Prospective, Randomized, Double-Blind Clinical Study Evaluating the Correlation of Clinical Outcomes and Cervical Sagittal Alignment

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BACKGROUND: Sagittal alignment of the cervical spine has received increased attention in the literature as an important determinant of clinical outcomes after anterior cervical diskectomy and fusion. Surgeons use parallel or lordotically fashioned grafts depending on preference or simple availability.

OBJECTIVE: To quantitatively assess and compare cervical sagittal alignment and clinical outcome when lordotic or parallel allografts were used for fusion.

METHODS: A prospective, randomized, double-blind clinical study that enrolled 122 patients was performed. The mean follow-up was 37.5 months (range, 12-54 months).

RESULTS: The mean postoperative cervical sagittal alignment was 19° (range, −7°-36°) and 18° (range, −7°-37°) in the lordotic and parallel graft patient groups, respectively. The mean segmental sagittal alignment was 6° (range, −4°-19°) and 7° (range, −3°-19°) in the lordotic and parallel graft patient groups, respectively. There were no statistically significant differences in clinical outcome scores between the lordotic and parallel graft patient groups. However, patients who had maintained or improved segmental sagittal alignment, regardless of graft type, achieved a higher degree of improvement in Short Form-36 Physical Component Summary and Neck Disability Index scores. This was statistically significant ($P < .038$).

CONCLUSION: The use of lordotically shaped allografts does not increase cervical/segmental sagittal alignment or improve clinical outcomes. Maintaining a consistent segmental sagittal alignment or increasing segmental lordosis was related to a higher degree of improvement in clinical outcomes.

KEY WORDS: Anterior cervical diskectomy and fusion, Cervical sagittal alignment, Clinical outcomes, Prospective clinical study

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Compared with lumbar sagittal alignment, which has received a large amount of attention in the literature, much less is known regarding the alteration of cervical sagittal alignment (CSA) and clinical outcomes. Although it is generally accepted that the physiological sagittal balance is important for normal function of the spine, whether maintenance and improvement of cervical and/or segmental lordosis have an effect on clinical outcomes after cervical spine surgeries remains to be proven. This could be partially related to the facts that the greatest normal physiological variations in spinal curvature occur between C2 and C7 in the cervical spine[1] and that most of the published studies examined sagittal alignment as the postoperative result without studying its relationships to the preoperative status. In addition, it is not easy to clearly demonstrate that the correction of kyphotic cervical deformity promotes improvement in clinical outcome scores when such improvement could be attributed to the spinal cord decompression itself.[2]

ABBREVIATIONS: ACDF, anterior cervical diskectomy and fusion; **CSA,** cervical sagittal alignment; **MCS,** Mental Component Summary + Score; **NDI,** Neck Disability Index; **PCS,** Physical Component Summary; **SSA,** segmental sagittal alignment; **VAS,** Visual Analog Scale

Device manufacturers and tissue banks offer cervical allografts and other interbody spacers that come in various sagittal profiles, including lordotic, parallel, or even convex designs that, according to indications, should restore lordosis, maximize surface area contact,or allow for patient-specific needs. However, these statements or improved long-term clinical outcomes have never been proven in any prospective, randomized clinical studies. The purpose of this study was to determine whether lordotic sagittal alignment and clinical outcomes could be improved in patients undergoing anterior cervical diskectomy and fusion (ACDF) with lordotically shaped vs parallel allografts.

METHODS

A prospective, randomized, double-blind clinical study was performed. Institutional Review Board approval was granted, and the study was initiated in January 2003. The study objectives and surgical procedure were explained, and informed consent was obtained from all patients who agreed to participate in the study. Patients were randomly assigned to 1 of the 2 groups and received either lordotic or parallel allograft(s) during the ACDF procedure. The allograft selection was performed after enrollment but before the surgery with the use of the JavaScript random-number generator (Research Randomizer version 3.0). Both the patient and the independent radiographic reviewer were blinded to whether lordotic or parallel allografts were used during surgery.

Clinical Outcome Assessment and Analysis

Standardized questionnaires were used to evaluate clinical outcomes. Health-related quality of life or functional outcomes were assessed with the Health-Related Quality of Life Questionnaire (Short Form-36 [SF-36] version 2). Two scores within the scoring algorithm were analyzed: the Physical Component Summary (PCS) and Mental Component Summary + Score (MCS). The Neck Disability Index (NDI) was used to evaluate chronic disability and activities of daily living. The severity of neck and arm pain was evaluated using VAS (Visual Analog Scale). In addition, patients were asked to complete a self-reported Patient Satisfaction With Results survey. A sample of the patient satisfaction survey and scoring methods are presented in Figure 1. A total score was calculated for each patient by averaging the scores from all 6 responses, and the means were compared between the lordotic and parallel allograft patient groups.

