

Early Morbidity of Multilevel Anterior Cervical Discectomy and Fusion with Plating for Spondylosis: Does the Number of Levels Influence Early Complications? A Single Surgeon's Experience in 519 Consecutive Patients

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Abstract

Final class of evidence - treatment Yes

Study design

RCT

Cohort •

Case control

Case series

Methods

Concealed allocation (RCT)

Intention to treat (RCT)

Blinded/independent evaluation of primary outcome •

F/U ≥85%

Adequate sample size •

Control for confounding

Overall class of evidence III

Keywords

- ▶ ACDFP
- ▶ cervical spine
- ▶ morbidity

Study Design This is a retrospective review of a prospectively maintained database of anterior cervical discectomy and fusion with plating (ACDFP) cases.

Objective The aim of this study is to evaluate within a clinical practice evidence-based results of short-term morbidity with multilevel ACDFP.

Methods Clinical morbidity, length of hospital stay, visual analog scale (VAS) and Odom scores, Neck Disability Index (NDI), hardware failure, and return-to-work (RTW) status were prospectively collected in an electronic database for 678 patients who underwent 1-, 2-, 3-, or 4-level ACDFP during an 8-year period. A total of 519 patients met the study criteria and were retrospectively analyzed.

Results The majority of all patients noted “Excellent” or “Good” status for 1 month (91%), 2 months (92%), and 3 months (96%). Patients with 1-, 2-, and 3-level ACDFP returned to work sooner, 60% at 1 month, 70% at 2 months, and 68% at 3 months. For 4-level patients, the majority did not RTW until 3 months (71%). The only significant increase in morbidity with increasing levels was hospital stay for 3- and 4-level ACDFP and RTW for 4-level ACDFP.

Conclusion Multilevel ACDFP can be performed with low initial morbidity. An individual practice can review results to allow for ongoing evidence-based care.

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Study Rationale and Context

There are theoretical advantages to approaching multilevel diseased cervical segments anteriorly with a single ACDFP rather than performing anterior-posterior or multiple setting surgeries. However, no large or homogeneous studies exist to support or refute whether multilevel anterior cervical discectomy and fusion with plating (ACDFP) carries an unacceptably greater initial morbidity.

Objective

Early morbidity as measured by perioperative complications, hospital stay, pain assessments, hardware failure, and RTW status was evaluated for 1-, 2-, 3-, and 4-level ACDFP during the first 3 months after surgery.

Methods

Study Design: Retrospective case series.

Inclusion Criteria: Patients who underwent 1-, 2-, 3-, or 4-level ACDFP by one surgeon at a single university-affiliated hospital using the modified Smith-Robinson¹ technique. Patients reflected the specific population seen by the senior author (D.E.B.); these were elective procedures done in relatively healthy individuals (see online supplementary material).

Exclusion Criteria: Patients were excluded for traumatic injuries, revision surgery, or if the patients had certain comorbidities that were known to increase the surgical morbidity: chronic steroid use, chronic dialysis, rheumatoid arthritis, and so on. For the subjective follow-up and return-to-work (RTW) portion of the study, workers' compensation and litigation patients were excluded.

Patient Population: A total of 678 patients underwent ACDFP between May 2001 and December 2009. Of these, 519 met study criteria and were retrospectively reviewed for the initial 3-month postoperative period (► Fig. 1).

Intervention:

- Discectomy was always performed utilizing the surgical microscope from the patient's right side.

- Standard constructs were employed: structural allografts or cages filled with biologic material with anterior plating. Esophageal catheters were not allowed during surgery and the endotracheal cuff was routinely deflated for 90 seconds at the time of the initial placement of the retractors.
- Patients were generally admitted for 23-hour observation and were given 10 mg dexamethasone and an antibiotic, generally 1 g of Ancef (GlaxoSmithKline, Research Triangle Park, NC, USA), prior to induction and two additional times over the next 18 hours.
- All patients wore hard collars while riding in cars; they were weaned from their collars at 2 weeks.

