The use of Zero profile cage plate for the management of cervical disc disease

Thesis submitted for partial fulfillment of the MD degree in orthopedics

By

Tamer Ramadan Ibrahim Badawy

MB.Bch,M.Sc.

Supervised by

Prof.Dr. Naguib Yousef Eldesoky Basha

Professor of orthopedic surgery, Cairo University

Prof.Dr. Hazem Bayoumi Elsebaie

Professor of orthopedic surgery, Cairo University

Dr. Mahmoud Abdel Karim

Lecturer of orthopedic surgery, Cairo University

Dr. Hisham Magdy Soliman

Lecturer of orthopedic surgery, Cairo University

<u>ACKNOWLEDGMENT</u>

All thanks to **ALLAH**, First and last for his countless gifts to me.

I would like to express my gratitude to **Prof. Dr. Naguib Basha**, Professor of Orthopaedic Surgery, for suggesting, his supervision, kind guidance, patience and continuous support.

I would like to express my deepest gratitude & appreciation to **Prof. Dr. Hazem Elsebaie** Professor of Orthopaedic Surgery, for his kind patience, kind guidance, and continuous support.

My deepest thanks and appreciation should go to **Dr. Mahmoud AbdeL karim**, Lecturer of Orthopaedic Surgery,

Cairo University for his constant guidance and constructive criticism and his continuous support.

My deepest thanks and appreciation should also go to **Dr. Hisham Magdy**, Lecturer of Orthopaedic Surgery, Cairo University, for his help, constant encouragement, continuous Support and everlasting skillful help.

Their favors will never be forgotten.

Then, I would like to extend my sincere gratitude to my Wife and my family especially my mother.

Then I would like to express my deepest thanks and appreciation to **my Late father** for his support all over my life.

Contents

Contents	Page No.
Acknowledgment	i
Contents	ii
List of figures	iii
List of tables	V
List of charts	vi
List of abbreviations	vii
Abstract	viii
Chapter 1: Introduction and aim of the study	1
Chapter 2:Review of literatures	5
A-relevant anatomy	6
B-Biomechanics and pathology	18
C-Management	25
D- Zero-p	38
E- Complications	49
Chapter 3: Patients and methods	55
Chapter 4: Results	80
Chapter 5: Cases presentation	92
Chapter 6 : Discussion	125
Chapter 7: Summary and conclusion	136
Chapter 8: References	151
Arabic Summary	159

List of Figures

NO	Figure Title	Page
1	Anatomy of neck muscles	9
2	Bony anatomy of cervical spine	10
3	Typical cervical vertebra	11
4	Anatomy of the 7 th cervical vertebra	12
5	Ligamentous structures between cervical vertebrae	14
6	Cervical facet joint during motion	15
7	Neural tissues configuration within cervical vertebrae	16
8	The planes of motion of a cervical motion segment	20
9	Pattern of motion of the cervical spine	22
10	Spurling's sign	28
11	MRI & X-ray cervical spine	30
12	Assessment of the sagittal alignment of cervical spine	32
13	Bone graft in ACDF	33
14	Corner-stone cage	33
15	Examples of anterior cervical plates	34
16	X-ray demonstrating cage subsidence	36
17	X-ray stress shielding causing non union	37
18	Sagittal cervical MRI showing adjacent segment degeneration	37
19	Zero-p implant	40
20	Zero-p implant (screws orientation)	42
21	The locking screw mechanism of zero-p	43
22	X-ray showing various screws complications	50
23	Clinical sheets of history and complications	60,61
24	Visual Analogue Score (VAS)	62
25	Zero-p implant (cage& screws)	67
26	Instruments used in zero-p application	68,69
27	Skin incision & patient positioning	71
28	Platysma Dissection	72
29	Incision of the superficial fascia	72
30	Exposure of the vertebral bodies and disc in-between	73
31	Intraoperative decompression discectomy and instruments used	73
32	Disc space after decompression and discectomy	74
33	Application of the trial spacer	75
34	The implant packed with bone graft	75
35	Application of the implant attached to aiming device into disc space	76
36	Drilling of the first pilot hole through the aiming device	76
37	Insertion of the first screw through the aiming device	77
38	Insertion of the remaining screws	77
39	Final screws tightening	78