Surgical Procedure

The surgical procedure has been previously described.[3] All ACDF procedures were performed with either lordotic or parallel allograft cortical spacers manufactured by Synthes Spine (West Chester, Pennsylvania) or Lanx (Broomfield, Colorado). The lordotic allografts had a 5° profile. Both parallel and lordotic allografts were available in variable heights ranging from 5 to 12 mm and were selected depending on the height of the intervertebral disk space. Two anterior cervical arthrodesis plating systems were used for patients in the study: the Zephir and Atlantis systems (Medtronic Sofamor Danek, Memphis, Tennessee).

Radiographic Assessment and Analysis

Two parameters were measured preoperatively and postoperatively on lateral neutral views of cervical radiographs: CSA and segmental sagittal alignment (SSA) (Figure 2A and 2B). Sagittal alignment was measured using the posterior tangent method described by Gore et al.[4] This method uses a technique in which the tangent to the C2 and C7 posterior vertebral body margins is calculated to determine the overall CSA. The SSA was determined by measuring sagittal alignment of the fused segment(s). The posterior tangent method has been regarded in the literature as more reliable than the Cobb method for lateral cervical radiographic analysis[5] and was therefore chosen for this study. We chose positive angulation as indicative of lordosis and negative angulation to represent kyphosis. The mean postoperative CSA and SSA values were compared between the 2 groups of patients who received lordotically shaped or parallel allografts during the surgery.

Correlation of Change in Sagittal Alignment and Clinical Outcomes

We also performed a posthoc analysis to examine whether the maintenance or enhancement of CSA and/or SSA regardless of allograft shape was predictive of a higher degree of improvement in clinical outcome scores. This was accomplished by calculating the difference between the preoperative and postoperative CSA and SSA for each patient. Changes in clinical outcome scores were calculated for each patient by the difference

The following are statements that people make about what they expect following a spinal surgery. For each statement indicate how true or false you think it is.

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
01. I can do the things I thought I would be able to after surgery.	○	○	○	○	○
02. I was helped as much as I though I would be by my surgery.	○	○	○	○	○
03. My pain was reduced as much as I expected it to be after surgery.	○	○	○	○	○
04. The benefits of my care outweight the setbacks it caused me.	○	○	○	○	○
05. Overall I am happy with the care I am receiving for my neck and/or arms.	○	○	○	○	○
06. All things considered, I would have the surgery again for the same condition.	○	○	○	○	○

FIGURE 1. *Patient Satisfaction With Results survey. Answers were scored on a scale from 0 to 100: 100 = definitely true; 75 = mostly true; 50 = don't know; 25 = mostly false; 0 = definitely false. Total (overall satisfaction) was calculated by averaging the scores from all 6 responses.*

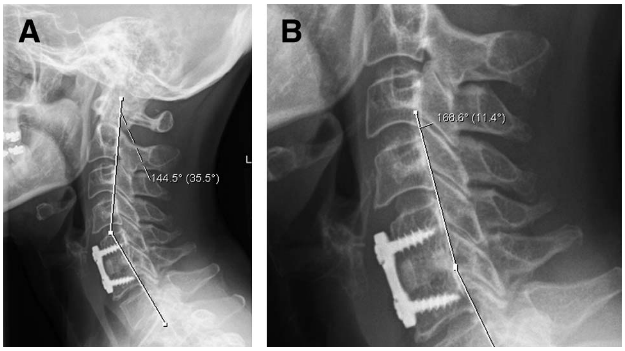

FIGURE 2. *Lateral neutral radiographs demonstrating cervical sagittal alignment (**A**) and segmental sagittal alignment (**B**) measurements.*

between preoperative and postoperative scores. The difference in clinical outcome scores was then compared for the subgroups (maintenance/change toward lordosis vs change toward kyphosis) for both SSA and CSA.

Statistical Analyses

Data are expressed descriptively as means (range) and percentages when applicable. Groups were compared by the use of Student *t* tests for all independent continuous quantitative variables. All categorical values were compared between groups with χ^2 analysis (with or without Yates continuity correction). Regression analyses were conducted to evaluate the relationship of the change in SSA with the change in CSA, as well as relationships between the SSA and CSA with each of the clinical outcome measures. Statistical significance was considered at values of $P \leq .05$.

