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

2015

ACKNOWLEDGMENT

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

List of Figures

List of Tables

List of Charts

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

Introduction: 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.

AIM: 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.

Materials & methods : 30 patients (16 male and 14 female) were selected to undergo ACDF with Zero-p implant, the mean age was 47.93(±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

–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

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