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ABSTRACT

- **Background**: There are wide treatment modalities for degenerative disc diseases of cervical spines. However, surgery is indicated when conservative treatment fails, and each procedure had its limitation.
- Aim of the work: To compare the outcome between cervical peek cage and dynamic cervical implant for anterior cervical discectomy fusion (ACDF) for patients with degenerated cervical disc disease.
- Patients and methods: Fifty patients with degenerative disk disease (DDD) were treated by cervical polyetheretherketone (PEEK) cage (25 patients) and another 25 with dynamic cervical implant (DCI). All patients assessed pre- and post-operatively by clinical and radiological examinations, with pain assessment by visual analogue scale and calculation of the range of motion. Any neurological deficits were documented in both pre-and post-operative periods.
- **Results:** Both groups were comparable regarding patient characteristics, preoperative pain and preoperative range of motion. The mean percentage of pain reduction was significantly higher among PEEK when compared to DCI group (81.93±7.07 vs 66.23±11.48 respectively). In DCI group, preoperative mean range of motion at the operated level was 7.56, changed to 6.64 postoperatively, which is statistically significant. Similarly, in PEEK cage group, preoperative mean range of motion at operated level was 7.60 Changed to 7.52 which is statistically non-significant. Complications were mild and treated conservatively.
- **Conclusion:** PEEK cage is associated with better alleviation of pain either at the neck or arm pain. On the other side, DCI is associated with slightly better range of motion. However, global range of motion is comparable between both groups.

Keywords: Cervical; Degenerative Disk Disease; Discectomy; Dynamic Cervical Implant; Polyetheretherketone Cage

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* Main subject and any subcategories have been classified according to research topic.

INTRODUCTION

Degenerative disorders of the cervical spine are a heterogeneous group of pathologies with many treatment modalities. For the common clinical entities, surgery is only indicated after an adequate trial of conservative management has failed^[1]. In 1955, Robinson and Smith reported on a surgical maneuver for removal of cervical disc and fusion with a horseshoe-shaped graft which became the corner-stone in management of disc herniation and cervical spondylotic radiculopathy. Anterior cervical discectomy and fusion [ACDF] with a tricortical bony graft harvested from the iliac crest is the most widely accepted maneuver and had become the gold standard for the management of radicul-opathy for many cervical vears^[2]. Physically, androgenetic alopecia is characterized by progressive miniaturization of hair follicles in the scalp and gradual transformation of terminal hairs into vellus hairs leading to progressive decrease in hair density^[2].

Different types of the cages had been used in the neurosurgical practice. The early clinical outcomes of the cages were encouraging. However, it was associated with some unwanted problems [e.g, migration, subsidence and structural failure, and some difficulties in postoperative magnetic resonance imaging were observed]^[3]. Poly-ether-ether-ketone [PEEK] cages have recently been used in cervical surgery. PEEK is polyetheretherketone, a semi-crystal polyaromatic linear polymer. The use of a PEEK cage is becoming popular because of better elasticity and radiolucency^[4]. In the spectrum of anterior cervical fusion techniques comes the dynamic cervical implant [DCI] which is, originally developed in 2002 by Dr. Guy Matge, Luxembourg, It was introduced in clinical use, by him, in 2004. The design was further optimized to better accommodate between implant and anatomy. In that second generation the footprint was changed from square to rectangular and more sizes were added. The DCI implant, with motion preservation, is more than a static cage. It stabilizes the spine and provide stable, limited, controlled flexion and extends motion permitting dynamic functionality of the spine. In addition, it works as a shock absorber, preventing accelerated degeneration in adjacent segments. Thus, the DCI implants aims to combine advantages of the fusion "Gold-standard] and preservation of motion. The DCI indications are

much greater than conventional static fusions and even TDR, because of the controlled rotation. Thus, degenerative arthro-pathy remains an indication of DCI insertion^[5]. DCI with motion preservation is more than a static cage it stabilizes the spine and still provide stable, limited and controlled flexion and extension motion to permit the dynamic functionality of the cervical spine. It also works as a shock absorber, preventing accelerated degeneration in adjacent segments^[6,7].