RESULTS

Patients

The study analyzed 122 patients who underwent 1- to 3-level ACDF surgeries between March 2003 and March 2006. All patients enrolled in the study failed at least 6 weeks of conservative therapy before surgery unless immediate surgical intervention was required (eg, severe progressive myelopathy). There were 63 male (51.6%) and 59 female (48.4%) patients. The average patient age was 49.9 years (range, 17-80 years). Patients were selected for surgery on the basis of clinical symptoms and included 84 patients (68.8%) who had intractable neck pain and radiculopathy caused by spondylosis and/or disk herniation, foraminal and/or central stenosis, or spondylolisthesis and 38 patients (31.2%) with myelopathy.

Clinical and radiographic patient evaluation was performed preoperatively and then at 3, 6, 12, 24, 36, and 48 months after surgery. The mean follow-up time was 37.5 months (range, 12-54 months).

Lordotic vs Parallel Allograft Patient Groups: Clinical Outcome and Sagittal Alignment Analysis

There were 57 and 65 patients in the lordotic and parallel allograft patient groups, respectively. Selected demographic and clinical patient data are presented in Table 1. There were no statistically significant differences in clinical diagnoses, duration of symptoms, previous surgeries, or preoperative clinical symptoms between the 2 patient groups. Selected operative data, including surgical levels, estimated blood loss, duration of procedure (operating room time), and length of hospital stay, for the lordotic and parallel allograft patient groups are presented in Table 2. There were no statistically significant differences identified between any of these parameters.

TABLE 1. **Selected Demographic and Clinical Data for Lordotic and Parallel Allograft [a]Patient Groups**

	Lordotic	Parallel	*P*
Demographic data			
Patients, n (%)	57	65	
Age, y	49.2 (34-78)	50.6 (17-80)	.52
Male/female	25:32	38:27	.11[b]
Clinical data			
Diagnosis			
Cervical radiculopathy, n (%)	39 (68.4)	45 (69.2)	.38[b]
Myelopathy, n (%)	18 (31.6)	20 (30.8)	
Pre-Op VAS neck	5.4 (0-10)	5.8 (0-10)	.53
Pre-Op VAS arm	5.1 (0-10)	4.5 (0-10)	.34
Pre-Op SF-36 PCS	38.5 (16.4-54.9)	37.3 (20.8-57.4)	.45
Pre-Op SF-36 MCS	41.9 (10.2-69.4)	43.4 (17.8-74.2)	.54
Pre-Op NDI	20.1 (1-45)	20.4 (0-41)	.88
Previous surgeries, n (%)	1 (1.7)	8 (12.3)	.06[c]
Duration of symptoms, mo	25.3 (0.5-240)	31.2 (0.1-288)	.53

[a]MCS, Mental Component Summary + Score; NDI, Neck Disability Index; PCS, Physical Component Summary; Pre-Op, preoperative; SF-36, Short-Form version 2 Health Survey; VAS, Visual Analog Scale. Student *t* tests were used for all calculations comparing the 2 groups except when noted, in which case χ^2 tests [b]without or [c]without the Yates correction were performed. Values are presented as means (ranges) when appropriate.

The mean clinical outcomes scores were almost identical in both patient groups that received either lordotic or parallel allografts (Table 3). Although improvement was noted in all postoperative clinical outcome measures, we found no statistically significant differences between the lordotic and parallel allograft patient groups. A power analysis was conducted using *t*-test sample sizes of 57 and 65 to evaluate the detectable effect size of our data. With the recommended power of 0.8, the present sample size would have been able to detect an effect size as small as 0.5.

The lordotic and parallel allograft patient groups did not significantly differ in their CSA or SSA ($P = .67$) preoperatively. The mean CSA was measured at 16° degrees (range, −8°-34°) and 17° (range, −10°-34°) in the patient groups that received lordotically shaped or parallel allografts, respectively. The mean SSA was measured at 1° (range, −10°-12°) and 2° (range, −13°-25°) in the lordotic and parallel allograft patient groups, respectively (Figure 3). Although both the lordotic and parallel allograft patient groups had increased mean CSA and SSA scores postoperatively, no statistically significant differences were found in mean

TABLE 2. Selected Surgical Parameters[a]

