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The Use of Zero Profile Cage Plate for the Management of Cervical Disc Disease

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Abstract

Background: 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 of Study: 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.

Material and 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 43 operated levels (20 patients one level operated, 7 patients 2 levels operated, and 3 patients 3 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 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.

Key Words: *ACDF – Zero profile – Plate – Dysphagia.*

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Introduction

DEGENERATIVE conditions of the cervical spine (e.g., 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 3% to 21% [5-7].

Additionally, the screw plate interface might lead to postoperative complications. Cases of migrating screws and subsequent soft tissue damage are reported [8-10]. 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 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±5º cranial/caudal angle and 2.5º medial/lateral angle, self tapping screws improve thread purchase. (Fig 1). In February 2008 The US Food and Drug Administration (FDA) approved the clinical use of Zero ProfileCage plate (Zero-P) in skeletally mature patients for degenerative cervicalspineconditions [13,14].

Material and Methods

This Study was conducted at Kasr Al-Ainy Hospitals.

Between February 2013 to February 2015, 30 patients were selected to undergo ACDF for cervical disc disease at levels from C3-C4 to C6-C7 that presented with neck pain with cervical radicular syndrome, with or without neurological deficits failing conservative treatment and corresponding findings in magnetic resonance imaging (MRI) studies. Patients' selection criteria were as follow:

Inclusion criteria:

1- Symptomatic cervical disc disease between C3-C4 to C6-C7 with neck or arm (radicular) pain and/or neurological or functional deficit.
2- Age between 18 to 70 years.

Exclusioncriteria:

1- Systemic or local infection.
2- Active rheumatoid arthritis or any other medical conditions that interfere with normal healing, or increase surgical risk.
3- Previous known allergy to the materials contained in the device, such as poly ether ether ketone or titanium alloy.
4- History of any invasive malignancy and spinal metastasis.

The patient population consisted of 16 males and 14 females and the mean age was 47.93 (±10.9) years ranging from 31 to 69 years. A total 43 levels were operated (20 patients with single, 7 patients with double, and 3 patients with multilevel disease). The contribution of each cervical level to the total operated levels was as in Table (1) & the mean follow-up periods were 12.3 months.

Table (1): Frequency of each level to the total operated levels.

Level	Frequency	Percentage %
C3-C4	3	7
C4-C5	11	25
C5-C6	21	49
C6-C7	8	19

Preoperative clinical evaluation was done; this included a preoperative full neurological examination and painful symptoms quantification using visual analogue scale (VAS) for neck and radicular pain of 0 to 10cm, neck pain disability scale (NDI) of 0% to 100%.

Preoperative radiological studies of the cervical spine included X-ray cervical spine (Antro-posterior and lateral views) and MRI (sagittal and axial planes).

Surgical technique: In the operation theater, patients were placed with a head extension in supine position under general anesthesia. To obtain the target disc space a standard anterior approach to cervicalspine was performed. After anterior decompression, trial spacers were usedto determine proper implant size that would be used. After the trial spacer was correctly fitted into the disc space, a corresponding zero-p implant (zero-p; Synthes GmbH, Oberdorf, Switzerland) filled with bone

graft was inserted with an implant aiming device. Implants' sizes used were as Table (2).

Table (2): Zero-p implant sizes used in study population .

Implant size	Frequency (n.43)	Percentage(%)
5 mm	1	2%
6 mm	4	10%
7 mm	21	49%
8 mm	17	40%

The correct position of the cage was controlled by using image in lateral and A-P views. The device should be placed 2mm behind the anterior column in lateral view and in the center of the disc space in A-P view. The three different implant configurations offered are with parallel shape endplate, a convex endplate, and a lordotic shaped endplate. The zero-p contains a polyether ether ketone body with tantalum markers to control the position during insertion.

Integrated a small plate containing four holed with internal screw threads. After drilling the pilot hole through the aiming device, the first locking screw was inserted. Implant system contains screws of 12mm, 14mm, and 16mm lengths, in most of our cases the 16mm screw length was used.

Subsequently, the other three holes were drilled using the guidance of the aiming device. The aiming device was then removed and the remaining screws were inserted using torque limitation (1.2Nm).

