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Single Neurosurgeon Experience with the ZimVie LDR-C ROI Implant: A Study of 236 Patients with Predictive Outcome Modeling

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Abstract

Study Design: Retrospective Review

Objective: The goal of the study is to show the device has acceptable performance and fusion rates with a predictive modeling analysis of poor outcomes.

Summary of Background Data: This is one of the larger single-surgeon studies using the same (ZimVie LDR-C ROI) stand-alone device in the treatment of cervical degenerative disease with an Anterior Cervical Diskectomy and Fusion (ACDF).

Methods: We reviewed the records of 236 patients over a 4-year period (2016 – 2020) including presentation, diagnosis, risk factors, outcome, Odom's Criteria, fusion status, and complication rate up to one year. We identified risk factors and performed a predictive modeling analysis for poor outcomes.

Results: Patients presented with radiculopathy (72%) or myelopathy (28%). Surgery included one-level (45.3%), two-level (47.8%) and three-level fusions (6.8%) with a total 384 levels. Three patients (1.2%) developed a wound hematoma; 11 (4.7%) patients had a prior fusion that needed re-exploration for possible pseudoarthrosis, and 13 (5.5%) developed adjacent segment disease. Odom's Criteria Scores for patients at 2 weeks, 1 month, 3 months and 1 year with an outcome of Excellent to Good were 68%, 74%, 78% and 89% respectively. Fusion rates at 1 month, 3 months, and 1-year were 33%, 69% and 92%. Predictive modeling showed that outcome in the short-term was fair to poor with a pre-operative history of motor deficit or narcotics history for pain. Fair to poor outcome in the long-term one was related to a history or worker's compensation injury, narcotics history for pain, and emotional lability.

Conclusion: The ZimVie LDR-C ROI is a safe device with low complication rate, commensurate fusion rate, and acceptable outcome scores.

Keywords: Spine Surgery; Cervical Fusion; Stand-Alone Device; Predictive Modeling; Outcome

Level of Evidence: Non-randomized controlled cohort/follow-up study

Abbreviations: **ACDF:** Anterior Cervical Diskectomy and Fusion; **OC:** Odom's Criteria

Introduction

Anterior Cervical Diskectomy and Fusion (ACDF) is one of the most

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common procedures done in spine surgery and routinely done in an outpatient setting [1]. Technology has also changed such that most surgeons have converted to stand-alone devices rather than plate plus cage or allograft because it can reduce operative time and dysphagia after surgery [3]. In this retrospective study, we review the experience of a single Neurosurgeon using the same stand-alone device and surgical technique over a 4-year period. Complications, fusion rates, and outcome scores are reported to one year. We also use predictive modeling to assess patients who had a fair or poor outcome at the one year follow up.

Materials and Methods

We reviewed the records of a single Neurosurgeon (JMA) who exclusively used the ZimVie LDR-C ROI Stand-Alone (Westminster, CO) fusion device in a series of 236 consecutive patients. Patient demographics, presenting symptoms, risk factors, diagnosis and outcomes including Odom's Sore [4], pain medication requirements, and fusion status were tracked out to one year after surgery. Patients who presented with cervical degenerative disease were included; those patients who sustained acute trauma or had surgery for metastases were excluded from the study.

All patients underwent surgery using the same method by the same surgeon. All approaches were from the left side and were done using the traditional anterior cervical diskectomy and fusion technique. After decompression, the ZimVie LDR-C ROI implant was filled with autograft. The operating Neurosurgeon has not used allograft in over 10 years and used bone chips from the Kerrison as well as bone dust collected during the diskectomy. After packing the implant with autograft, the surgeon covers the superior and inferior portion of the cage with a thin layer of Hemasorb Plus (Abyrx, Stamford, CT) to hold the autograft in place. Hemasorb Plus is a non-settable and resorbable hemostatic bone putty with calcium phosphate and Vitamin E Acetate. After surgery, patients undergoing 1-level or 2-level procedures were discharged home; 3-level procedures were admitted overnight and discharged the next day.

Patients were treated through a Best Practices Protocol after surgery developed by the senior Neurosurgeon to minimize post-operative visits and reduce unnecessary imaging after surgery. Post-operative visits were at 2 weeks, one month, three months and one year. Patients underwent X-Ray imaging at month one, three and twelve. They were also given the option for Physical Therapy at month one. Patients were placed in bone growth stimulators with a smoking history or revision surgery.

Data Analysis for outcome was based on complications, fusion status and outcome that was based Odom's Criteria. Data was reviewed and analyzed using Chi-Squared Analysis and Multivariate Predictive Modeling. Results were controlled for the following variables: patient demographics, comorbidities, symptomology, pain medication usage, operative time, number of operative levels, level type, graft type, blood loss and length of stay.