Outcomes:

- Length of hospital stay and rate of complications were recorded and evaluated.
- At 1-, 2-, and 3-month follow-ups, patients had detailed clinical examinations and were assessed using the Odom scale; lateral X-rays in flexion, neutral, and extension; VAS scores for neck, hand, arm, and shoulder; Neck Disability Index (NDI); and RTW status.
- The radiographs were reviewed by the senior author, three clinicians, a radiologist, and by a second independent neuroradiologist if needed for hardware failure or structural problems.

Analysis: Statistical analysis was conducted by Synthes Research and by a second independently contracted statistician, using a generalized version of Fisher exact test for an $R \times C$ contingency table to generate the *p* values.

Results

- **Patient Characteristics:** Mean age for patients was as follows: 45, 49, 52, and 53 years for 1-, 2-, 3-, and 4-level ACDFP, respectively. For gender, 45% were male (► Table 1).
- **Complications:** The most common complication across all four ACDFP levels was swallowing/speech dysfunction ($n = 10$), followed by uncontrolled pain ($n = 3$), then hematoma and reoperation ($n = 2$). There were no

Table 1 Patient characteristics

| | No. (%) | |
|------------------------------------|------------------------------|------------------------------|
| | 1 and 2 levels ($n = 251$) | 3 and 4 levels ($n = 268$) |
| Demographics ($N = 519$ patients) | | |
| Male | 100 (39.8) | 133 (49.6) |
| Mean age (range) | 48.2 (16–78) | 52.6 (31–75) |
| Type of comorbidity | | |
| Smoking | 33 (13.1) | 50 (18.7) |
| Hypertension | 31 (12.4) | 68 (25.4) |
| Obese | 24 (9.6) | 26 (9.7) |
| IDDM | 4 (1.6) | 6 (2.2) |
| NIDDM | 10 (4.0) | 12 (4.5) |

Abbreviations: IDDM, insulin-dependent diabetes mellitus; NIDDM, non-insulin-dependent diabetes mellitus.

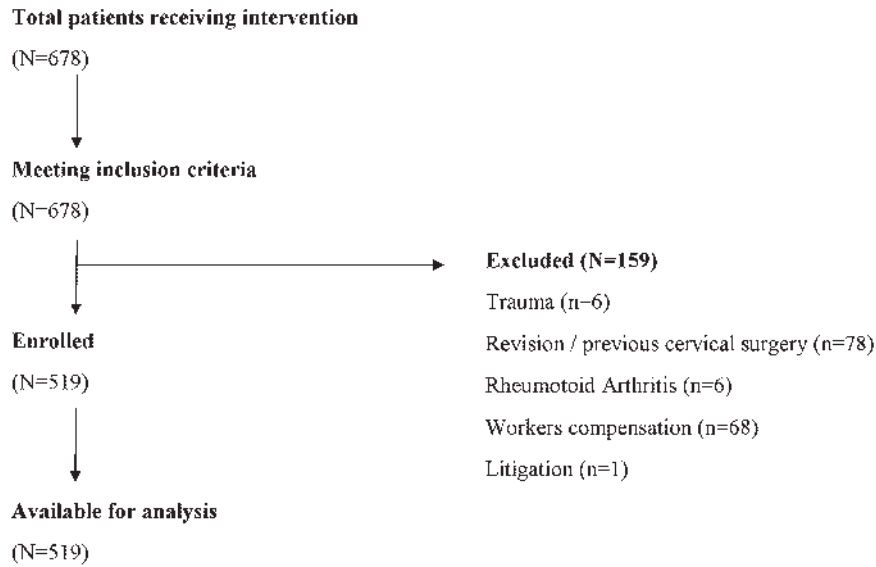


Fig. 1 Patient sampling and selection.

reported infections, hospital readmissions, or instances of hardware failure.

- **Hospital Stay:** Patients who underwent 3- or 4-level ACDFP had a significant difference in length of stay ($p < 0.0001$ for both levels), but this generally represented one additional night for 3-level ACDFP and one or two nights for 4-level ACDFP.
- **Odoms, VAS, NDI:** There was no statistically significant clinical difference among the results with relationship to number of levels surgically treated (► **Fig. 2**).