	Lordotic	Parallel	P
1-Level fusions, n (%)	29 (50.9)	37 (56.9)	.65[b]
C2-C3	0	1	
C3-C4	2	3	
C4-C5	5	5	
C5-C6	13	14	
C6-C7	9	11	
C7-T1	0	3	
2-Level fusions, n (%)	23 (40.3)	21 (32.3)	
C3-C5	2	1	
C4-C6	9	8	
C5-C7	12	12	
3-Level fusions, n (%)	5 (8.8)	7 (10.8)	
C3-C6	2	3	
C4-C7	2	2	
C5-T1	0	1	
C3-C5, C6-C7	1	0	
C3-C5, C7-T1	0	1	
Operative and hospitalization data			
EBL, mL	98.3 (25-500)	107.7 (25-500)	.59
Operation time, min	89.8 (50-190)	98.1 (40-240)	.26
LOS, d	1.3 (0.2-8.4)	1.0 (0.1-4.0)	.24

[a]EBL, estimated blood loss; LOS, length of hospital stay. Values are presented as means (ranges) when appropriate. Student *t* tests were used for all calculations comparing the 2 groups except when noted, in which a [b]χ^2 test was performed.

postoperative CSA and SSA scores. The mean postoperative CSA was 19° (range, −7°-36°) and 18° (range, −7°-37°) in the lordotic and parallel graft patient groups, respectively. The mean postoperative SSA was 6° (range, −4°-19°) and 7° (range, −3°-19°) in the lordotic and parallel graft patient groups, respectively.

Change in Sagittal Alignment and Clinical Outcomes

Thirteen patients were lost to follow-up, and 22 patients had either adjacent-level or posterior cervical fusion surgeries preventing the change in sagittal alignments to be calculated, leaving 85 of 122 patients for these analyses. Results were analyzed in the following subgroups. One subgroup consisted of 68 patients who had improved (change toward lordosis) or preserved sagittal alignment at the surgical level (SSA). Another 17 patients had a loss of sagittal alignment (change toward kyphosis) at the surgical level (SSA). Both groups were quite different before the surgery in terms of the SSA and were comparable postoperatively; thus, a considerably higher degree of angle correction was achieved in the patient group with maintained or improved SSA (Figure 4). The average loss of 3° (range, −9°-−1°) at the surgical level was detected in patients who lost SSA.

Postoperatively, both groups had decreased mean VAS (arm and neck) and NDI scores, as well as increased mean SF-36 (PCS and MCS) scores, indicating an improvement in all clinical outcome measures. However, analysis of the change in clinical scores between the 2 groups showed that patients who had maintained or improved SSA also achieved a statistically significant and higher degree of improvement in SF-36 PCS and NDI

TABLE 3. Postoperative Clinical Outcome Data for Lordotic and Parallel Allograft Patient Groups[a]

Clinical Outcome Data	Lordotic	Parallel	P
Post-Op VAS (neck)	2.8 (0-7.5)	2.8 (0-8)	.93
Post-Op VAS (arm)	2.1 (0-8)	2.2 (0-9)	.87
Post-Op SF-36 PCS	44.9 (16.5-60.3)	45.3 (19.7-58.2)	.85
Post-Op SF-36 MCS	47.0 (25.2-64.7)	47.7 (11.7-63.2)	.71
Post-Op NDI	11.1 (0-32.5)	11.5 (0-36)	.83
Patient Satisfaction Survey	77.2 (9.4-100)	73.1 (15-100)	.36

[a]MCS, Mental Component Summary + Score; NDI, Neck Disability Index; PCS, Physical Component Summary; Post-Op, postoperative; SF-36, Short-Form version 2 Health Survey; VAS, Visual Analog Scale.
Values are presented as means (ranges).
Student t-tests were used for all calculations comparing the 2 groups.

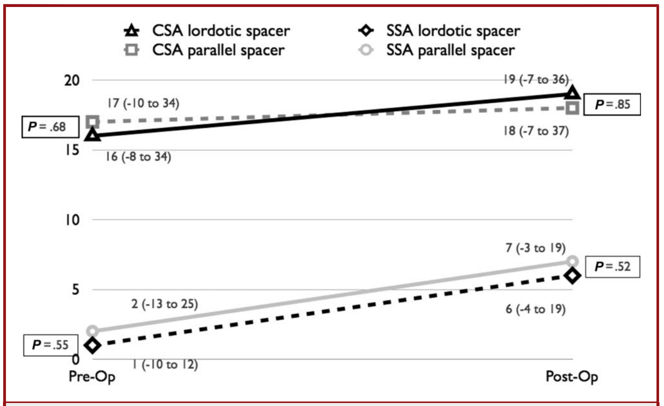

FIGURE 3. *Mean sagittal alignment in lordotic vs parallel allograft patient groups. Student t tests were used for all calculations comparing the 2 groups. CSA, cervical sagittal alignment; Post-Op, postoperative; Pre-Op, preoperative; SSA, segmental sagittal alignment.*

