Prospective Randomized Clinical Study
Evaluating the Correlation of Clinical
Outcomes and Cervical Sagittal Alignment

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Introduction

- Sagittal alignment of the C spine has recently received increased attention in the literature as an important determinant of clinical outcomes following ACDF.

- Could cervical sagittal alignment be improved using lordotically-shaped allografts?
A prospective, double-blinded, randomized clinical study was performed (IRB approval received prior to the study)

Primary Objective - quantitatively access and correlate sagittal alignment with clinical outcomes when lordotic or parallel allografts were used

Secondary Objective - determine if alterations in cervical alignment correlated with a higher degree of improvement in clinical outcomes
Clinical Study

- A total of 122 patients were enrolled
  - 57 patients - received lordotic allografts
  - 65 patients - received parallel allografts
- The mean follow up was 37.5 (12 - 54) months
<table>
<thead>
<tr>
<th></th>
<th>Lordotic</th>
<th>Parallel</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>57</td>
<td>65</td>
<td>-</td>
</tr>
<tr>
<td>Age</td>
<td>49.2 (34 - 78)</td>
<td>50.6 (17 - 80)</td>
<td>&gt; 0.52</td>
</tr>
<tr>
<td>M/F ratio</td>
<td>25:32</td>
<td>38:27</td>
<td>&gt; 0.11</td>
</tr>
<tr>
<td>Previous Surgeries</td>
<td>1 (1.7%)</td>
<td>8 (12.3%)</td>
<td>&gt; 0.06</td>
</tr>
<tr>
<td>Duration of Sympt.</td>
<td>25.3 months</td>
<td>31.2 months</td>
<td>&gt; 0.53</td>
</tr>
</tbody>
</table>
Methods

- Pre- and postoperative clinical assessments and radiographical measurements

- Clinical Outcome Measurements
  - VAS (Visual Analog Scale)
  - SF-36 (Health related quality of life)
  - NDI (Neck Disability Index)
  - Patient Satisfaction
  - Time to return to work
Methods

- Sagittal alignment was measured using the posterior tangent method on lateral neutral views of cervical radiographs

- Two sagittal alignment parameters were measured:
  - Segmental sagittal alignment (SSA) - surgical level
  - Cervical sagittal alignment (CSA) - C2 - C7
Methods

- Surgical Procedure
  - Allograft spacers (Synthes/Lanx)
  - Lordotic graft has a 5-degree profile
  - Heights from 5 mm to 12 mm
  - Plating system (Zephir/Atlantis)
- 66 one-level fusions (54.1%), 44 two-level fusions (36.1%), and 12 three-level fusions (9.8%)
### Methods

<table>
<thead>
<tr>
<th></th>
<th>Lordotic</th>
<th>Parallel</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBL (mL)</td>
<td>98.3 (25-500)</td>
<td>107.7 (25-500)</td>
<td>&gt; 0.59</td>
</tr>
<tr>
<td>OR Time (min)</td>
<td>89.8 (50 - 190)</td>
<td>98.1 (40-240)</td>
<td>&gt; 0.26</td>
</tr>
<tr>
<td>LOS (days)</td>
<td>1.3 (0.2 - 8.4)</td>
<td>1.0 (0.1 - 4.0)</td>
<td>&gt; 0.24</td>
</tr>
</tbody>
</table>
Results

Sagittal Alignment - Lordotic vs. Parallel Allograft Patient Groups

<table>
<thead>
<tr>
<th></th>
<th>Pre-Op CSA</th>
<th>Post-Op CSA</th>
<th>Pre-Op SSA</th>
<th>Post-Op SSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lordotic</td>
<td>15.9</td>
<td>18.6</td>
<td>0.7</td>
<td>5.9</td>
</tr>
<tr>
<td>Parallel</td>
<td>16.7</td>
<td>18.2</td>
<td>1.5</td>
<td>6.6</td>
</tr>
</tbody>
</table>

P > 0.67
P > 0.84
P > 0.54
P > 0.51
Results

VAS - Lordotic vs. Parallel Allograft Patients Group

<table>
<thead>
<tr>
<th></th>
<th>Lordotic allograft</th>
<th>Parallel allograft</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Op Neck</td>
<td>5.4</td>
<td>5.8</td>
<td>&gt;0.53</td>
</tr>
<tr>
<td>Post-Op Neck</td>
<td>2.8</td>
<td>2.8</td>
<td>&gt;0.93</td>
</tr>
<tr>
<td>Pre-Op Arm</td>
<td>5.1</td>
<td>4.5</td>
<td>&gt;0.34</td>
</tr>
<tr>
<td>Post-Op Arm</td>
<td>2.1</td>
<td>2.2</td>
<td>&gt;0.87</td>
</tr>
</tbody>
</table>
Results

