Choice of plate may affect outcomes for single versus multilevel ACDF: results of a prospective randomized single-blind trial

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Abstract

BACKGROUND CONTEXT: Conflicting views exist according to the individual philosophy about various plate designs that can be used in anterior cervical discectomy and fusion (ACDF) to achieve clinical and radiological improvement within shortest time period. No prospective randomized study has ever been conducted to clarify the relationship between clinical outcomes, fusion rates, and the choice of plate (static vs. dynamic design).

PURPOSE: To compare the clinical and radiological outcomes of patients treated with one-level or multiple levels ACDF using cervical plates of dynamic (slotted-holes) versus static (fixed-holes) design.

STUDY DESIGN: Single masked, prospective, randomized study.

PATIENT SAMPLE: Over a 4-year period, 66 patients (M:F=37:29) had ACDF using either dynamic (n=33) or static (n=33) plates for intractable radiculopathy as the result of degenerative cervical spine disease. Overall, 28 patients had single-level fusion and 38 had two or three levels fused.

OUTCOME MEASURES: Visual Analogue Pain scores (VASs), Neck Disability Index (NDI), and radiological criteria of established fusion.

METHODS: The qualifying subjects were randomized to receive ACDF using either fixed-holes (static) or the slotted-holes (dynamic) anterior cervical plates. Clinical and radiographic data were collected and analyzed. Paired-sample t test was used to correlate clinical and radiological outcomes and General Linear Model Analysis of Variance (GLM ANOVA) with repeated measures was used to detect outcome differences between the two groups for single and multiple fusions.

RESULTS: At a mean follow-up of 16 months (range, 12–24), 49 patients (73.7%) had clinical success and 56 (85%) showed radiological fusion. Although clinical success was a predictor of fusion (p=0.043), the reverse was not true (p=.61). In single-level fusion, no statistical difference of outcome was observed between the two groups but multilevel fusions with dynamic plate showed significantly lower VAS and NDI than those with static plates (p=.050).

CONCLUSIONS: Although clinical improvement is a good predictor of successful ACDF, radiological evidence of fusion alone is not reliable as a parameter of success. The design of plate does not affect the outcomes in single-level fusions but statistics indicate that multiple-level fusions may have better clinical outcome when a dynamic plate design is used.

Keywords: Cervical DDD; ACDF; Static and dynamic plates; Clinico-radiological outcomes

Introduction

Anterior cervical discectomy and fusion (ACDF) is a widely accepted and performed surgical procedure to manage radicular symptoms that result from degenerative disc disease (DDD) of the cervical spine. In the early 1980s, Caspar et al. popularized anterior cervical plating in collaboration with Aesculap [1]. The Caspar et al.’s plates were unrestricted backout plates. These constructs did not
have a fixed-moment arm and, furthermore, had limited fixation at the screw-plate interface. This facilitated greater exposure of the graft to compressive forces, allowing for a higher chance of fusion. The plate however required a bicortical screw purchase. The system of locking plates (Cervical Spine Locking Plate [CSLP], Synthes Spine Company, Westchester, PA) was introduced in United States in 1991 by Synthes. The Synthes CSLP did not require a bicortical purchase because a titanium expansion screw was used to affix the screw rigidly to the plate [2]. The next generation of anterior cervical plating systems was the dynamic plates that allowed motion of the construct. Dynamic plates have been classified into rotational plates, which allow rotation at the plate-screw interface, and translational plates, which allow axial translation and rotation [3]. Movement at the screw-plate interface was planned to avoid stress shielding so that, theoretically, fusion rates would increase and time to fusion would diminish. This concept follows the Wolff law, which suggests that loading alters bone integrity and bone healing, that is, bone heals more optimally when exposed to a compressive load.

Despite the existence of several anecdotal and single institution studies in the literature supporting different plate designs [4,5] opinions remain divided according to the individual philosophy of surgeons about the optimum choice of plates in various clinical settings. This question becomes even more complex when fusion involves multiple levels. No prospective randomized study has ever been conducted to clarify the relationship between clinical outcomes, fusion rates, and the choice of plate. This single-masked, prospective, randomized study was performed to compare the clinical and radiological outcomes of patients treated with one-level or multiple-level ACDF using cervical plates of dynamic (slotted-holes) versus static (fixed-holes) design.