Angled instruments for drilling and inserting screws in the upper and lower spine were used.

The mean operative time was131.83 (±34.950) minutes recorded ranged from 90-220 which is increasing with more levels operated, the mean Intraoperative blood loss was (206.67±84.8cc), and no patient required Intraoperative blood transfusion.

Postoperative intravenous antibiotics first generations cephalosporin (cefazoline) for 3 days, postoperative analgesia, and mobilization from the first day postoperatively. Miami collar was recommended postoperatively for 12 weeks and X-ray A-P and lateral was done for all patients before discharge from the hospital.

The mean postoperative hospital stay was 3.78 (±1.167) days ranged from 3 to 7 days.

Postoperative clinical outcome evaluation was undertaken immediately postoperatively then at 1,3,6,9, and 12 months and consisted of the same preoperative clinical examination and scoring in addition to Bazaz-Yoo dysphagia index. All complications were recorded as implant-related or surgery-related.

Postoperative radiological evaluation with X-ray of cervical spine (A-P and lateral) immediately postoperatively then 1,3,6,9, and 12 months for assessment of implant position and fusion.

Statistical analysis:

Differences between preoperative and post operative VAS, NDI, and Bazaz-Yoo scores were calculated using Freidman's test with posthic multiple 2-group comparisons. p-value less than 0.05 was considered statistically significant. All statistical calculations were done using computer program SPSS® (statistical package for the social science; SPSS Inc., Chicago, IL, USA) software version 15.0.1.

Results

Post operative VAS was assessed for 30 patients for neck and radicular pain and at 1,3,6,9 and 12 months follow-up, all patients had a statistically significant reduction in VAS radicular pain ($p<$ 0.0001), and neck pain ($p<0.0001$) within the first 3 months, (Fig. 2) and such positive trend was maintained at the following follow-up with reduction of the mean VAS sore of neck pain from 7.33 preoperatively to 1.73 at 12 months follow-up, and reduction of the mean VAS score for radicular pain from 8.70 preoperatively to 0.27 at 12 months-follow-up.

Post-operative NDI was assessed for 30 patients for assessment of functional improvement and at 1,3,6,9, and 12 months follow-up, all patients had a statistically significant reduction in NDI in the first 3 months ($p<0.0001$) and such a positive trend was maintained at the following follow-ups with reduction of the NDI from 68.87% preoperatively to 8.60% at12 months.

Among the study population 11 of 30 patients 36.6% complained of post operative dysphagia ranged from mild dysphagia (score 1) to moderate dysphagia (score 2), this number was reduced to 4 patients at 1 month follow-up and only one patient at 3 months follow-up, none of patient complained of dysphagia at 6 months follow-up. None of our patients has preoperative dysphagia.

We reported one case developed dysphagia of mild type according to Bazaz score at 3 months follow-up that was not before at 1 month and preoperative, further assessment of this patient

revealed screw back-out, symptoms of dysphagia disappeared after revision surgery to extract the screw.

All patients had radiological signs of fusion by 3 months except one case, according to criteria of Pitzen (the absence of radiolucent gap between the graft and the endplates, the presence of continuous bridging trabeculae between the endplates and the absence of motion between the spinous processes on flexion/extension radiographs Fig. (4).

Regardless the occurrence of post-operative dysphagia, the incidence of complications in this case series study was low; one complication in one patient out of 30 patients. One patient 3.3% developed one screw pull-out and loosening appeared at 3 months follow-up was due to failure of the locking mechanism of one of the screws. (Fig. 5)

No other post-operative complications were recorded as wound infection, hoarseness of voice, neurological or vascular injures subsidence, and screw cut-through or cage dislodgment.

