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Patient Outcomes for Anterior Multi-level Cervical Fusions: A Comparative Analysis of AO and DOC Instrumentation

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Running Head: Patient Outcomes with Instrumented ACDFs

ABSTRACT

The purpose of this study is to compare the efficacy of the DePuy-Acromed DOC implant with the Synthes AO plate by means of analysis of subjective and objective data.

A retrospective review of 56 consecutive instrumented, anterior multi-level cervical fusions by two orthopedic spine specialists was completed. Biographical, clinical, surgical and radiographic data was collected for patients who underwent anterior multi-level cervical fusions between 12/13/96 and 4/8/99. Twenty-five of the patients received a DOC implant and 31 received the AO plate.

No major complications occurred during or following surgery directly related to either implant. Both groups however, did contain cases of transient dysphasia and lingering pain. Generally, patients that received the DOC implant experienced a greater percent decrease in post-operative pain levels though both study groups exhibited significant improvement. The use of a DOC implant was also correlated with a loss of fewer working days amongst those in the study group. Psuedoarthrosis and a return to pre-operative pain levels occurred in patients using the AO implant at higher frequencies than in those with the DOC. Screw loosening occurred less frequently with the AO plate than with the DOC implant. However, the one case of AO screw loosening required subsequent hardware removal.

The DOC also appears to have the added benefit of offering a dynamic system that can reduce the amount of load shielding of the bone graft during the time that it is fusing.

It appears that the newer DOC implant offers desirable benefits over the traditional AO locking plate. The dysphasia and cost were liabilities that seem to be offset by the patient satisfaction level with surgeries involving the DOC implant.

INTRODUCTION

Over the last 40 years, anterior cervical decompression and fusion has become a popular method for the treatment of cervical spin disorders and pathologies such as pain, radiculopathy, and myelopathy[1,2,4,10,12]. The interbody fusion is performed in order to maintain spinal stability after compression of the spinal cord or nerve roots is relieved. Anterior multi-level fusions are more recently being supplemented with instrumentation in order to prevent graft extrusion, facilitate load sharing and to add stabilization during the healing phase[3,5-8]. It has been reported that anterior cervical discectomies that include a method of fixation result in a higher fusion rate and decreased rate of pseudoarthrosis in comparison to non-instrumented cases[3,8,9,11].

Some biomechanical studies have reported an increased stiffness in the segments that contain interbody bone grafts with plates[19,20]. This stiffness in the implant supports a greater proportion of the axial load and this action interferes with bone regrowth at the graft site[14,16]. It is the axial load which helps stimulate bone growth. Other studies report that the graft is not shielded from load but shares in the load bearing with the plate[13]. This would appear to suggest that the graft is still experiencing sufficient enough load to stimulate bone growth.

In the past 15 years, the number of instrumentation types used in conjunction with cervical decompression and fusion has increased[12]. A literature search reveals several studies discussing non-instrumented fusion, extolling the virtues of a single plate, or comparing non-instrumented fusion with instrumented fusion[6,8,11,12,15,17,18,20]. However, there are relatively few articles dealing with the direct comparison of one anterior plating system to another.

This study compares the relative benefits and complications of two cervical plating systems---the newer DePuy-Acromed DOC segmental plating system which has a dynamic load-sharing system and the traditional Synthes' AO locking plate. Outcomes data are both objective

and subjective, involving the manufacturers, the physicians, patient files, and patient feedback. Through the use of pre- and post-operative clinical, diagnostic, and surgical data, as well as through patient questionnaires and telephone interviews, the success or failure of the patient's surgery and their overall satisfaction are assessed. The completed data set is used to compare the efficacy of one system to another.

It is believed that the DOC instrumentation will offer a greater decrease in pain, faster healing times and a decrease in recurrent spinal problems. Because of it's high profile, more cases of dysphasia might be expected.

MATERIALS AND METHODS

A retrospective review of 56 patients who underwent anterior cervical discectomy and fusion with instrumentation, between December 1996 and April 1999, was performed. All surgeries were performed by two orthopedic spine surgeons in one practice. Potential subjects were eliminated from the study group if posterior instrumentation was used in conjunction with the anterior plate. All approaches were anterior approaches except for one upper level cervical fusion which required a retropharyngeal approach.

The average follow-up was 16.5 months (range 6.0 to 32.3 months). The average patient age was 52.2 years (range 29 to 85 years). Gender distribution was 52% female and 48% male. Of the twenty-five patients receiving the DOC instrumentation, 44% were female. Fifty-seven percent of the thirty-one patients in the AO group were female. Demographic data is summarized in Table 1.