- **Return to Work:** There was no statistical difference between 1-, 2-, and 3-levels for 1, 2, and 3 months. The 4-level patients had a significant difference from 1- and 2-levels at all time points ($p = 0.0029$ for 1 month, $p = 0.003$ for 2 months, and $p = 0.015$ for 3 months).

Discussion

- One of the criticisms of multilevel ACDFP is that there is a significant increase in perioperative morbidity. However,

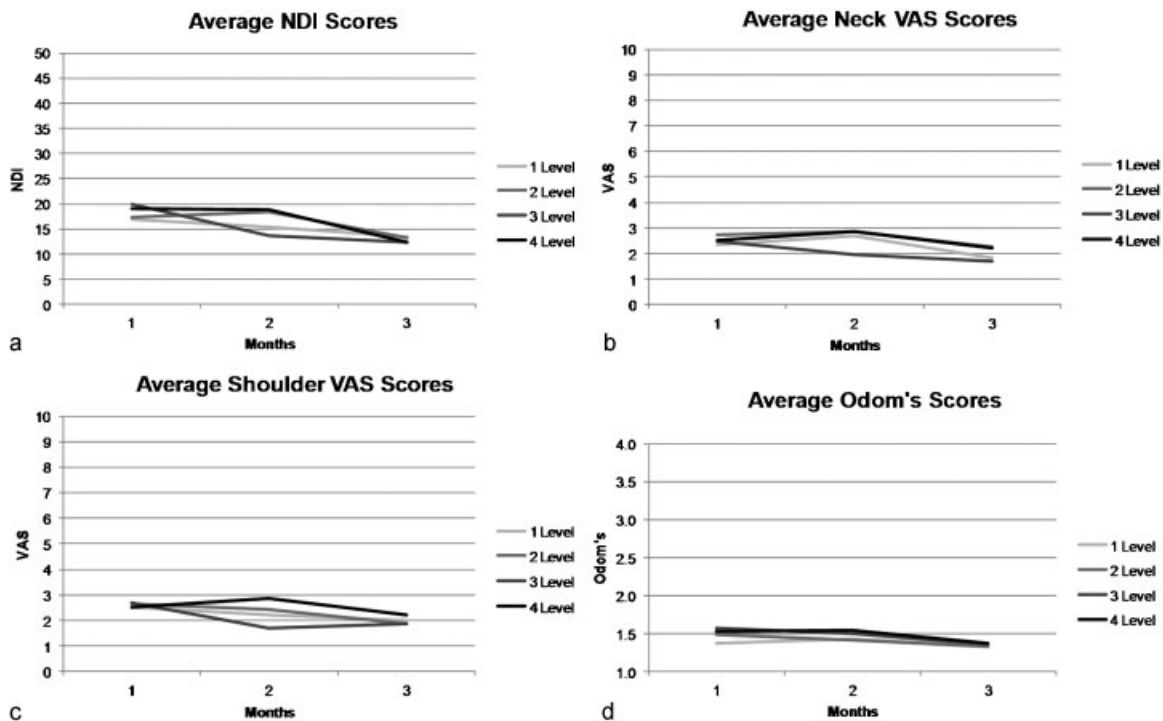


Fig. 2 Line graphs showing similar trends in Neck Disability Index (NDI) (a, b), visual analog scale (VAS) scores (c), and Odom scores (d). Odom scores are rated as 1 for Excellent, 2 for Good, 3 for Fair, and 4 for Poor.

the reports in the general literature are highly variable.²⁻⁹ A recent article used a meta-analysis of published literature for the surgical treatment of cervical disease during the period from 1990 to 2005. Unfortunately, the limitations of the study prevented the application of their findings to general practice of multilevel disease because of the relatively small size of the studies reviewed and the heterogeneity of the techniques employed.^{10,11}

- To address these issues, we have prospectively collected and retrospectively evaluated clinical data and utilized a consistent surgical approach in a large number of patients. To our knowledge, our patient database is the largest group reported on in the literature.
- We recognize that this is a selected patient population and that these results cannot be applied to trauma or other high-risk populations.
- Our study shows that multilevel ACDFP can be performed with minimal initial morbidity in a group of generally healthy patients. We also believe that this study shows that an individual's clinical practice can be driven by careful data collection.