Zero-P

40	Intraoperative final image of the construct	78
41	X-ray signs of fusion in case N 4	89
42	X-ray implant failure in case 15	90,91
43	Case (1) preoperative x-ray &MRI	94
44	Case (1) postoperative x-ray	95
45	Case (1) follow-up x-ray at 12 months	95
46	Case (2) preoperative x-ray &MRI	97
47	Case (2) postoperative x-ray	98
48	Case (2) follow-up x-ray at 12 months	98
49	Case (3) preoperative x-ray &MRI	100
50	Case (3) postoperative x-ray	101
51	Case (3) follow-up x-ray at 20 months	101
52	Case (4) preoperative x-ray &MRI	103
53	Case (4) postoperative x-ray	104
54	Case (4) follow-up x-ray at 18 months	104
55	Case (5) preoperative x-ray &MRI	106
56	Case (5) postoperative x-ray	107
57	Case (5) follow-up x-ray at 12 months	107
58	Case (6) preoperative x-ray &MRI	109
59	Case (6) postoperative x-ray	110
60	Case (6) follow-up x-ray at 15 months	110
61	Case (7) preoperative x-ray &MRI	112
62	Case (7) postoperative x-ray	113
63	Case (7) follow-up x-ray at 12 months	113
64	Case (8) preoperative x-ray &MRI	115
65	Case (8) preoperative CT	116
66	Case (8) postoperative x-ray	116
67	Case (8) follow-up x-ray at 6 months	117
68	Case (9) preoperative x-ray &MRI	119
69	Case (9) postoperative x-ray	120
70	Case (9) follow-up x-ray at 14 months	120
71	Case (10) preoperative x-ray &MRI	122
72	Case (10) postoperative x-ray	123
73	Case (10) X-ray at 3 months follow-up showing screw back-out	123
74	Case (10) CT axial & sagittal at 3 months follow-up	124
75	Case (10) X-ray after removal of the backed-out screw	124

List of Tables

NO	Table Title	Page
1	Presentations of radiculopathy for individual nerve	28
2	Sex of patient distribution	57
3	Frequency of each cervical level to the total operated levels	58
4	Multiplicity of operated levels in one patient	58
5	Frequency of implant sizes used	59
6	Bazaz-Yoo dysphagia index	62
7	NDI scoring system	63,64
8	Comparison between pre &postoperative VAS for neck pain	82
9	Comparison between pre &postoperative VAS for arm pain	82
10	Pain score for neck pain for patients pre &postoperatively	83
11	Pain score for arm pain for patients pre & and postoperatively	84
12	Comparison between pre &postoperative NDI %	86
13	NDI sore in patients pre &postoperatively	87
14	Comparison between dysphagia score pre &postoperatively	88
15	Bazaz dysphagia score for patients pre &postoperatively	88
16	Comparison of patients criteria in different studies	127
17	Comparison of dysphagia rate in different studies	128
18	Comparison of fusion rate in different studies	130
19	Comparison of complication rate in different studies	132
20	Comparison of surgical revision rate in different studies	133
21	Comparison between operative time in different studies	134
	1	

List of Charts

NO	Chart Title	Page
1	Age distribution in patients groups	57
2	Sex of patients distribution	57
3	Frequency of each level to total operated levels	58
4	Multiplicity of levels operated in one patient	58
5	Frequency of implant sizes used	59
6	Relation of the mean operative time to the numbers of levels operated	81
7	Pre &postoperative VAS for neck and arm pain	82
8	Presentation of pre &postoperative change of NDI score	86
9	Comparison of dysphagia rates in different studies at 3 months	129
	follow-up	
10	Comparison of fusion rates in different studies	131
11	Comparison of total incidence of complications in different studies	133
12	Comparison between the mean operative times in different studies	134

List of Abbreviations

Zero-p	Zero profile cervical cage plate
ACDF	Anterior cervical discectomy and fusion
PEEK	Polyetheretherketone
OPLL	Ossified posterior longitudinal ligament
EMG	Electromyography
MRI	Magnetic Resonance Image
CT	Computed Tomography
A-P	Antro-posterior
TIH	Total intervertebral height
VAS	Visual Analogue Scale
NDI	Neck Disability Index
ROM	Range of motion

Abstract

<u>Introduction:</u> Several studies reported fusion rates are higher with anterior cervical decompression and fusion (ACDF) procedure if supplemented with a plate. However, plates may be associated with postoperative morbidity and higher rates of dysphagia. Zero-p implant for stand-alone cage plate used in ACDF was developed to avoid complications associated with anterior cervical plates owing to the zero profile of the construct.

<u>AIM:</u> The aim of this study to evaluate the functional as well as radiological outcome of Zero-p cage plate for the management of cervical disc disease.

<u>Materials & methods</u>: 30 patients (16 male and 14 female) were selected to undergo ACDF with Zero-p implant, the mean age was $47.93(\pm 10.9)$ years, a total of 43operated levels (20 patients one level operated, 7 patients two levels operated, and 3 patients three levels operated, and the mean follow-up was 12.3 months.