Results

There was a total of 236 patients who underwent surgery from 2016 – 2020. The ages ranged from 24 years to 84 years with a mean age of 54.3 years and 55% male patients. There were 6 patients over the age of 80 years (Table 1). Most patients presented with radiculopathy (72%) compared to myelopathy (28%); 49% of the patients had a history of a former or current smoker. Payor distribution was as follows: Commercial (53%), Worker's Compensation (16%), No Fault (8%), Medicare (22%), and Medicaid (1%).

Patients either underwent a one-level (45.3%), two-level (47.8%), or three-level fusion (6.8%) for a total of 384 levels (Table 2). In terms of complications: three (1.2%) patients required a revision within thirty-days for wound hematoma; 11 (4.7%) patients had a prior fusion that needed re-exploration for possible pseudoarthrosis, and 13 (5.5%) developed adjacent segment disease due to a prior fusion.

Table 1: Patient Demographics

Total Patients	**236**
Age Range (mean)	24 – 84 (54.3 years)
20 – 29 years	3
30 – 39 years	16
40 – 49 years	55
50 – 59 years	77
60 – 69 years	59
70 – 79 years	19
> 80 years	6
Male/Female	129/107
Radiculopathy/Myelopathy	169/67
Smoker, Current or Former	115 (49%)
Insurance Providers	
Medicaid	3
Medicare	51
No Fault	20
Worker's Compensation	38
Commercial	124

Table 2: Surgical Demographics

Number of Levels	
One	106 (45.3%)
Two	112 (47.8%)
Three	18 (6.8%)
Total Levels	384
Revisions (< 90 days)	3 (1.2%)
Re-Exploration, Prior Fusion	11 (4.7%)
Adjacent Segment Disease	13 (5.5%)

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All patients followed up for their first post-operative visit, whereas only 145 patients made it to the one-year visit (Table 3). Outcome was tracked using Odom's Criteria at each time point through an electronic form sent to the patient at each visit. In addition, patients were followed for fusion status, short-term (< 30 days), and long-term (> 90 days) complications. Outcome scores for patients at 2 weeks, 1 month, 3 months and 1 year with an outcome of Excellent to Good were 68%, 74%, 78% and 89% respectively. The number of patients on pain medications at those same time points was 37%, 34%, 31% and 24%. Short-term complications (< 30 days) included wound hematoma (n = 3), and new neurologic deficit requiring re-exploration (n = 1); long-term complications included hardware failure or pseudoarthrosis (n = 5), with overall complication rate of 3.8%. Fusion rates at 1 month, 3 months, and 1 year were 33%, 69% and 92%. There was a total of 13 patients who developed adjacent segment disease requiring additional surgery or 5.5%.

Predictive Modeling

Predictive modeling was used to correlate data with outcome at specific time points including 2 weeks, one month, three months, and one year. Based on patient demographics, the following factors were found to be significant in outcome: (1) myelopathy (2) history of pre-operative narcotics (> 90 days), (3) pre-operative motor deficit, (4) payor of worker's compensation, (5) multilevel surgery, and (6) depression or anxiety. We outline the factors with significant contributions to unfavorable outcome based on an Odom's Criteria of fair to poor at the specific time points of follow up (Table 4).

Table 3: Postoperative Outcome.

	Two Weeks	One Month	Three Months	One Year
No. Patients (n)	236	201	170	145
OC Score				
Excellent	81	76	66	61
Good	80	73	67	68
Fair	53	40	29	12
Poor	22	12	8	4
On Pain Meds				
n (%)	88 (37)	69 (34)	51 (30)	35 (24)
Fusion	N/A	33%	69%	92%
Complications				
Wound Hematoma	3	-	-	-
Pseudoarthrosis	-	3	1	-
Hardware Failure	-	1	-	-
New Arm Weakness	-	-	1	-

Table 4: Clinical Outcome by Predictive Modeling at Post-Operative Time Points

Factor	2 Weeks	1 month	3 Months	12 Months
Myelopathy	OR 2.01 CI 1.06 – 4.11 p = 0.033	-	-	-
Pre-op Narcotics	OR 3.04 CI 1.57 – 5.90 p = 0.001	-	OR 1.81 CI 1.02 – 3.02 p = 0.002	-
Revision ACDF	-	-	-	-
Pre-Operative Motor Deficit	OR 1.93 CI 1.04 – 3.58 p = 0.036	-	-	OR 2.86 1.28 – 6.32 p = 0.51
Payor = WC/NF	-	OR 2.10 CI 1.22 – 3.62 p = 0.008	OR 2.24 CI 1.33 – 3.78 p = 0.002	OR 3.87 1.99 – 7.53 p = 0.001
Multilevel	-	-	OR 1.75 1.01 – 1.03 p = 0.47	-
Anxiety /Depression History	-	-		OR 2.26 1.02 – 4.95 p = 0.042