Of the levels fused (range C3-T1), the number of levels ranged from 2 to 4 (mean 2.21). Ten patients attempted fusion at 3 levels, one over 4 levels and the remaining forty-four were attempted cervical fusions over 2 levels. The most common fusion was two levels from C5-C7.

Patients were sent a packet with a letter requesting their cooperation in maintaining a high level of surgeon/patient communication regarding the success and effectiveness of the spinal surgery performed. Included with the letter were the visual analogue scale (VAS), and the Oswestry Low Back Pain and Disability Questionnaire (OSW) to be completed by the patient. The OSW is designed to assess the effects of *lower back* pain on the patient's lifestyle. However, it is believed that the OSW is also valid when assessing a patient who has undergone a cervical

surgery when it is used as a subjective tool to measure the functional disability in activities of daily living as perceived by the patient him/herself.

Biographical data such as age, sex, date of birth, address, and social security numbers were gathered for use in patient contact. Surgical data including operative time, estimated blood loss, graft type, hospital stay length, and total hospital charges were obtained from the providing hospitals. Other data fields including the patient's smoking status (23%), whether worker's compensation (20%) or litigation (5%) were involved with the surgery, and how much time the patient missed from work after the surgery were gathered from the patients themselves via personal contact. See Table 1.

Potential subjects were also eliminated from the study if they could not be contacted or chose not to respond after a prolonged period of time had been allowed for response.[*1]

A random sample of 10 AO patients' post-operative x-rays were examined for fusion and 10 DOC patients received CT scans with sagittal/coronal reconstruction 9 months ($\pm$ 2 mo.) after their surgery so as to ascertain the percentage of subjects who attained fusion before a nine-month recovery period had transpired.

Pre- and post-operative VAS and OSW data were analyzed using a paired t-test in order assess the level of improvement and to reveal any significant changes following surgery. Additionally, the surgical data and percentage change in the VAS and OSW scores were compared for the AO versus DOC groups using ANOVA to determine if any significant differences existed.[*2]

[*1] This elimination may lend itself to a non-response bias in the results. However, because the remaining pool is quite large and homogenous, the study was conducted on the remaining members. No attempt was made by this researcher to calculate in any non-response percentage factors.

[*2] This data was analyzed by and independent statistician for statistical relevance of trends and comparisons in the necessary fields

RESULTS

No patient suffered any complications during surgery such as recurrent or superior laryngeal nerve and vertebral artery injuries. Both study groups experienced similar levels of persistent pain and transient dysphasia.

After surgery, the patients in the AO study group experienced a significant percent decrease in pain perception, as measured by the VAS, of –46.6%. Their perception of how this pain affected their lives, as measured by the OSW, decreased –37.9%. The patients in the DOC also measured a significant decrease in their pain level and it's effect on their lives, -57.2% and -44.4%, respectively. These scores are also noted in Table 1.

The 80% patients who received the AO implant and were employed before the surgery lost an average time from work of 212 days after the surgery. The comparable group of DOC patients lost an average of 116 days from the jobs they were employed at prior to surgery.

No patients within the DOC group suffered from psuedoarthrosis during the follow-up period of the study. Two cases of pseudoarthrosis were reported among the AO study group. At the time of radiographic analysis, both groups had achieved 100% fusion within a random sample.

Screw loosening was a problem for both implants. The DOC instrumentation suffered from screw loosening more often (2 instances) than the AO implant (1 instance). However, the only case needing a revision surgery was amongst the AO group. Dysphasia was a reported problem in 16% and 10% of the DOC and AO cases, respectively.

The hospital stay length for AO study patients was 2.0 (Range 1-3) days. The average hospital stay length for those patients receiving the DOC implant was 2.3 (Range 1-7) days.

The average cost for surgeries requiring the AO or DOC plate, regardless of number or location of fused levels was $10,252.40 and $14,936.65, respectively.

DISCUSSION

Though the AO patients reported a significant decrease ($p<0.01$) in levels of pain interference in their normal lifestyles, their reported interference before surgery was much higher than the comparable score for DOC patients. However, the indications of the VAS scoring show a greater percent decrease in the patients' perceived pain after surgeries involving the DOC instrumentation although the patients' percieved pain levels were similar before entering surgery regardless of which group they were included in.

It would appear that the DOC ranks higher than the traditional AO plate in overall patient satisfaction levels. Both plates offer significant improvement in pain and functional capacity; but, the differences in the DOC and AO group test score's percentage decreases were not ruled to be significant.