Material and methods

Enrollment

The study was approved by the Institutional Review Board and conducted according to the guidelines of the Office of the Human Research Protection. All patients with symptoms of cervical radiculopathy who had failed conservative management were screened for participating in the trial. Although there are no set norms in the literature about the time of eligibility of cervical DDD patients for surgical procedure, we follow our own institutional policy of offering surgery only to the patients who satisfy certain clinical criteria. The patients satisfying the primary clinical criterion of persistent neck and/or upper extremity pain are initially referred for conservative management including pain medication and a physical therapy program requiring active patient participation for at least 4 to 6 weeks. The only exception to this rule is the patients who demonstrate progressive neurological deficit. All other patients report back at 4 weeks and those with no significant relief of symptoms without neurological deterioration are subjected to diagnostic electro-physiological electromyogram (EMG) studies and are offered the option of therapeutic selective nerve root block injections by pain-care specialists. Only those patients who failed the above-mentioned conservative management algorithm were offered surgical intervention and were screened for participation in the trial. The criteria for
inclusion into the trial were age 18 to 75 years; symptomatic disc disease at 1 to 3 levels of cervical spine between C3 and C7; radiographic evidence of compressed cervical nerve roots or spinal cord by ossified bony elements or herniated nucleus pulposus; radiculopathy symptoms concordant to the compressed nerve roots; and patients who were candidates for ACDF procedure. Patients with acute trauma, predominant severe myelopathy (muscle strength <3/5), marked cervical instability, radiographic evidence of severe facet disease, posterior augmentation or revision fusion, and previous surgery at the index level(s) were excluded from the trial.

Data

As per the above-described selection criteria, out of the 708 patients who presented to our clinic with symptoms of neck and/or upper extremity pain, 117 were determined as candidates for surgical intervention and screened to participate in the trial. Sixty-six patients qualified to participate in the trial and were randomly assigned to receive ACDF for DDD using either fixed-holes (static) or the slotted-holes (dynamic) anterior cervical plates. Randomization was performed with the use of a computer-generated block randomization list to ensure appropriate number of subjects in each group without a bias. The study was single masked by the fact that the patients were blinded to the type of plate.

The clinical data collected were Visual Analogue Pain scores (VASs) from the patient that were expressed in millimeters on a scale of 0 to 100 mm; Neck Disability Index (NDI) assessed as per the patient’s response; and quality-of-life data collected by SF-12 health survey. In addition, patients were subjected to a complete neurological examination by a qualified clinician. Radiological data included plain radiographs of cervical spine in four views (AP, lateral in neutral, flexion, and extension positions). Data at the baseline were collected at the time of enrollment.

Procedure

The randomized patients underwent ACDF at 1, 2, or 3 levels by a single surgeon (PDN) using the modified Smith Robinson Technique. Cortical bone allograft was used in all cases for fusion. The use of DBM or BMP was not permitted in the protocol. Anterior plating was done at the levels as per the protocol randomization. The plates used for the purpose were CTEK-plates (BioMet Spine, Inc., Parsippany, NJ). Sixty-six enrolled patients (M:F=37:29) had ACDF using either dynamic (n=33) or static (n=33) design. Twenty-eight patients had single-level fusion and 38 had two or three levels fused. Various demographic features of the enrolled patients are listed in Table 1. Out of the 38 patients with multiple-level disease, 23 were randomized to receive the dynamic plate, whereas 15 patients received the static plate. In patients with single-level disease (n=28), 10 had dynamic plates, whereas 18 received the static plates. The mean preoperative VAS was 60 mm (standard deviation [SD] 16.43) and the mean NDI was 44% (SD 13). Figure 1 shows histograms depicting the quartile distribution of patient population according to the initial VAS (top) and NDI (bottom) at the baseline. Only six patients (9%) demonstrated objective neurological deficits. Three had relevant motor weakness.

Table 1

<table>
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<tr>
<th>Characteristic</th>
<th>Range</th>
<th>Number (%)</th>
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<tr>
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<tr>
<td>Slotted</td>
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Fig. 1. (Top) Histograms depicting the quartile distribution of patient population according to the initial Visual Analogue Pain scores at the baseline. (Bottom) Histograms depicting the quartile distribution of patient population according to the initial Neck Disability Index at the baseline.
(power 4/5), one had diminished sensation at the relevant dermatome distribution, and two had hyporeflexia. All of these patients had multiple-level disease.