AIM OF THE WORK

The current trial had been designed to compare clinical and radiological outcomes between anterior cervical discectomy and fusion [ACDF] by PEEK cage or dynamic cervical implant for degenerated cervical disease.

PATIENT AND METHODS

This is a prospective comparative study to evaluate the results of treatment of patients with degenerative cervical disc disease by polyetheretherketone [PEEK] cage and dynamic cervical implant [DCI] respectively. The assignment of patient to group was carried randomly, where a number of closed envelops [contain the surgical maneuver] were prepared and patient assigned one envelope blindly before operation, which opened by a nurse not incorporated in the study.

It was carried out during the period between January 2016 to January 2019, at Department of Neurosurgery, Damietta Faculty of Medicine, Al-Azhar University. Twenty-five patients with cervical degenerative disk disease [DDD] had been included in PEEK cage group and twenty-five patients had been included in DCI group. The same inclusion and exclusion criteria were adopted for both groups. The inclusion criteria were: degenerative disc disease within levels between C3-C7 presented by neck and/or arm pain with functional/neurological deficit, degenerated disc origin determined by plain x-ray and/or MRI, and patients were refractory to conservative treatment for at least three months. On the other side, exclusion criteria were: marked cervical instability, history of prior cervical laminectomy and posterior compressive amenable disease not to decompression through anterior approach. rheumatoid arthritis [RA], ankylosing spondylitis, or other autoimmune disease, malignancy or active infection.

The study protocol was approved by local

research and ethics committee of our institution. All patients signed an informed consent, after full elucidation of the study protocol, and assurance about their confidentiality and their right to withdraw at any time without any harm.

All patients had cervical disc herniation[s] with variable degrees of other degenerative changes at the levels from C3/4 to C6/7. All patients [100%] had axial neck and radicular arm pain [cervical brachialgia]. The preoperative assessment had been carried out clinically and radiologically. Clinical evaluation included general condition, risk factors, pain analysis [neck and radicular pain by visual analogue scale], and neurological deficits] were evaluated. The radiological assessment had been carried out plain radiography [Anteroposterior, lateral and dynamic views] and magnetic imaging [MRI] cervical resonance spine. Postoperatively, patients were re-assessed as in the preoperative period. In addition, radiological outcome was documented. Dynamic X-ray examinations were carried out to search for cervical spine alignment, stability, position of the implanted prosthesis, and fusion of the operated level. In addition, the cervical motion and global range of motion had been evaluated and documented. Visual analogue scale was used to assess pain as described by Chien et al.^[8]. Assessment of range of motion [ROM] at affected level was done manually using Cobb's method by measuring the angle between the perpendicular to the superior end plate of upper vertebra and the perpendicular to the inferior end plate of lower vertebra^[9]. Assessment of global range of motion [from C2 to C7] had been carried out manually through measuring the difference, in both flexion and extension, between an angle formed between a line parallel to the superior end plate of C7 and a line joining the anterior edge of the superior end plate of C7 to the anterior edge of the inferior end plate of C2^[9]. PEEK cage and DCI were completed under general anesthesia as described by Eldin and Mohammed^[10]. On the other side, PEEK cage implantation was also done under general anesthesia after a set of trial implants were used to determine the ideal implant size and to determine the size of the most suitable cage, and the maneuver had been completed as described by Wang et al.^[11]. Postoperatively, a soft cervical collar was worn for four weeks in PEEK cage group and for three days in DCI group, and patients were allowed to move their heads immediately postoperative in collars as tolerated. After the initial six weeks, patients had been permitted to participate in normal daily activities. After 8 weeks [the final follow up visit related to the current study, as many patients lost follow up after that time], patients had been permitted to return to all normal activities. Post-operative oral pain medications were administered as needed. Antibiotics were given intravenously for three days then orally for one week. Postoperative plane radiography is done [^{10]}. Device related complications and approach related complications were documented.

