cervical disease among patients in MRI postoperative and no osteophytes among patients in CT cervical postoperative, 12 patients (80%) had cervical curve in x-ray in control group and 11 patients (73.3%) in cases group, with statistically insignificant distinction among 2 groups. (Table 3)

Regarding postoperative ODI, most of our patients 10 (66.7%) in control group were not affected, while in cases group 12 patients (20%) were not affected, with statistically insignificant distinction among 2 groups (Table 4).

According to Postoperative visual pain analogue scale, most of our patients 12 (80%) in control group were not affected, while in cases group 13 patients (86.7%) were not affected, with statistically insignificant among 2 groups. (Table 5)

Table 1: Comparison among the 2 examined groups regarding age (years):

Age (years)	Control (n = 15)		Cases (n = 15)		χ2	P-value
	No.	%	No.	%		
30 – 40	**7**	**46.7**	**6**	**40.0**	**0.136**	**0.713**
41 – 50	**8**	**53.3**	**9**	**60.0**		

χ2: Chi square test p: p value for comparing among control and cases

Table 2: Comparison among the 2 examined groups regarding postoperative neurological examinations:

Postoperative neurological examinations	Control (n = 15)		Cases (n = 15)		χ2	P-value
	No.	%	No.	%		
Motor:						
• Deficit	3	20.0	4	26.7	0.186	$FE_{p=}$
• No deficit	12	80.0	11	73.3		1.000
Sensory as radiculopathy:						
• Yes	5	33.3	4	26.7	0.159	$FE_{p=}$
• No	10	66.7	11	73.3		1.000
Sphincteric disorder	0	0.0	0	0.0	-	-
Other neurological symptoms as myopathy hypereflexia	0	0.0	0	0.0	-	-

χ2: Chi square test FE: Fisher Exact p: p value for comparing among control and cases.

Table 3: Comparison among the 2 examined groups regarding postoperative radiological findings

Postoperative radiological findings	Control (n = 15)		Cases (n = 15)		$\chi 2$	P-value
	No.	%	No.	%		
MRI: • Degenerative cervical disease	0	0.0	0	0.0	-	-
CT cervical: • Osteophytes	0	0.0	0	0.0	-	-
X – Ray cervical curve	12	80.0	11	73.3	0.186	FE_{p} 1.000

$\chi 2$: Chi square test FE: Fisher Exact p: p value for comparing among control and cases.

Table 4: Comparison among the 2 examined groups regarding postoperative Oswestry Disability Index (ODI):

ODI	Control (n = 15)		Cases (n = 15)		$\chi 2$	P-value
	No.	%	No.	%		
Affected	5	33.3	3	20.0	0.682	0.682
Not affected	10	66.7	12	80.0		

$\chi 2$: Chi square test FE: Fisher Exact p: p value for comparing among control and cases.

Table 5: Comparison among the 2 examined groups regarding postoperative visual pain analogue scale:

Visual pain analogue scale	Control (n = 15)		Cases (n = 15)		$\chi 2$	P-value
	No.	%	No.	%		
Affected	3	20.0	2	13.3	0.240	1.000
Not affected	12	80.0	13	86.7		

Selected case presentation

Case:

Age: 39 Years, **Sex:** Female, **duration of Symptoms:** 2 years, **main symptoms:** left upper limb weakness, left brachialgia and numbness, **Signs:** left upper limb motor weakness (grade 4+), left C6 dermatomal hypothesia, left (-ve) Hoffman sign, **radiological findings:** C5-6 central and left posterolateral cervical disc herniaton, **Surgery:** C5-6 anterior discectomy with insertion of dynamic cervical implant, **Operative time:** 100 minutes and **post-operative:** resolved brachialgia, improved motor weakness, no early complications and discharged 4 days post-operative.

A. Preoperative MRI for C5-6 cervical disc herniation

B. Intraoperative view for C5-6 cervical disc herniation

C. Postoperative dynamic view

D. Six months follow-up x-ray

Figure (1): Preoperative, intraoperative, postoperative and six month follow-up views of a female patient underwent anterior discectomy with insertion of dynamic cervical implant.

Discussion

The successful surgical therapy of radiculopathy resulting from cervical degenerative spondylosis and cervical disc diseases is anterior cervical discectomy and fusion (ACDF). However, there are adverse effects to fusion following anterior cervical decompression, including the potential of biomechanical changes in the adjacent segment and complications such as pseudarthrosis [5].

There have been statistically insignificant outcomes as regard the sensory outcome within both groups ($P>0.05$), while with assessment of the axial cervical pain, there have been statistically insignificant outcomes ($P<0.05$). among both examined groups regarding the axial neck pain results.