A large factor in determining an instrumentation's efficacy for a patient would be its ability to allow the patient to return to work after undergoing surgery. The average DOC patient's turnover rate was almost 2 times faster than the average AO patient's.

When comparing the average hospital stay lengths, blood loss, and operative time, no significance was noted between the two groups.

The DOC provides a dynamic implant system which allows load sharing between the instrumentation and the bone graft. The design inherently allows for necessary controlled settling during the healing process (fusion). This fact alone would give the DOC an edge over any static competitor.

The success of the DOC does not come without it's drawbacks however. Though the rates of transitory dysphasia were similar in both study groups, (DOC 13%, AO 10%), one DOC patient reported persistent problems with dysphasia up to four months after the surgery was

performed. Though the DOC plate carries the risk of dysphasia due to its larger profile, this can be limited by ensuring that the plate is seated directly over the midline of the vertebral bodies.

The DOC implant also seems susceptible to more hardware "failure" such as screw loosening. This effect may be due more to surgical technique than inherent hardware problems. As screw loosening with the DOC implant was never accompanied with adverse effects and a similar failure in the AO plate was, one could consider the DOC plate superior in this respect, also.

The cost of the DOC procedure was considerably more than the similar AO procedure. With the average cost of fusion involving the DOC instrumentation being 46% more than the analogous AO procedure, the cost of the DOC procedure may be a valid concern for some patients.

CONCLUSION

With similar post-surgical effects witnessed in both study groups, this study has shown that the DOC system does provide a safe and effective alternative to the traditional AO plate when attempting to achieve anterior cervical fusion. It is believed that the dynamic nature of the DOC system is an attribute that has proven beneficial by allowing a greater percentage of the axial load to be shared between the graft and the instrumentation. This quality stimulates fusion while continuing to maintain a sufficiently stable environment for fusion to occur.

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Table 1. Demographic and outcomes data.

Variable	AO Plate	DOC Plate
Number	31	25
Male/Female	13 / 18	14 / 11
Age	49.5 (range, 29-85)	55.8 (range, 35-73)
Smokers	10 (32.3%)	3 (12.0%)
Litigation Pending	2 (6.5%)	1 (4.0%)
Worker' Compensation	7 (22.6%)	4 (16.0%)
Blood Loss (ml)	90.0 (range, 20-200)	113.2 (range, 25-750)
Operative Time (min)	120.3 (range, 61-220)	110.7 (range, 80-181)
Hospital Stay (days)	2.0 (range, 1-3)	2.3 (range, 1-7)
% Change in VAS	-46.6%	-57.2%
% Change in OSW	-37.9%	-44.4%
Average work time lost (days)	212	116

SOUTHERN SCHOLARS SENIOR PROJECT

Name: Joe Peterson Date: 8·31·99 Major: Biology

SENIOR PROJECT

A significant scholarly project, involving research, writing, or special performance, appropriate to the major in question, is ordinarily completed the senior year. The project is expected to be of sufficiently high quality to warrant a grade of A and to justify public presentation.

Under the guidance of a faculty advisor, the Senior Project should be an original work, should use primary sources when applicable, should have a table of contents and works cited page, should give convincing evidence to support a strong thesis, and should use the methods and writing style appropriate to the discipline.

The completed project, to be turned in in duplicate, must be approved by the Honors Committee in consultation with the student's supervising professor three weeks prior to graduation. Please include the advisor's name on the title page. The 2-3 hours of credit for this project is done as directed study or in a research class.

Keeping in mind the above senior project description, please describe in as much detail as you can the project you will undertake. You may attach a separate sheet if you wish:

I will be completing a primary research project. The subject matter concerns anterior multilevel cervical diskectomies and fusions. Specifically, patient outcome surveys will be completed and patient files will be reviewed. Radiographic data also. The objective and subjective data will be analyzed for success of surgery using two different stabilization systems (plates)— The DePuy-Acromed Doc locking system and the Synthes AO plate. Some fields of comparison are surgical cost, patient satisfaction, complication & fusion rates, and work missed.

Signature of faculty advisor Linda Ann Foster Expected date of completion 12·99

Approval to be signed by faculty advisor when completed:

This project has been completed as planned: yes af

This in an "A" project: yes af

This project is worth 2-3 hours of credit: yes af

Advisor's Final Signature Linda Ann Foster

Chair, Honors Committee _____ Date Approved: _____

Dear Advisor, please write your final evaluation on the project on the reverse side of this page. Comment on the characteristics that make this "A" quality work.