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- **Post-operative Visit One (Two Weeks):** A total of 75 patients (32%) had an unfavorable clinical outcome. Factors discovered via multivariate analyses to be significantly correlated were symptoms of myelopathy, pre-operative narcotics and motor deficit (Table 4). As per the 0.1 alpha level criteria, these patient factors were included in the binary logistic regression model and controlled for as covariates. The binary logistic regression model was statistically significant ($p < 0.001$) and was a good fit for the data (non-significant Hosmer-Lemeshow p-value of 0.378).
- **Post-operative Visit Two (One Month):** A total of 52 patients (22%) had an unfavorable clinical outcome. Factors discovered via multivariate analyses to be significantly correlated with an unfavorable clinical outcome were only payor of worker's compensation. The binary logistic regression model was statistically significant ($p<0.001$) and was a good fit for the data (non-significant Hosmer-Lemeshow p-value of 0.733).
- **Post-operative Visit Three (Three Months):** A total of 27 patients (11%) had an unfavorable outcome. Factors discovered via multivariate analyses to be significantly correlated with an unfavorable clinical outcome were pre-operative narcotics, payor of worker's compensation, and multilevel fusion. As per the 0.1 alpha level criteria, these factors were included in the binary logistic regression model and controlled for as covariates. The binary logistic regression model was statistically significant ($p<0.001$) and was a good fit for the data (non-significant Hosmer-Lemeshow p-value of 0.65).
- **Post-operative Visit Four (One Year):** A total of 16 patients (6%) had an unfavorable clinical outcome. Factors discovered via multivariate analyses to be significantly correlated with an unfavorable clinical outcome were pre-operative motor deficit, payor of worker's compensation, and a history of depression or anxiety. As per the 0.1 alpha level criteria, these factors were included in the binary logistic regression model and controlled for as covariates. The binary logistic regression model was statistically significant ($p<0.001$) and was a good fit for the data (non-significant Hosmer-Lemeshow value of 0.401). The predictive accuracy of the model was 70.6%, a 7% improvement from the null model.

Discussion

The purpose of this study was to highlight the efficacy of single device through the technique of a single surgeon. Compared to other studies, our results were similar [1,5,6]. Stand-alone devices were developed to simplify the procedure, reduce overall operative time, and diminish the irritation of the esophagus in the treatment of cervical degenerative disc disease. Duan et al. [3] performed a meta-analysis of eleven studies to systematically compare the safety and effectiveness of an ACDF with a zero-profile device to a plate and cage for the treatment of cervical degenerative disc disease. They showed that zero-profile devices were associated with lower operation time in two-level procedures, less blood loss, higher subsidence rate, and lower incidence of dysphagia in short-term and long-term.

Robertson et al. [5] published one of the largest single-surgeon series on ACDF with 2,579 such procedures performed between 1998 and 2017. The overall complication rate was 7.0% including dysphagia (1.9%), graft/hardware failures (1.3%), and postoperative hematomas (0.9%). Karamian et al. [6] studied the outcome effects in ACDF based on duration of the procedure and patient reported outcomes after surgery. All groups improved after ACDF regardless of surgical duration and this was not a predictor of differing improvement in physical function or disability. McClelland et al [1] reviewed seven studies encompassing a 21-year timespan with Level 3 evidence totaling 2,448 outpatient ACDF patients. The overall complication rate was 1.8%; only 2% of patients required readmission. McGirt et al. [2] evaluated 2000 patients who underwent 1 to 3 level ACDF in a single ASC from 2006 to 2018 in a retrospective analysis to show that the procedure was safe in the outpatient setting.

Out study showed the safety and efficacy of the same device using the same surgical technique. The complication rate, adjacent segment disease rate and fusion rates were all acceptable. The predictive modeling analysis confirmed that in the short term, poor outcome is correlated with patients who have poor pain tolerance because of narcotic history or those with myelopathy. Over time as follow up visits progressed, patients who presented with worker's compensation insurance, narcotics history and emotional lability prevailed with fair to poor outcome. As patient cohorts become larger with more detailed data sets, predictive models can become more accurate to assess which patients may need inpatient versus outpatient surgical settings for care.

Conclusions

This is one of the larger single-surgeon study using the ZimVie LDR-C ROI stand-alone fusion device for the treatment of cervical disc disease. Our study supports acceptable outcome and patient satisfaction when using this device.

Declarations

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