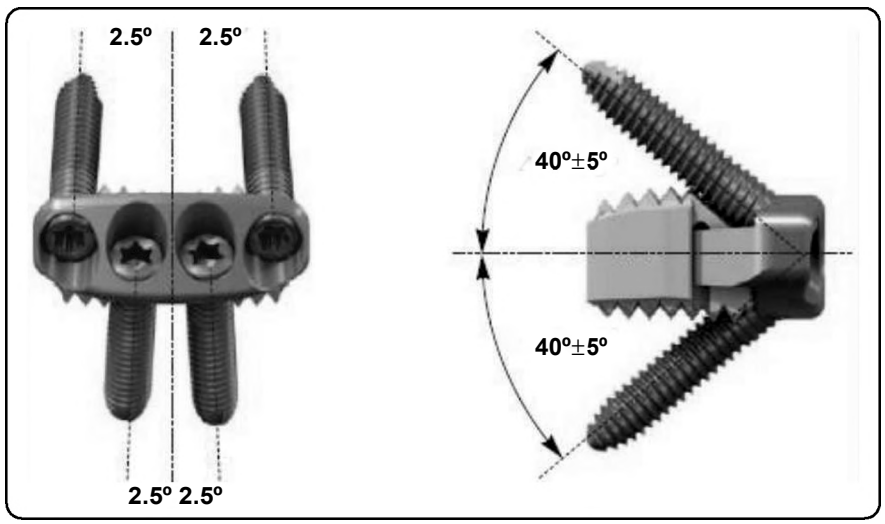

Fig. (1) Zero-p implant [15].

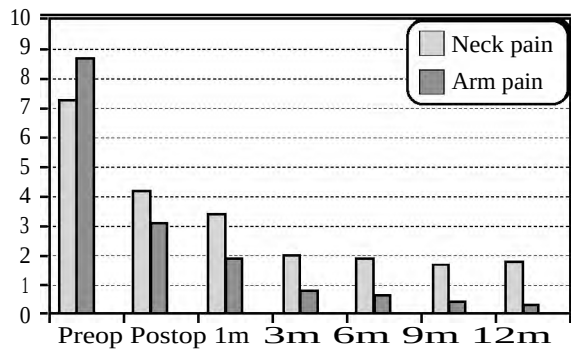

Fig. (2): Bar graph representing pre and post-operative arm and neck pain as 0 to 10 VAS over the follow-ups.

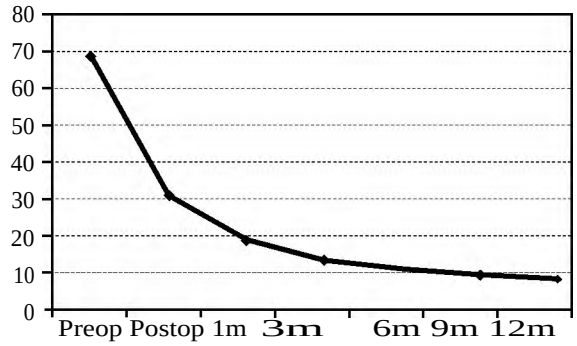

Fig. (3): Graphic representing the pre and post-operative changes in NDI scores.

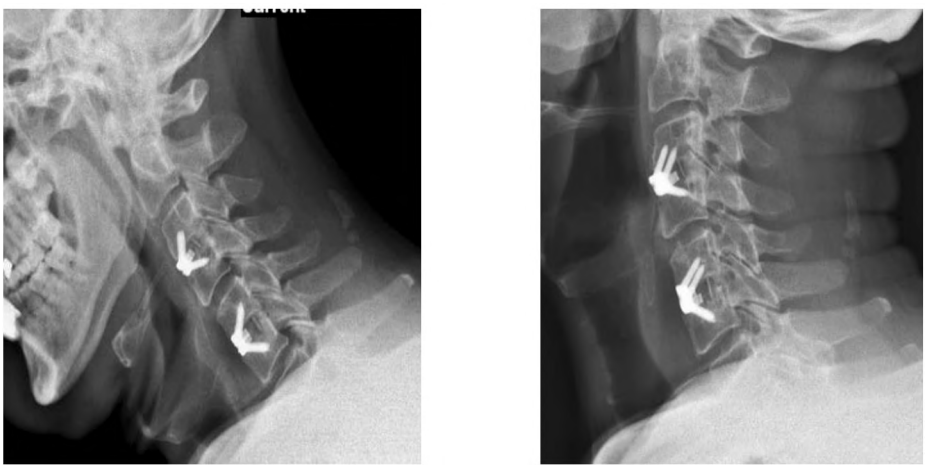

Fig. (4): Postoperative dynamic lateral views shows evidence of fusion and implant related complications at 12 months follow-up.