Follow-up

All patients were evaluated clinically and radiologically at 12 to 24 months follow-up (mean follow-up period 16 months). Clinical criteria of success were 20 mm or more reduction in the VAS without regular use of narcotics; more than 10% reduction in NDI scores from the baseline; and absence of new neurological deficit. The numeric parameters of success were decided based on the initial scores for the population as mentioned above. A reduction of 20 mm or more in the VAS translates to an average 30% reduction from the baseline level. Similarly, a 10-point or more reduction in the NDI from the baseline amounted to at least 25% change. These were considered to be minimally worthwhile relief from the symptoms. All three criteria had to be satisfied to mark the patient as clinical success. Radiological criteria for fusion were demonstration of bony bridges; absence of lucent lines; and <3 mm motion as measured in lateral view on flexion/extension. Demonstration of bony bridges or absence of lucent lines along with absence of motion was considered as “progressing fusion” (Fig. 2) and satisfaction of all three radiological criteria was classified as “complete fusion” (Fig. 3).

Statistics

All data management and statistical analysis were performed using SPSS version 15.0 (SPSS Inc., Chicago, IL). Single-group comparisons were performed to measure intrapatient variance and differences on all clinical and radiological parameters. Descriptive frequencies and percentages were tabulated. The factors affecting the outcome were adjusted and weighted for their effect or influence. Paired-sample ‘t’ test was used to correlate clinical and radiological outcomes and GLM ANOVA with repeated measures was used to detect outcome differences between the two groups for single and multiple fusions. Statistically, significant difference between comparative groups was considered at the 80% confidence interval (p<0.05).

Results

Clinical success

Table 2 shows the clinical parameters at the last follow-up for all patients as compared with the baseline inputs. The mean VAS and NDI were 29.8 mm (SD 29.5) and 22% (SD 20.8) at the last follow-up, respectively. The 50th percentile postoperative scores for VAS and NDI for the patients were 20 and 18, respectively. Figure 4 shows histograms depicting the quartile distribution of patient population according to the final VAS (top) and NDI (bottom) at the last follow-up. Paired-sample ‘t’ test showed a mean reduction of 59% in the VAS and 44% in the NDI at 12 to 24 months postprocedure (p<0.001). Overall, 49 patients (73.7%) met the criteria for clinical success. Eleven patients reported worse VASs as compared with the baseline. Out of these, six had concomitant worsening in the NDI, whereas the others reported a reduced NDI despite worsening pain scores. Similarly, out of the 14 patients who reported either no change or worsening NDI, 6 patients had worse VASs, whereas other 8 actually had improved VAS. Regardless of these facts, as previously stated, all 17 patients (27.7%) were labeled as clinical failures for the purpose of analysis. Five of these patients (29%) were claimants of worker’s compensation benefits, which was
comparable to the proportion of worker’s compensation benefits patients within the general patient population. All six patients with demonstrable neurological deficit showed complete recovery on clinical examination at 6-month visits. Four of these patients received slotted-hole plates, whereas two had fixed-hole plates. Because the proportion of these patients was very small, no statistical conclusions could be drawn based on the neurological recovery. Hence, this data was not included for further statistical analyses.

Radiological success

Radiologically, 57 patients (86%) showed either complete fusion (63.2%) or progressing fusion (22.8%). Nine patients had unsatisfactory result (pseudoarthrosis or screw breakage).

Clinico-radiological correlation

There was a subset of eight patients (14.2%) who demonstrated radiological success but were not clinical success. Within this subset, five (8.1%) showed established fusion and three (6.1%) showed probable fusion. Although clinical success was a predictor of fusion (p = .043), the reverse was not true (p = .61). Pearson’s test did not show both ways linear correlation between radiological and clinical success rates (p = .70).

Plate design versus success

In the overall population, the plate design (static vs. dynamic) did not significantly affect the reduction in VASs (p = .49) or NDI scores (p = .31). It is therefore a logical conclusion that the plate design does not have any effect on the clinical outcome of patients receiving ACDF when number of levels fused was not taken into consideration.

However, interesting trends are noted in the available results for the correlations between the type of plate and number of levels fused: 1) In single-level fusion, no statistical difference of outcome was observed between the two groups; and 2) Multilevel fusions with dynamic plate showed significantly better improvement than those with static plates (p = .050).