Regarding the motor result, the motor outcome presented insignificant outcomes as comparing both study groups; Matsumoto [6] demonstrated that the DCI implant is a safe and clinically effective solution for the management of neck and arm pain in cases of DDD, cervical disc herniation, and cervical canal stenosis.

The planning of our surgical procedure was greatly facilitated by this, as we have discovered that the CT and MRI were complementary for this purpose. The heterotopic ossification (H.O.) has been statistically insignificant in either examined group after one year of radiological monitoring for all cases 2 years after operation. The data collected did not yield any statistically significant results ($P>0.05$) among both examined groups during the initial year of monitoring. During the 2-year monitoring, the adjacent level and the radiological results at the site of surgery have been statistically significant ($P<0.05$) as assessed regarding the original McAfee classification that was previously discussed [7].

The operative segment's range of motion (ROM) in relation to its intact configuration, DCI preserve the dynamic flexion – extension movement with no significant change in lateral bending plane movement, while the fixed surgery by cage application show significant restriction for both lateral bending planes and flexion – extension, According to B. Welke1 C. et al., additional investigations have indicated that the DCI implant has a tendency to stabilize the segment in flexion and extension while allowing for a certain amount of residual mobility. In lateral bending, the implant significantly reduced movement, thereby stabilizing the affected segment [8].

Zhong Jun Mo et al. [9] stated that The DCI implant could be more effectively maintain the spinal kinematic motion, maintain the load transfer pattern in flexion-extension, and exert minimal influence on the adjacent soft tissues. Adjacent segment degeneration (ASD) or adjacent level disease is a condition that frequently happens subsequent to spinal fusion. ASD can occur anywhere along the spine and affects the intervertebral disc, end plates, intervertebral ligaments, and joint(s) above and below the area addressed by the operation, where it was normal at the time of the original surgery. Symptomatic adjacent segment disease was diagnosed by the presence of new radicular or myelopathic symptoms that were indicative of a degenerated level in the adjacent segment on two consecutive visits.

Yong-Hwan Cho et al. [10] demonstrated that cases who have dynamic implants have a significantly lower risk of reoperations at both the index and adjacent levels, according to recent publications of prospective randomized controlled trials that compare motion-preserving implants

with fusion. ACDF-treated cases showed an approximately fivefold increase in reoperation rates as a result of adjacent segment disease at the five-year mark. Our investigation concentrated on the development of myelopathy or new radiculopathy in a motion segment adjacent to the site of a previous anterior cervical arthrodesis, which referred to symptomatic adjacent segment illness of the cervical spine.

In our research, the adjacent segment disease is assessed by the Nurick scale assessing the clinical follow and its reflection upon the re-operation for the disease segment. Clinically the all-study groups had no decrease in Odom score between the initial postoperative situation and the one-year monitoring, two years later; the dynamic group presented insignificant change as regard the Odom's criteria and the myelopathic findings. With two years follow up two patients had reported myelopathic changes in the form of walking with a slight amount of difficulty that doesn't prevent employment and doesn't interfere with normal the daily activity, (grade 2 Nurick Scale) which correlated with the level insulted by the spondylotic changes. This insult was the indication for re-operation should done for the diseased segment.

DCI cervical arthroplasty appears to be an appropriate choice for cases with minimal cervical spondylosis and symptomatic cervical radiculopathy. Preserving the dynamic decompression that is reflected in the neural foramen and canal stenosis because of osteophytes, spondylosis, and ossification formation at the same level and the adjacent segment to achieve a positive sensory and motor outcome. While arthroplasty may be linked to a reduced incidence of adjacent-level illness at two years, additional analysis and monitoring are required to establish this result.

In an investigation conducted by Hilibrand et al. [11], it was demonstrated that stenosis and symptomatic adjacent level spondylosis occur in over twenty five percent of cases within eight to ten years of ACDF. Additionally, a significant number of these cases need additional surgery. reported a 2.9% annual rate of adjacent level surgeries and stated that at ten years following cervical fusion [12].

The average duration of our investigation has been 2.5 years, which revealed the early changes at the adjacent level. Consequently, it is suggested that this research be conducted over a longer period of time for enhancing other investigations.

In keeping with these previous reports, we attempted to study the effect of DCI implant in treating cervical disc diseases, and improving patient quality-of-life outcomes The cervical spine is stabilized by the DCI implant, which also enables the spine to be functionally dynamic through providing stable, controlled motion. As compared to a neutral position, flexion and extension are permissible.

The implant acts as a shock absorber to effectively prevent accelerated degeneration in the segments above and below the level of operation following its insertion.

Conclusion

The DCI implant is a safe simple technique for managing single or multiple level cervical disc disease. The main benefits of this implant are stability, immediate dynamic, the absence of implant-related morbidity or complications and a positive clinical response.

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