Data analysis: Collected data were coded and fed to a personal computer excel program and subsequently transferred to statistical package for social science [SPSS] software computer package, version 19 [IBM, SPSS, Inc., USA] for analysis. Numerical variables had been represented in mean, standard deviation, [minimum to maximum [range]], while categorical data presented in number [frequency] and percentages. The percentage of difference between pre and postoperative values were calculated by subtracted [preoperative values - postoperative values] and subdivided by the preoperative values, and the results is multiplied by 100. Data presented in mean ± SD, were compared by student [t] test and paired samples [t] test was used to compared preoperative to corresponding postoperative data [in the same group]. Finally, Chi square test was calculated to compare categorical parameters. To interpret data, P value < 0.05 was considered significant.

RESULTS

This study includes 25 patients treated by DCI [Group1] with minimum age 28 years and maximum age 79 years. In addition, 25 patients treated by PEEK cage [Group 2] with minimum age 35 years and maximum age 57 years. The study enrolled 11 females [44%] and 14 males [56%] in Group 1, and 14 females [56.0%] and 11 males [44.0%] in Group 2. The most common level affected was [C5/C6] which accounts for [40.0% and 36.0% of G1 and G2 respectively] while the least affected was [C6/C7] which accounts for [8% and 12% in G1 and G2 respectively]. There was no significant difference between both groups regarding patient gender, age or affected level [Table 1]. All patients complained from neck and brachialgia in both groups; 88% suffered from neurological deficit [22 sensory deficit and 3 with

motor deficit] in DCI group, while 80% suffered from neurological deficit [20 sensory and 5 with motor deficit] in PEEK cage group. Improvement was more in sensory deficit postoperatively in both groups.

Preoperative pain score of the neck ranged 6 to 9 on visual analogue scale [VAS] score, with no significant difference between DCI and PEEK groups [7.52 \pm 0.87 vs 7.88 \pm 0.83 respectively]. Post-operatively, the VAS core of neck pain ranged between 1 and 4 with significant decrease among PEEK when compared to DCI group [1.4 \pm 0.50 vs 2.52 \pm 0.82 respectively]. The mean percentage of pain reduction was significantly higher among PEEK when compared to DCI group [81.93 \pm 7.07 vs 66.23 \pm 11.48 respectively]. However, in both groups, there was significant pain reduction after intervention when compared to corresponding preoperative values **[Table 2].**

Regarding brachialgia, there was no significant difference between both DCI and PEEK groups regarding pre- or post-operative values. Both techniques had been associated with significant reduction of post operative VAS when compared to corresponding pre-operative values [i.e., both groups nearly alleviated arm pain to the same extent] [Table 3].

According to range of motion there is significant difference from preoperative to post-operative values in both groups. In DCI group, preoperative mean range of motion at the operated level was 7.56, changed to 6.64 postoperatively, which is statistically significant. Similarly, in PEEK cage group, preoperative mean range of motion at operated level was 7.60 Changed to 7.52 which is statistically non-significant [Table 4]. On the other side, there was no significant difference between pre and post-operative global range of motion among both groups [Table 5].

In the present work, three patients [6.0%] reported persistent neck pain, two cases with persistent arm pain and no motor deterioration was reported in any case. In addition, transient postoperative swallowing difficulty was reported among by one patient [2.0%] and another patient reported mild hoarseness. Another patient developed remote spondylodiscitis at [C6–7] below the operative site. That patient had been managed conservatively and resolved within 3 months.

		DCI group [G1]	PEEK group [G2]	Chi-squar	e test
		No. = 25	No. = 25	X²/t	P-value
Gender	Female	11 [44.0%]	14 [56.0%]	0.72	0.39
	Male	14 [56.0%]	11 [44.0%]		
Age	Mean ± SD; Range	49.08 ±9.34; 28-79	45.64 ± 5.67; 34-57	1.57	0.12
Affected	3-4	3[12.0%]	6[24.0%]	1 70	0.61
Level	4-5	10[40.0%]	7[28.0%]	1.78	0.61
	5-6	10[40.0%]	9[36.0%]	1	
	6-7	2[8.0%]	3[12.0%]	1	