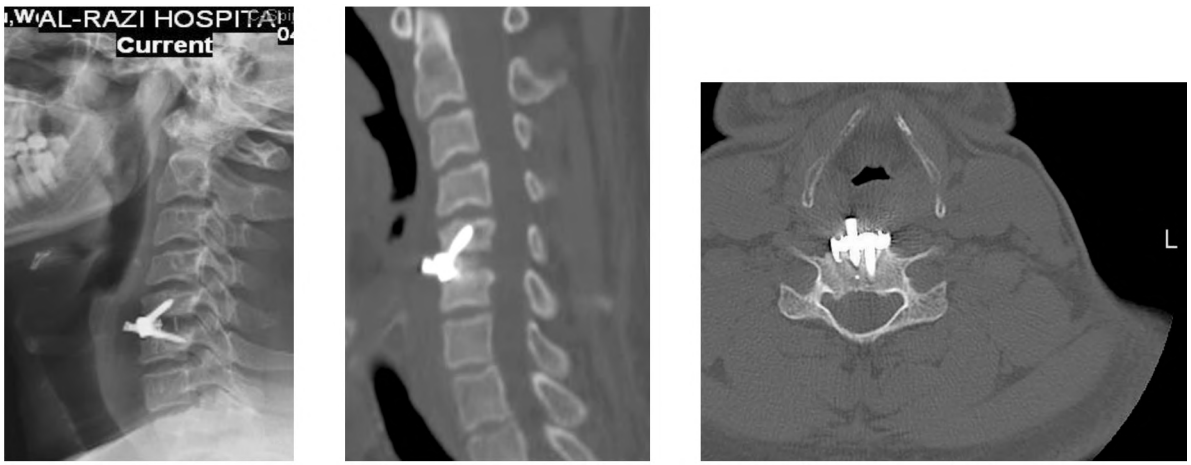

Fig. (5): X-ray lateral view and CT sagittal and axial view of one of the cases at 3 months follow-up showing pullout of one of implants' screws, and no radiological signs of fusion.

Discussion

Operative treatment in cervical disc disease is considered when the conservative treatment such as medications, physiotherapy and local injection fails and if there is neurological or functional deficit **[14]**.

There are two different philosophies to treat diseased motion segment after cervical spine anterior decompression: An interbody fusion or disc prosthesis. ACDF is considered the "gold standard" surgical treatments in cervical disc disease and for patients contraindicated for the use of cervical prosthesis as patients with posterior facet arthropathy and sever myelopathy **[14]**.

The ideal cervical fusion technique should achieve success in terms of fusion rate and neurological recovery, anterior instrumented fusion after discectomy is important to maintain cervical alignment, resorption and arrest of osteophytes formation, elimination of potential instability, preservation of disc height, reduction the compression on nerve roots, and prevent graft related complications **[16]**.

Cervical cages were developed to prevent disc space collapse and decrease donor site morbidity which was reported to follow the use of autologous bone graft. Furthermore, cage construct achieve internal fixation while permitting bone formation in and around the device **[17,18]**.

The addition of plate reduces the incidence of graft and cage complications, acting as a buttress prevents graft extrusion preventing graft collapse and subsidence and maintaining cervical lordosis, results in a higher incidence of fusion, less incidence of pseudoarthrosis especially in multilevel ACDF **[4]**, **[19]**. However, the use of additional plate is associated with side effects including dysphagia and implant associated complications. **[5-7]**.

Postoperative dysphagia is a common event after ACDF with or without plating, occurring with a frequency 2 to 67%. The incidence of long term dysphagia can be caused by adhesions between posterior esophagus and the plate; the no-profile design of zero-p implant avoids its contact with the soft tissue in front of cervical spine as it contained within the disc space and doesn't protrude past the anterior wall of the vertebral body, so seems to prevent mechanical irritation of the esophagus and explain the low dysphagia rate. Also short operative time in comparison to the traditional cervical cage and plate fusion with less time exposure for soft tissue retraction during the surgery reduces the incidence of post-operative dysphagia **[4,16,19]**.