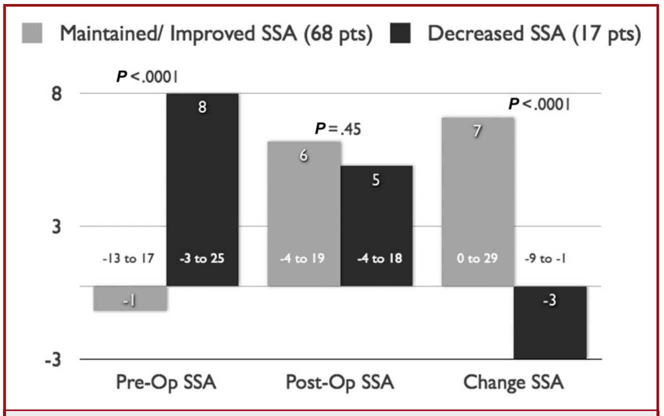

FIGURE 4. *Change in segmental sagittal alignment (SSA) radiographic analysis. Student t tests were used for all calculations comparing the 2 groups. Post-Op, postoperative; Pre-Op, preoperative.*

scores. Although there was a higher degree improvement in VAS neck and SF-36 MCS scores in the maintained or improved SSA patient group, it did not reach statistical significance (Figure 5).

In addition to demonstrating that a higher degree of improvement in clinical outcomes was related to qualitative change in the alignment (change toward lordosis in SSA), regression analyses were conducted to determine a possible quantitative relationship between improvement in clinical outcomes and degree change in SSA. In other words, the analyses tested whether a higher degree change in SSA was associated with a greater change in each of the clinical outcome measures. The results illustrate that a higher degree of SSA change was not directly proportional to the changes in either of the quantitatively significant clinical outcome scores: NDI (R^2 = 0.004, B = −0.08, $F_{(1,72)}$ = 0.25, P = .62) and SF-36 PCS (R^2 = 0.010, B = 0.16, $F_{(1,73)}$ = 0.76, P = .39).

We also analyzed 52 patients who had maintained or improved (change toward lordosis) CSA and 33 patients who had lost (change toward kyphosis) CSA. These 2 subgroups of patients were compared to establish how changes in CSA correlated with clinical outcomes. The CSA preoperative and postoperative measurements are presented in Figure 6. The 2 subgroups of patients did not significantly differ in the changes of their clinical outcome scores (Figure 7).

To compare the effect of the change in SSA on the change in CSA, a regression analysis was conducted (Figure 8). As can be predicted, the regression analysis found that a change in SSA was a significant predictor of a change in CSA (R^2 = 0.25, B = 0.37, $F_{(1,83)}$ = 28.08, $P < .0001$).

Fusion Rates and Additional Surgeries

The nonunion rate was 7.4% (9 of 122) for the entire patient population. A total of 22 patients required additional surgery, 13 of which were performed for symptomatic adjacent-level degenerative disease. There were no statistically significant differences in the number of patients who underwent surgery for adjacent-level degenerative disk disease between the lordotic and parallel allograft patient groups or improved/maintained and decreased SSA patient groups.

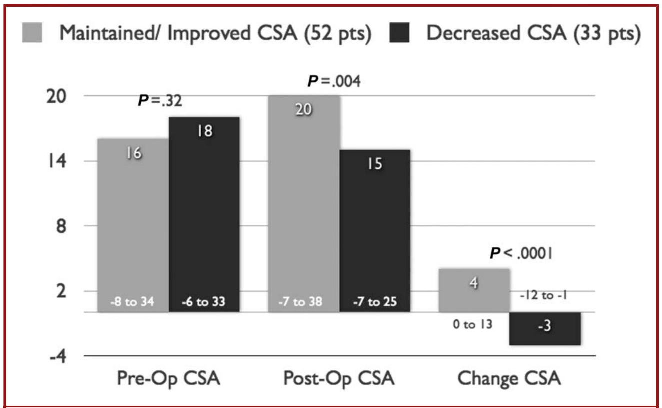

FIGURE 6. *Change in cervical sagittal alignment (CSA) radiographic analysis. Student t tests were used for all calculations comparing the two groups. Post-Op, postoperative; Pre-Op, preoperative.*