SF-36 Health Survey - Lordotic vs. Parallel Allograft Patient Groups

- Pre-Op PCS: Lordotic 38.5, Parallel 37.3 | P > 0.45
- Post-Op PCS: Lordotic 44.9, Parallel 45.3 | P > 0.85
- Pre-Op MCS: Lordotic 41.9, Parallel 43.4 | P > 0.54
- Post-Op MCS: Lordotic 47.0, Parallel 47.7 | P > 0.71
Results

Neck disability - Lordotic vs. Parallel Allograft Patient Groups

- Pre-Op NDI:
  - Lordotic: 20.1
  - Parallel: 20.4
  - P > 0.88

- Post-Op NDI:
  - Lordotic: 11.1
  - Parallel: 11.5
  - P > 0.83
Change in SSA Analysis

- In order to analyze whether the maintenance or enhancement of the SSA was predictive of a higher degree of improvement in clinical outcomes:
  - 68 patients had the SSA preserved/improved (change towards lordosis)
  - 17 patients had a loss of the SSA (change towards kyphosis)
Change in SSA Analysis

- **Maintained/Improved SSA (68 pts)**
  - Pre-Op SSA: -0.7
  - Post-Op SSA: 8.4
  - Change SSA: 6.7
  - P < 0.0001

- **Decreased SSA (17 pts)**
  - Pre-Op SSA: -13 to 17
  - Post-Op SSA: -3 to 25
  - Change SSA: -3.4
  - P > 0.46

- **Post-Op SSA**
  - -3.5 to 19.4
  - P < 0.0001

- **Change SSA**
  - -9 to -1
SSA and Clinical Outcomes

- **Maintained/Improved SSA (68 pts)**
  - Δ VAS Neck: -3.2
  - Δ VAS Arm: -3.1
  - Δ SF-36 PCS: 10.1
  - Δ SF-36 MCS: 4.0
  - Δ NDI: -5.4

- **Decreased SSA (17 pts)**
  - Δ VAS Neck: -1.9
  - Δ VAS Arm: -3.3
  - Δ SF-36 PCS: 5.8
  - Δ SF-36 MCS: 1.4
  - Δ NDI: -10.7

**P-values**
- P < 0.036
- P > 0.07
- P > 0.12
- P > 0.7
- P < 0.0373
Change in CSA Analysis

- 52 patients that maintained/improved the CSA
- 33 patients - the CSA was decreased (change towards kyphosis)
- There was no statistically significant changes in clinical outcome scores for these two groups of patient
Change in CSA Analysis

- **Maintained/Improved CSA (52 pts)**
- **Decreased CSA (33 pts)**

<table>
<thead>
<tr>
<th>Pre-Op CSA</th>
<th>Post-Op CSA</th>
<th>Change CSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>-8 to 34</td>
<td>-6 to 33</td>
<td>-8 to 34</td>
</tr>
<tr>
<td>16.0</td>
<td>18.0</td>
<td>20.0</td>
</tr>
<tr>
<td>0 to 13</td>
<td>-12 to -1</td>
<td>-3.4</td>
</tr>
</tbody>
</table>

- **P > 0.31**
- **P < 0.004**
- **P < 0.0001**
Case Study

- 45-year-old male with intractable neck pain and left upper extremity radiculopathy (numbness, weakness, paresthesias)
- VAS (neck) - 8/10; VAS (arm) - 6/10
- MRI - a large broad-based disc herniation at C6/C7 causing severe neural foraminal impingement on the left and complete effacement of the cerebrospinal fluid around the spinal cord
- C 6/7 fusion a with lordotic allograft
Pre-Operative
Follow-up

- VAS (neck) - 0/10; VAS (arm) - 1/10
- NDI - 3 (improved by 18 points)
- SF-36 PCS - 53.4 (improved by 17.3 points)
- SF-36 MCS - 54.7 (improved by 12 points)
- Return to work 26 days
- Satisfaction - 96%
2 years
Conclusions

- 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 outcome scores.
Thank you