Summary and Conclusion

Our results show that multilevel ACDFP can be done without significantly higher morbidity rates and that a practice can evaluate its results to adjust treatment recommendations accordingly. We saw transient increases in dysfunction in 3- and 4-level ACDFP, but none of the increases were statistically significant other than for hospital stay for 3- and 4-level ACDFP and RTW for 4-level ACDFP.

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The authors received grant support from the Synthes Research Foundation for the development and maintenance of the database used in this study.

Editorial Perspective

The field of medicine is changing rapidly with an increased emphasis on the paradigm "to do more with less." As certain surgical procedures are becoming more commodity oriented, health-care transaction timelines for clinical studies are rapidly becoming standardized due to more consistent regulatory definitions. The 90-day window is commonly used to assess perioperative complications, healing, and reoperations; early functional recovery is assessed by 24 months, and long-term quality of life and health utilization studies (efficiencies) are determined by 5 years and more.

The present study by Bullard et al was accepted by *EBSJ* due to its unusually large number of cases included and its consistent techniques employed (all surgeries performed by

Previous Presentations of Paper

A portion of this work was presented as an electronic poster at the 2010 American Association of Neurological Surgeons meeting in Philadelphia, PA, and as an invited talk at the North Carolina Spine Society meeting in Charlotte, North Carolina, August 27 to 28, 2010.

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a single surgeon using a uniform technique). The stated goal of this study was to assess complications in the short, 90-day postoperative term using a more patient-friendly, single approach anterior procedure and comparing multilevel to one- or two-level procedures. The 90-day review period has a strong relevance as it is increasingly used as a hallmark for assessment of surgically related complications. Our *EBSJ* reviewers found a number of issues that could not be addressed in the present study, but by discussion could help future study designs.

Dysphagia: Aside from bone healing, multilevel anterior procedures are notoriously afflicted by some degree of dysphagia, with number of levels and higher levels being more prominently affected, in addition to a number of other

potential variables (such as age of patient, gender, retraction technique, implants used, etc.). Since dysphagia is such an important aspect of care related to anterior neck surgery, the reviewers suggested using a more dedicated swallowing assessment for the determination of the presence or absence of swallowing dysfunction. Perhaps the scoring system suggested by Bazaz, Lee, and Yoo can serve as an industry standard to formalize ratings and increase awareness.¹

Regarding length of stay, the reviewers suggested more precise calculations of timelines and reporting of causes of delay in discharge. As to complications, the reviewers felt that some important comorbidities were potentially overlooked. This includes body mass index, sleep apnea, COPD, preoperative opioid use, osteoporosis, use of steroids, and chronic anti-inflammatories. These are significant variables (along with preoperative stability and deformity), which may affect complication rates and healing. While smoking and diabetes were addressed in this study, other factors listed may significantly contribute to perioperative risks. In general, it is advisable that for many reasons, we as spine surgeons place greater emphasis on comorbidities and document these in a systematic fashion. This will allow for better risk stratification of our study results reporting.

Finally, all reviewers strongly expressed their hopes that this study is just the precursor for a more formal 2-year follow-up study. From such a study with such a sizeable cohort, determination of revision rates due to nonunion, adjacent segment pathology, and other reinterventions (speech, swallowing) would be possible. Outcome-related questions that need to be answered then include functional outcomes. How many improved at final postop visit? Did any of the patients meet the MCID (minimum improvement)/SCB (substantial benefit) criteria? How many failed to meet these criteria as stratified by level? How many patients got worse in terms of functional outcomes?

This present study is an excellent start with a very large and homogeneous appearing study population. *EBSJ* encourages its authors to continue their data collection and present their 2-year follow-up study.

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