DISCUSSION

Despite the continuous progress in surgical instrumentation and techniques, little is known regarding the relationship of cervical alignment and clinical outcomes. Several authors concluded that the degree of cervical lordosis is important in achieving good outcomes for cervical surgical interventions in patients with neurological deficits, and postoperative kyphosis would deteriorate neurological function. Jenkins et al[6] indicated that there was a significant increase in complaints of cervical pain

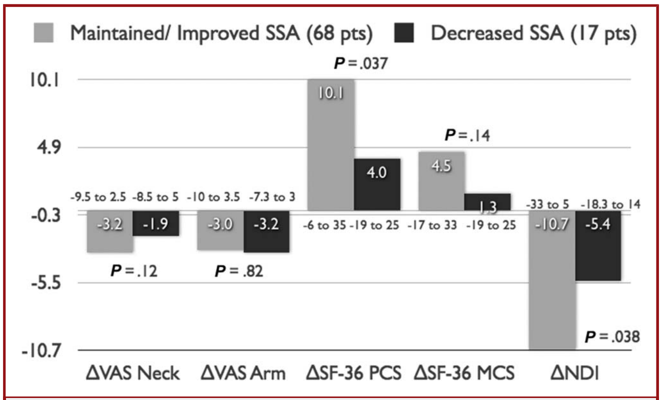

FIGURE 5. *Correlation between segmental sagittal alignment (SSA) and clinical outcomes. Values are presented as changes between preoperative and postoperative clinical outcomes scores. MCS, Mental Component Summary + Score; NDI, Neck Disability Index; PCS, Physical Component Summary; SF, Short Form; VAS, Visual Analog Scale.*

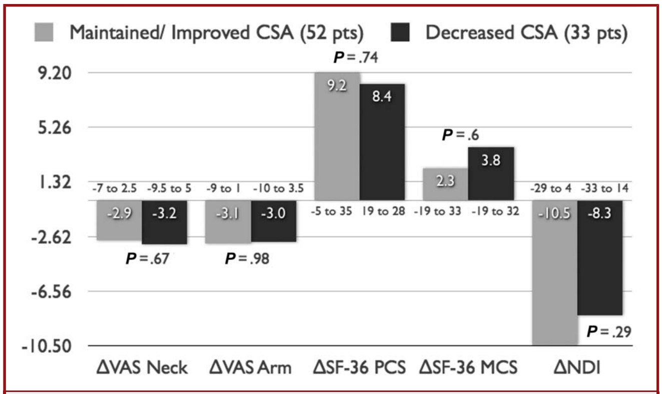

FIGURE 7. *Correlation between cervical sagittal alignment (CSA) and clinical outcomes. Values are presented as changes between preoperative and postoperative clinical outcomes scores. MCS, Mental Component Summary + Score; NDI, Neck Disability Index; PCS, Physical Component Summary; SF, Short Form; VAS, Visual Analog Scale.*

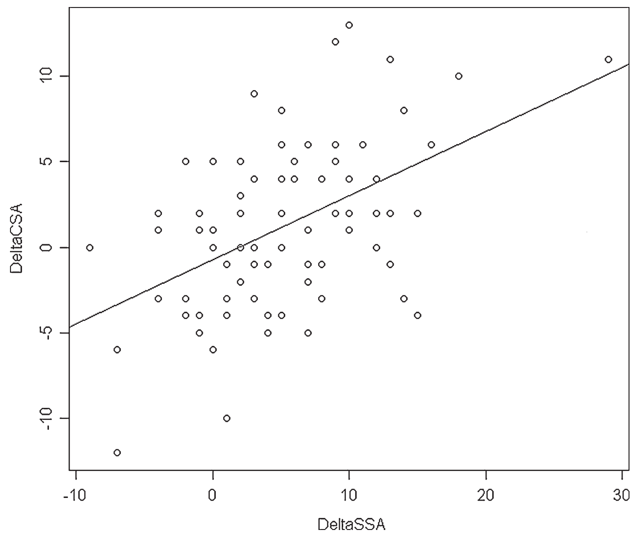

FIGURE 8. *Correlation between the changes (delta) in segmental sagittal alignment (SSA) and cervical sagittal alignment (CSA).*

in patients with kyphosis of > 20° after cervical spine trauma surgery. Naderi et al[7] studied correlations between sagittal and coronal geometry of the spine and neurological deficit and concluded that the presence of abnormal cervical curvature correlated with less neurological improvement. After examining patients undergoing an open-door laminoplasty, Baba et al[8] suggested that posterior cord migration plays an important role in recovery of spinal cord function. The authors showed that reduced lordosis postoperatively is associated with a negative impact for neurological recovery. Kawakami et al[9] reported that axial symptoms such as neck pain and stiffness, shoulder pain, neck dullness, and interscapular pain are directly related to the loss in cervical lordosis.