Table [1]: patient characteristics and affect levels among studied groups

DCI: Dynamic cervical implant; PEEK: Polyetheretherketone; SD: standard deviation; X²: Chi square

Table	[2]:	Clinical out	ome regardir	ig neck	pain am	ong studied	group	ps
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		DCI group	PEEK group	Independent t-test	
		No. = 25	No. = 25	t	P-value
Pre VAS neck	Mean ± SD; Range	7.52± 0.87; 6.0- 9.0	7.88± 0.83; 7.0-9.0	1.49	0.14
Post VAS neck	Mean ± SD; Range	2.52 ± 0.82; 1-4	1.4 ± 0.50; 1-2	5.81	<0.001*
% change	Mean ± SD; Range	66.23±11.48; 42.86 – 83.33	81.93±7.07; 71.43- 88.89	5.82	<0.001*
Paired t-test	t	22.36	30.98		
	P-value	<0.001*	<0.001*		

DCI: Dynamic cervical implant; PEEK: Polyetheretherketone; SD: standard deviation; VAS: Visual analogue scale; *: significant difference

		DCI group	PEEK group	Indeper	ndent t-test
		No. = 25	No. = 25	t	P-value
Pre VAS [Arm]	Mean ± SD; Range	6.32 ± 0.90; 5.0 – 8.0	6.04 ± 0.84; 4.0 – 7.0	1.13	0.26
Post VAS [Arm]	Mean ± SD; Range	1.48 ± 0.58; 1-3	1.28 ± 0.45; 1-2	1.34	0.18
% change	Mean ± SD; Range	76.02±10.22; 57.14-87.50	78.58±7.58; 60.0-85.71	1.01	0.32
Paired t-test	t	21.88	27.06		
	P-value	<0.001*	<0.001*		

Table [3]: Clinical outcome regarding arm pain among studied groups

DCI: Dynamic cervical implant; PEEK: Polyetheretherketone; SD: standard deviation; VAS: Visual analogue scale; *: significant difference

Table	[4]:	Range	of motion	among	studied groups	
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		DCI group	PEEK group	Indepe	ndent t-test
		No. = 25	No. = 25	t	P-value
Pre ROM	Mean ± SD; Range	7.56 ± 0.58; 7-9	7.60 ± 0.50; 7-8	0.26	0.97
Post ROM	Mean ± SD; Range	6.64±0.81; 5-8	7.52±0.51; 7-8	4.59	<0.001*
% change	Mean ± SD; Range	12.03±9.96; 0-28.57	0.92±5.20; -14.29 to 12.50	5.05	<0.001*
Paired t-test	t	6.05	1.0		
	P-value	<0.001*	0.37		

DCI: Dynamic cervical implant; PEEK: Polyetheretherketone; SD: standard deviation; ROM: Range of motion; *: significant difference

Table [5]: Global	range	of motion	among	studied	groups
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		Dynamic group	Fixed group	Indeper	ident t-test
		No. = 25	No. = 25	t	P-value
Pre GOM	Mean ± SD; Range	29.96 ± 1.20; 28-33	30.00 ± 0.76; 29-31	0.14	0.88
Post GOM	Mean ± SD; Range	29.32 ± 1.93; 26-33	29.96 ± 1.20; 28-32	1.40	0.17
% change	Mean ± SD; Range	2.10±5.73; -7.14 to 13.33	0.14±2.82; -6.90 to 3.45	1.53	0.13
Paired t-test	t	1.85	0.23		
	P-value	0.08	0.81		

DCI: Dynamic cervical implant; PEEK: Polyetheretherketone; SD: standard deviation; GOM: Global range of motion

DISCUSSION

PEEK cages had been popularly used in cervical surgery, due to better elasticity and radiolucency. However, it had the disadvantages of increased motion and intradiscal pressure in the adjacent levels to fused vertebrae and some researchers reported an increased risk of adjacent segment degeneration [ASD]^[12-14].