The graphical representation of the results of GLM multivariate ANOVA to study the effect of plate design on the outcomes based on the number of levels (single vs. multiple) fused is presented in Fig. 5 (top and bottom). When final VAS and NDI are used as affected cofactors with radiological fusion as the successful endpoint, the clinico-radiological success was achieved in significantly higher fraction of patient population fused with the slotted plates within the group that underwent multilevel fusions. This correlation was not established in patient undergoing single-level fusion where the success was achieved in a comparable fraction of patients for both the slotted- and fixed-hole plate recipients.

Discussion

ACDF is one of the most commonly performed cervical spine procedures by both orthopedic and neurosurgeons. Because the first description by Cloward [6] and subsequent modification by Smith and Robinson [7], the technique has been fairly standard with extremely satisfactory results [8]. Although high fusion rates and good clinical outcomes have been repeatedly reported without the use of supplemental anterior plating [9], most studies have established that anterior instrumentation improves the results in multilevel fusions [10,11]. Recently, more emphasis has been paid to the design characteristics of the plates used for multilevel ACDF rather than the necessity of the plate itself. Until recently the majority of the published series with multilevel ACDF has used the fixed-plate system [12,13].
It is accepted universally that static- or fixed-plating system provide rigid internal fixation but this also reduces the load sharing across the bone-graft interface. Reidy et al. studied the characteristics of cervical spine loading in a cadaveric corpectomy model and showed that dynamic plating allows significantly higher load transmission by the graft [14] and Brodke et al. suggested that in vitro, dynamic plate allows for load sharing without apparent loss of rigidity [15].

DuBois et al. in 2007 have published the most recent clinical data comparing the outcome of patients undergoing ACDF with either static or dynamic plates [16]. In this study, the authors failed to confirm any clinical or radiographic advantage of using the dynamic plates over the static plates in ACDF procedures. This was, however, a retrospective data collection study for patients operated by two different surgeons. The bone grafts used for patients were structural allograft or iliac crest grafts depending upon surgeon’s preference. The clinical data collected in the study was either from their last follow-up visit or a telephonic interview. There was no specific clinical parameter for quantitatively comparing the results except for Odom’s criteria, which is a very objective outcome parameter. The authors found a higher rate of nonunion (5%) in the group with dynamic plates and hypothesize the higher incidence to increased motion at the graft-bone interface. However, they also acknowledge that 80% of the nonunion patients had allograft thus adding another variable to the already biased analysis.

There has been no published prospective randomized class I study that has compared the outcomes for these patients without any pre-existing bias. The current study was designed from the beginning to avoid all possible bias related to patient selection, surgical technique, and bone-graft factors. Plates of both designs were made by the same manufacturer thus further eliminating a possible bias. We believe that the difference between our results and the previously published ones could be attributed to these measures that we adapted to eliminate all possible bias. We found no statistically significant outcome advantage of using the dynamic plates for single-level fusions and this finding is in accordance with previously published literature [9]. However, our analysis reveals a statistically solid clinical advantage of using the dynamic plates in patients requiring multilevel fusion. We believe that such advantage was detected because the study design used careful collection of consistent, numeric, and objective clinical parameters that were obtained from both the patient’s and the clinician’s inputs.

**Shortcoming**

In patients with multiple-level disease, trend was noticed where the upper one or two levels were fused, whereas the lowermost level displayed failure or pseudarthrosis. These patients were grouped as failures or success based on the clinical outcome in the present analysis because the number of patients was not sufficient to draw statistical conclusions for individual levels. However, the protocol is still actively enrolling and the power analysis reveals the need for 115 subjects (50 per group plus 15% LTF) to perform analysis within each group for individual levels. As they become available, the results of such analyses will be shared in the future.

Secondly, the radiological details of the constructs like the “settling” of the graft, migration of the plates, or subsidence at various follow-up time points as well as the adjacent segment disease have not been considered in the present study because we felt that the analysis of those details will warrant a separate manuscript oriented more toward the radiological findings as opposed to the clinical issues. The data are being analyzed for future submission.

![Fig. 5. (Top) GLM ANOVA bar chart predicting significant effect of plate design on Visual Analogue Pain score and (Bottom) Neck Disability Index when the number of fused levels is taken into consideration.](image-url)
Conclusion

Despite the aforementioned shortcomings of the study, the following conclusions were drawn after analyzing the available data with statistically significant confidence: Although clinical improvement is a good predictor of successful ACDF, radiological evidence of fusion alone is not reliable as a parameter of success. The design of plate does not affect the outcomes in single-level fusions but statistical trends indicated that multiple-level fusions may have statistically better functional outcome when a dynamic plate design is used.

References