There have also been reports that argued the importance of cervical alignment and any significant relationships with clinical outcomes.[10-14] Jagannathan et al[15] investigated sagittal alignment and clinical outcome in 170 patients who underwent single-level ACDF with allograft and no plating. They reported a mean change of 7.4° toward kyphosis postoperatively in all 36 patients (21%) who had preoperative kyphotic segmental angles. No significant relationship was determined between change in the segmental angle and postoperative functional status. In addition, no significant changes in the mean C2-C7 Cobb angles were detected. Kwon et al[16] investigated 30 patients who underwent single-level ACDF with anterior cervical plating and 4 patients who underwent ACDF with threaded cervical cage and no plate. They found no significant relationship between disk space angulation and clinical outcomes but noted a trend that more kyphosis correlates with greater VAS scores for neck pain. Xie et al[17] compared anterior cervical diskectomy vs diskectomy with fusion and diskectomy with fusion and instrumentation. They found a significant loss of segmental lordosis in the patient group that had anterior cervical diskectomy but did not detect any differences in clinical outcome scores.

The occurrence of segmental kyphosis after Bryan cervical disk implantation has recently received attention in the literature, but no significant relationship with clinical outcomes was reported.[18-22]

Lordotic vs Parallel Allografts

One of the hypotheses tested in this study was that the use of lordotically shaped allografts during ACDF would improve sagittal alignment and subsequently clinical outcomes. Considering that normal lordosis of the cervical spine is determined mainly by lordotically shaped intervertebral disks, it may seem intuitive to think that such an allograft shape would increase lordotic curvature of the cervical spine and therefore hold potential for promoting better clinical outcomes than parallel allografts. In our study, both lordotic and parallel allograft patient groups demonstrated a slight average increase toward lordosis in overall CSA of 3° and 1°, respectively. A larger mean increase toward lordosis was observed at the surgical level (SSA) with a mean change of 5° for both the lordotic and parallel allograft patient groups. However, there were no statistically significant differences in restoration of CSA or SSA, and we did not find any significant differences in clinical outcomes between the lordotic and parallel allograft patient groups. There are likely other factors in this equation that need to be considered like the height of the allograft, angle and depth of the insertion, or anatomic characteristics of the endplates. Some degree of the allograft or bone collapse probably took place, but then it would most likely have the same effect on the parallel and lordotic allograft patient groups.

Change in Sagittal Alignment and Clinical Outcomes

Although all patients improved postoperatively, we analyzed whether the alterations in sagittal alignment influenced clinical outcomes. It was determined that the maintenance of or change in SSA toward lordosis was an important factor responsible for a higher degree of improvement in clinical outcomes after single and multilevel ACDF. In our investigation, patients who had the SSA change toward lordosis demonstrated a significantly higher degree of improvement in NDI and SF-36 scores. This conclusion potentially supports all previously published findings that postoperative kyphosis may or may not be responsible for inferior clinical outcomes compared with lordotic postoperative sagittal alignment. This could be attributed to the fact that regardless of sagittal alignment, a majority of the patients still improve as a result of decompression and restoration of the intervertebral disk height even if the segmental/sagittal alignment becomes kyphotic. From our results, it seems that a change in segmental alignment toward lordosis may have a positive impact in this process. The mechanism of this effect is not clear but most likely acts through complex muscle and ligament interactions related to posture rather than affecting a radicular component of the cervical pain. Although not significant, the patients in our study had a higher degree of improvement in neck VAS scores but not arm VAS scores in the maintained/improved SSA patient group.

Further examination of the clinical outcome regression analysis results suggests that the actual angle measure that the SSA changes is not what predicts or relates to the bettering of the patient clinical outcomes. This supports the decision to test clinical outcome improvement by comparing the difference in means of the clinical outcomes between those whose sagittal alignment stayed constant or improved and those whose alignment decreased. The very close mean values for these 2 groups' postoperative SSA (Figure 4), along with the results of the clinical outcome regression analyzes, highlight the notion that it does not appear to be the mean postoperative SSA itself or the actual degree measure of change but whether or not the patients maintained/ improved or decreased their SSA.