In this study postoperatively, 11 patients complained of dysphagia 36.6%, according to Bazaz dysphagia score, 4 patients had mild dysphagia 13.4%, and 7 patients had a moderate dysphagia 23.2%, at one month follow-up 4 patients complained of dysphagia 3 of them are moderate 10% and 1 mild 3%, at 3 months 1 patient had a mild dysphagia that was not present in the previous follow-ups was due to screw back- out that relieved after revision surgery, and none of patient had dysphagia by 6 months follow-up.

In this study there are fewer rates of dysphagia postoperatively 36.6% than Scholz et al., (62%) and Azab w et al., (76%) some of them of moderate grade as in Barbagallo et al., 8 patients out of 11 (72.7%) who suffered from postoperative dysphagia are multi-level operated with longer operative time

that resolved spontaneously by 1 month Follow-up. In this study, rate of dysphagia is similar to Scholz et al., at 3 months follow-up (3%).

In this study it was noted that all patients that suffered from moderate dysphagia had undergone surgery at C4-C5 or C5-C6, either a single or multiple level surgery, this result is similar to that reported by Barbagallo et al., although other studies for dysphagia following ACDF suggest that the more cranial the operated the disc level (i.e., C3-C4) the higher the risk of postoperative dysphagia.

Pain relief after ACDF using zero-p was rapid and evident postoperatively, the pain relief was sustained for up to 12 months after the procedure. This effect was shown by reduction of VAS score for neck pain by mean of 3 points decrease and 5 points decrease for radicular pain postoperatively, and continous decrease of VAS score points in all patients till 12 months follow-up. There is marked improvement in functional outcome assessment using NDI score, this shown by improvement of NDI score from mean 69% preoperatively to 31% postoperatively, the improvement was continous by 1 month follow-up 19% till 12 months follow-up 8%. Clinical outcome in our series was similar to the results reported in literature of ACDF using Zero-P implant.

In this study All patients had radiological signs of fusion by 3 months except one case, according to criteria of Pitzen (the absence of radiolucent gap between the graft and the endplates, the presence of continuous bridging trabeculae between the endplates and the absence of motion between the spinousprocesses on flexion/extension radiographs), with fusion rate 96.6%.

In comparison to other studies, similar rate of fusion to Barbagallo et al., (94.5%) at 3 months follow-up, there was radiological evidence of fusion in all patients in studies of Scholz et al., and Azab W et al., In ACDF with anterior cervical plating, the screw-plate interface may lead to postoperative complications. Examples of such implant related complications include screw loosening, screw breakage, and plate breakage, screw pullout with or without migration. Rarely erosion of anterior cervical plate into pharynx with pharyngotracheal fistula or pharyngocutaneous fistula may occur, in addition other surgical complications can occur, and for example postoperative haematoma, dysphagia, injury to recurrent laryngeal nerve, postoperative wound infection, vascular and spinal cord injuries can also occur **[20-23]**.

Implant related complications in ACDF with anterior cervical plating were reported by Vaccaro et al., an incidence of screw and plate loosening between 0% to 15.4%, screw breakage between 0% and 13.3%, plate breakage between 0% and 6.7%, plate and graft displacement between 0% and 21.4%, and implant malposition 0% and 12.5%. **[16, 20]**.

In the studies by Scholz et al., and Azab et al., there were no implant relatedcomplications, Scholz et al., referred the lack of implant migration or screw loosening in their study to the design of locking plate-screw interface of the zero-p implant; the plate with an internal screw thread engages with the outer screw thread located in the head of the screw providing a safe, constrained, and angle-stable screw fixation. In this study there was no implant related complications except one case of screw back-out in a healthy young patient was reported at 3 months follow-up it was attributed to failure of the locking mechanism of one of the implant's screws, this was similar to the study by Barbagallo et al., they reported screw back-out at 1 month follow-up in a patient treated many years with steroid for a renal disease and with poor bone quality. Other types of implant related complications was not recorded in this study; Barbagallo et al., reported device malposition with a screw encroaching the lateral surface of the vertebral body toward foramen transverserium.

We didn't report surgery related complications as postoperative haematoma, hoarseness of voice, superficial infection etc, postoperative haematoma that need surgical evacuation was recorded in one patient in the studies by Barbagallo et al., and 2 patients with Scholz et al.,

In general our complications incidence rate 3.3% is lower than Barbagallo et al., (9.3%) Scholz et al., (5.8%) and is near to Azab et al., (2.7%).