These patients underwent pre- and postoperative clinical and neurological evaluation and scoring systems using visual analogue scale VAS for neck and radicular pain, neck disability index NDI, and Bazaz-Yoo dysphagia index for postoperative dysphagia.

Postoperative X-ray evaluation was done for evaluation of fusion and implant associated complications at 1,3,6,9, and 12 months.

Results: All patients had significant reduction in arm and neck pain and NDI maintained over the follow-up period p value was (<0.0001) with reduction of VAS for neck pain from 7.33 preoperatively to 1.37 at 12 months follow-up and also VAS for radicular pain from 8.70 preoperatively to 0.27 at 12 months follow

Zero-p

-up, and reduction of NDI from 68.87% preoperatively to 8.60% at 12 months

follow-up. None had dysphagia after 6 months postoperatively, one patient

developed back-out of one of the implant screws that was surgically extracted, and

otherwise no other implant related complications.

Conclusion: the Zero-p implant is a valid alternative to anterior cervical plating

after ACDF with a very low incidence of chronic dysphagia, and implant-related

complications. However, good decompression technique, vertebral endplate

preparation, and good soft tissue handling affects the patients' outcome rather than

implants' design.

Keywords:

Zero-p- EMG- ACDF-NBI

ix

INTRODUCTION AND AIM OF THE STUDY

Degenerative conditions of the cervical spine (eg, degenerative disc diseases or cervical spondylotic mylopathy) are a major indication of anterior cervical discectomy and fusion (ACDF) in treatment of radicular pain and neurological deficit. There are different methods for cervical fusion for treatment of cervical disc disease, as anterior interbody fusion with iliac autograft, anterior plate fixation with iliac autograft, cage fusion and cage fusion with anterior plate fixation. (1).

Anterior decompression and fusion of the cervical spine (ACDF) was introduced in the late 1950s by Smith and Robinson, the goals of this surgery include decompression of neural structures, reduction of deformity, immediate stability and creation of conductive environment for fusion to occur. (2).

In order to obtain fusion, it is generally agreed that intervertebral motion should be minimized so bone growth can occur. Furthermore, the position of any interbody graft or spacer should be maintained to prevent its extrusion, irritation of surrounding tissues, and to allow union with the adjacent vertebrae. (3).

Uninstrumented anterior cervical discectomy and fusion (ACDF) has unacceptably high complication rates and pseudoarthrosis and propensity for kyphosis at the operative levels and patients commonly had significant neck pain until fusion was achieved. Graft dislodgment was a frequent complication and patients were maintained in an external orthosis for extended periods of time. Many surgeons prefer to add plate in fusion procedures for enhancing stabilizing properties, as several studies suggest this lead to increased fusion rates, reduced failure rates (particularly in multilevel procedures) and reduced incidence of cervical kyphosis. (4).

The addition of a plate is, however, not without side effects. Although the profile of the current anterior plates is thinner than that of earlier designs, the plates are still bulky. The incidence of chronic dysphagia related symptoms after ACDF ranges from 5% to 69 %.(5), (6), (7).

Additionally, the screw-plate interface might lead to postoperative complications. Cases of migrating screws and subsequent soft tissue damage are reported. (8), (9), (10).

There is a higher incidence of adjacent-level degenerations of an additional plate was used. The authors stated this finding is consistent with inappropriate sized or misaligned plates interfering with the adjacent-level disc space. (11), (12).

Zero profile cage plate (Zero-p) acts as stand-alone implant for use in cervical interbody fusion its design combines the functionality of a cervical interbody spacer and the benefits of an anterior cervical plate. The Zero profile implant is contained within the excised disc space and doesn't protrude past the anterior wall of the vertebral body as do anterior cervical plates and so avoid these complications. The Zero profile cage plate consists of spacer component which is made of PEEK optima (polyetheretherketone), the PEEK optima contain carbon fibers reducing the risk of systemic uptake and local connective tissue formation, and teeth on the implant surface provide initial stability. Titanium alloy plate provides a secure, rigid screw locking interface, locking head screws with a 40±5° cranial/caudal angle and 2.5° medial/lateral angle, self tapping screws improve thread purchase. In February 2008 The US Food and Drug Administration (FDA) approved the clinical use of Zero Profile cage plate

(Zero-P) in skeletally mature patients for degenerative cervical spine conditions. (13), (14).

The objective of this study:

The aim of this study is to evaluate the functional as well as radiological outcome of zero-p cage plate for management of cervical disc diseases.

CHAPTER 1:

REVIEW OF LITERATURE