Hilibrand et al.^[15] reported that approximately 25% of patients who underwent single-level ACDF developed ASD within 10 years. These limitations encouraged researchers to investigate motion-preserving surgery such as artificial cervical disc arthroplasty. DCI is a new type of implant that enables anterior decompression without cervical fusion, and is mainly used to treat cervical DDD.

DCI arthroplasty has the following theoretical advantages; 1] It can be adapted to a wider scope with relatively simple surgery; 2] The U-shaped structure absorbs vibrations; 3] it restricts excessive flexion, extension, and rotation, thereby protecting the small cervical joints; and 4] as there is no grinding of metal, polyethylene, or ceramic, there is no local or systemic reaction to debris^[16].

The present work was designed to compare between DCI and PEEK cages, and results revealed that, PEEK cage was associated with better alleviation of pain either at the neck or at the arm. On the other side, DCI is associated with slightly better results for range of motion. However, global range of motion is comparable between both groups. In the present work, three patients [6.0%] reported persistent neck pain, two cases with persistent arm pain and no motor deterioration was reported in any case. **Mohi Eldin** ^[5] evaluated the safety and effectiveness of DCI as a form of dynamic instrumentation to treat single level cervical disc disease among 15 patients. They reported improvement of neck pain and radiculopathy in 86.7%, and myelopathy improved among 50% of cases.

In the present work, transient postoperative swallowing difficulty was reported among by one patient [2.0%] and another patient reported mild hoarseness. Another patient developed remote spondylodiscitis at [C6–7] below the operative site. That patient had been managed conservatively and resolved within 3 months.

Li et al. ^[17] compared the clinical and radiological outcomes of DCI arthroplasty versus ACDF for cervical DDD. They included 81 patients. Complains were radiculo-pathy, myelopathy and some were radiculo-myopathy. They reported comparable outcome to the present work regard neck and arm pain with significant pain reduction. However, they reported significant improvement of global ROM in dynamic group when compared to fixed group.

In addition, **Faldini et al.**^[18] demonstrated the clinical and radiological outcomes of PEEK cage after anterior cervical discectomy. Segmental and global range of motion had been maintained.

Elsawaf et al.^[19] demonstrated the clinical and radiological outcomes of PEEK cage after anterior cervical discectomy for 20 patients. The reported that, the global range of motion showed a statistically significant increase from pre- to post-operative to postoperative values and global alignment had been maintained.

Also, **Rollinghof et al.**^[20] reported the clinical and radiological outcomes of PEEK cage & prestige arthroplasty prosthesis for 42 patients. The VAS neck decreased significantly from $[7.9\pm2.8]$ preoperative to $[1.8\pm2.2]$ postoperative and VAS arm significantly decreased from $[7.03\pm1.75]$ & $[6.95\pm1.97]$ preoperative to $[1.95\pm1.02]$ & $[1.72\pm0.96]$ postoperative. Segmental range of motion maintained and global range of motion decreased. These results are comparable to the present work.

Donk et al.^[3] in a randomized study compared

three techniques for treatment of single levels DDD of cervical spine and could not detect a significant difference between three modalities. They added, ACDF without implant appears to be comparable to ACDF by cage stand-alone or with disk implants.

On the other side, **Cheung et al.**^[21] in his metaanalysis, concluded that, ACDF using a cage-only maneuver seems to have better clinical outcomes than the cage-plate technique, although radiological imaging revealed increased rates of subsidence and cervical lordosis restoration was lesser.

In conclusion, the present work did not show major significant differences between DCI and PEEK cage for cervical DDD in improvement of clinical symptoms, but DCI resulted in slightly better cervical and segmental ROM at the treated level than ACDF with peek cage. However, pain reduction was significantly better in PEEK cage group. However, both groups reduced pain to a significant level when compared to preoperative values. Here, DCI take the upper hand in better results of ROM. So, we advise DCI arthroplasty especially in single level DDD. However, we could not globalize our results due to small number of patients included in the present work. More studies with a long term follow up are encouraged to reach a final conclusion about the gold-standard technique.

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