Preservation or improvement in SSA has directly affected some of the clinical outcome measures, whereas the alterations in CSA did not. Overall, after a mean 37.5-month average follow-up of our entire patient population, we found a significant mean SSA increase toward lordosis of 5° ($P < .0001$), from a mean preoperative SSA of 1° to the mean postoperative 6°. We found a nonsignificant mean CSA increase toward lordosis of 2°, from a mean preoperative CSA of 16° to a mean 18°, postoperatively for the entire patient population. It is likely that adjacent-level intervertebral disks "absorb" a significant proportion of such segmental alterations before any substantial and significant effect on cervical alignment or clinical outcomes can be noted.

The regression coefficient of the regression analysis evaluating the effect of SSA change on CSA change shows that 25% of the variance in CSA measures can be attributed to the change in SSA measures (see Change in SSA vs Change in CSA*)*. Although a significant result, this model suggests that 75% of the change in CSA measures is left unexplained. As outlined by the model, for every 1° change in SSA, the CSA changes about 0.37°.

When considering the comparison between degree changes in one's CSA and SSA, we can dilute a degree measure change in SSA in 1- to 3-level procedures when including all cervical levels. Ferch et al[2] suggested that "correction of local kyphotic deformity had a variable effect on the regional sagittal alignment." These findings have also been repeatedly reported in the literature related to ACDF[13] or cervical artificial disk replacement surgeries.[18,22] Jagannathan et al[15] investigated sagittal alignment and clinical outcome in 170 patients who underwent single-level nonplated ACDF with allograft and noted: "The fact that the overall alignment between C2 and C7 did not change significantly in spite of kyphosis indicates that the untreated segments of the cervical spine compensated for focal kyphosis." Our study further contributes to this idea.

Limitations

We investigated only whether lordotic allografts can improve sagittal alignment and subsequently affect clinical outcomes. Although we have accounted for demographic, surgical, and clinical variables that may contribute to the final outcome, multiple variables such as height of the disk, angle and depth of the allograft insertion, allograft subsidence, or patient positioning remained unaccounted and require further investigation.

The study did not specifically analyze the postoperative loss of sagittal alignment, but we did not observe any excessive variations in that regard. This study also most likely was affected by sagittal alignment measurement errors, which are unavoidable with the measurement techniques available to us.

The kyphotic alignment could be among multiple factors that contribute to acceleration of the degenerative changes in the cervical spine. A correlation between the progress of degeneration and loss of lordosis has been demonstrated,[23,24] and kyphotic alignment of the cervical fusion segment was shown to increase the load sharing of the anterior plate under flexion.[25] We have not been able to demonstrate this correlation but will investigate it further in subsequent studies.

CONCLUSION

This is the first study that compared lordotic and parallel allografts in clinical settings and in a prospective, randomized, long-term clinical study. The use of lordotically shaped allografts does not increase CSA or SSA and does not correlate with improved clinical outcomes. However, maintaining a consistent or improving SSA was related to a higher degree of improvement in clinical outcome scores.

Disclosure

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COMMENT

In this article, the authors present the results of a prospective, randomized study of 122 patients who underwent anterior cervical diskectomy and fusion with instrumentation for a variety of indications. The patients were randomized to receive either parallel or lordotic allograft bone grafts.

The results showed no differences between the 2 groups in terms of segmental or regional lordosis, functional outcome, or pain scores. Further analysis demonstrated that patients with preserved or improved segmental lordosis experienced significantly greater improvements in Short Form-36 Physical Component Summary and Neck Disability Index scores.

As stated by the authors, the significance of sagittal alignment as an important parameter in cervical spine surgery is complex and a subject of great interest. It is interesting to note that, in the present study, preservation or improvement in segmental lordosis appeared to have a direct bearing on certain outcome measures, whereas regional lordosis did not. It is not clear whether this is an effect of sample size or the result of some other yet-to-be-defined parameter. It is also interesting to note that in this study there does not appear to be a threshold for negative cervical sagittal balance below which outcomes begin to fall. Finally, although studies regarding thoracolumbar global sagittal balance have noted an increase in the nonunion rate for patients with postoperative positive sagittal balance, it is intriguing that this study showed no such effect in the cervical region.

Although there is clearly much more to this story, the present article provides useful and applicable information for the practicing spinal surgeon.

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