In literatures, another advantage associated with zero-p is reduced risk of inducing adjacent level degeneration and spondylotic changes; it has been shown that cervical plates reaching the adjacent disc levels can induce and accelerate disc degeneration and osteophyte formation. The zero-p minimizes such risk as it remains within the disc space, far from adjacent-level disc spaces, in our study no occurrence of adjacent level segments detected but long term follow-up will be required to determine whether or not zero-p reduce the risk of adjacent level degeneration **[19]**. Another advantage of zero-p is saving the in-between non-diseased

levels during surgery, i.e. for example a diseased C3-C4 segment and a diseased C5-C6 segment and not to include the in-between C4-C5 non-diseased level with less operative time needed than conventional plate and cage, in addition revision if needed can be done for each level separately in multilevel fusion without attacking the other operated levels.

Study limitations:

We note several limitations to our study; the study was performed as an observational study without a control group (graft/cage and plate) available for comparison, small number of patients in comparison to other studies, longer follow-up is advisable for further confirmation of our results and also for evaluation of the incidence of adjacent level degeneration.

In conclusion Zero-p cage plate is a valid alternative to anterior cervical plating in patients undergoing ACDF and characterized by low incidence of chronic dysphagia owing to the 'zero'implant profile and low incidence of implant related complications.

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استخدام الأقفاص العنقية المدمجة مع الشرائح المنعدمة البروز لعلاج أمراض الغضروف العنقى

تعتبر أمراض الغضروف العنقى هى الداعى الأكبر لاجراء عملية رفع الضغط عن الأعصاب واستئصال الغضروف العنقى وعمل لحام فقارى من المدخل الأمامى لعلاج آلام الذراع والرقبة والتأثيرات العصبية الناتجة عن ضغط الغضاريف على جذور الأعصاب والقناه العصبية.

توجد طرق متعدده لعمل اللحام العنقى الفقارى منها بواسطة الرقع العظمية،الشريحه الأمامية مع الرقعة العظمية والأقفاص العنقية مع الشريحة الأمامية العنقية.

الكثير من الجراحين يفضل اضافة الشريحة العنقية الأمامية لتحقيق ثبات أكثر مما يؤدى لمعدل أكبر فى اللحام وتقليل درجه التحدب فى الفقرات العنقية وتقليل مضاعفات اللحام الفقارى.

لكن وجود هذه الشرائح ليس بدون مضاعفات ، حيث يتراوح معدل حدوث صعوبة فى البلع بعد العملية من٥٪ الى ٦٩٪ وكذلك مضاعفات خاصة بالشريحة ذاتها مثل كسر الشريحة او المسامير أو تحركهما وفشل عملية اللحام الفقارى،أو التأثير على المستويات المجاوره لمكان اللحام الفقارى.

يعتبر أستخدام الأقفاص العنقية المدمجة مع الشرائح منعدمة البروز لعلاج أمراض الغضروف العنقى عمل اللحام الفقارى أفضل فى تجنب المضاعفات السابقة. حيث انها تكون مدمجه داخل الفراغ الغضروف لايوجد بروز يسبب ضغط على البلعوم وبالتالى تقليل حدوث صعوبة البلع بعد العملية مباشرة وايضا على المدى الطويل. وكذلك تقليل حدوث فشل الشرائح واللحام الفقرى.

النتائج الأولية تبين لنا سهوله وأمان استخدام الأقفاص العنقية المدمجة مع الشرائح المنعدمة البروز فى علاج أمراض الغضروف العنقى وأقل فى المضاعفات الخاصة بفشل الشرائح واللحام الفقارى وكذلك حدوث صعوبة البلع بعد العملية وعلى المدى الطويل وتعد بديلا جيدا لشرائح التثبيت العنقى الأمامى المعتادة.

تشمل هذه الدراسه على ٣٠ مريض (٤٣ مستوى). ١٦ ذكور و١٤ أناث، متوسط العمر للمرضى كان ٤٧.٩٣ سنه وتتروا ح اعمارهم بين ٣١ و٦٩ سنه وكان متوسط فترة المتابعة حوالى ١٢.٣ شهرا.