Range of Motion on Flexion and Extension at Long-Term Follow-Up After Cervical Total Disc Arthroplasty: A Systematic Review and Meta-Analysis

Athan G. Zavras, BA; Navya Dandu, BS; Michael T. Nolte, MD; Arash J. Sayari, MD; T. Barrett Sullivan, MD; Matthew W. Colman, MD

Rush University Medical Center, Division Orthopaedic Spine Surgery
• Cervical total disc arthroplasty (TDA) is an alternative to anterior cervical discectomy and fusion (ACDF) for cervical radiculopathy and myelopathy refractory to conservative management.

• TDA has shown to be equivalent or even superior to ACDF with regards to:
  • Patient reported outcomes (PROs)
  • Device-related serious adverse events
  • Subsequent surgery at the index and adjacent levels

• Considering that the modern generation of cervical TDA devices were introduced recently, there is a paucity of studies quantitatively evaluating how ROM is maintained over long-term follow-up greater than 5 years.
• **Purpose:** This study sought to perform a systematic review and meta-analysis of the literature of all prospective studies reporting mid- to long-term ROM outcomes following cervical TDA.

• **Study Design:** Systematic review and meta-analysis
PubMed and MEDLINE were searched utilized a combination of the keywords “total disc arthroplasty”, “total disc replacement”, “cervical disc arthroplasty”, and “cervical disc replacement”.

**Inclusion criteria:** prospective studies reporting the ROM outcomes of patients who underwent single-level cervical TDA between C3 and C7 with a minimum of 60 months (5 years) follow-up.

**Exclusion criteria:** retrospective studies, review studies, studies whose cohorts included multilevel TDAs, early trial results, studies reporting on patients also described elsewhere (i.e., results from a single institution participating in a multicenter trial), and studies not reporting ROM at a minimum of two time points (preoperatively, at 1 year, and/or at follow-up ≥ 5 years)
METHODS

Primary Outcomes

• ROM on:
  • flexion/extension
  • sagittal plane translation
  • lateral bending
• ROM outcomes were recorded at the preoperative, 1 year postoperative, and final long-term follow-up time points.

Secondary Outcomes

• Age
• Number of patients
• Duration of follow-up

Statistical Analysis

• Heterogeneity of study data was evaluated using Cochran’s Q test and I$^2$
• ROMs were reported as means with standard deviations (SDs), along with weighted mean differences (MD) and corresponding 95% confidence intervals (CI).
RESULTS

• **12 studies** were included reporting the outcomes of **1456 patients**.

• Eight studies were the long-term follow-up reports of FDA IDE trials.

• Follow-Up:
  • 5 years: 1 study
  • 5 and 7 years: 1 study
  • 7 years: 4 studies
  • 10+ years: 6 studies

• **8 studies** reported adequate data for pooled estimate calculation (mean and SD data from at least 2 time points) and were included for Meta-Analysis
RESULTS

• Flexion/Extension – **Preoperatively and One Year**
  - 4 studies included reporting on **708 patients**
  - There was no difference found in flexion/extension ROM preoperatively and at 1 year postoperatively.
  - Sensitivity analysis found that one study significantly influenced the results.
    - By excluding this study, ROM on flexion and extension **improved at 1 year** when compared to baseline preoperative ROM ($p < .001$)

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>1-Year</th>
<th></th>
<th>Pre-Op</th>
<th></th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Phillips et al. 2015</td>
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<td>218</td>
<td>7.9</td>
<td>4.7</td>
</tr>
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<td>Vaccuro et al. 2018</td>
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<td>240</td>
<td>8.5</td>
<td>4.82</td>
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<td>10.82</td>
<td>5.853</td>
<td>164</td>
<td>8.21</td>
<td>4.49</td>
</tr>
</tbody>
</table>

**Total (95% CI)**

- Heterogeneity: Tau² = 4.64; Chi² = 75.64, df = 3 ($p < 0.00001$); I² = 96%
- Test for overall effect: Z = 0.83 ($p = 0.41$)

**B**

<table>
<thead>
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<th></th>
<th>Pre-Op</th>
<th></th>
<th>Mean Difference</th>
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</tr>
</tbody>
</table>

**Total (95% CI)**

- Heterogeneity: Tau² = 0.39; Chi² = 5.75, df = 2 ($p = 0.06$); I² = 65%
- Test for overall effect: Z = 4.28 ($p < 0.0001$)

![Graph](image1.png)

![Graph](image2.png)
RESULTS

- Flexion/Extension – **Preoperatively and Long-Term Follow-Up**

- 7 studies included reporting on **760 patients**

- The pooled estimate of the effect size indicated no significant difference (p = .760)

![Results Table and Diagram]

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Mean Long-Term</th>
<th>SD Long-Term</th>
<th>Total Long-Term</th>
<th>Mean Pre-Op</th>
<th>SD Pre-Op</th>
<th>Total Pre-Op</th>
<th>Weight IV, Random, 95% CI</th>
<th>Mean Difference IV, Random, 95% CI</th>
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</thead>
<tbody>
<tr>
<td>Dejaegher et al. 2017</td>
<td>8.59</td>
<td>5.85</td>
<td>72</td>
<td>8.79</td>
<td>5.6</td>
<td>92</td>
<td>13.5%</td>
<td>-0.20 [-1.97, 1.57]</td>
</tr>
<tr>
<td>Gornet et al. 2019</td>
<td>6.85</td>
<td>4.96</td>
<td>120</td>
<td>5.67</td>
<td>3.69</td>
<td>280</td>
<td>15.6%</td>
<td>1.18 [0.19, 2.17]</td>
</tr>
<tr>
<td>Han et al. 2019</td>
<td>9.5</td>
<td>5.4</td>
<td>66</td>
<td>9.5</td>
<td>4.5</td>
<td>66</td>
<td>13.7%</td>
<td>-0.50 [-2.20, 1.20]</td>
</tr>
<tr>
<td>Phillips et al. 2015</td>
<td>5.2</td>
<td>3.8</td>
<td>163</td>
<td>7.9</td>
<td>4.7</td>
<td>218</td>
<td>15.9%</td>
<td>-2.70 [-3.55, -1.85]</td>
</tr>
<tr>
<td>Radcliff et al. 2017</td>
<td>10.2</td>
<td>6.3</td>
<td>84</td>
<td>8.21</td>
<td>4.49</td>
<td>164</td>
<td>14.3%</td>
<td>1.99 [0.48, 3.50]</td>
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<tr>
<td>Song et al. 2018</td>
<td>8.5</td>
<td>5.3</td>
<td>71</td>
<td>9.7</td>
<td>4.5</td>
<td>71</td>
<td>14.0%</td>
<td>-1.20 [-2.82, 0.42]</td>
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<tr>
<td>Zhao et al. 2019</td>
<td>6.6</td>
<td>3.5</td>
<td>27</td>
<td>6.6</td>
<td>3.9</td>
<td>27</td>
<td>12.9%</td>
<td>0.00 [-1.98, 1.98]</td>
</tr>
</tbody>
</table>

**Total (95% CI)**: 603, 918, 100.0%

Heterogeneity: $\tau^2 = 3.34$; $\chi^2 = 48.04$, df = 6 ($P < 0.00001$); $I^2 = 88$

Test for overall effect: $Z = 0.30$ ($P = 0.76$)
RESULTS

• Flexion/Extension – **One Year and Long-Term Follow-Up**

  • 3 studies included reporting on **524 patients**

  • The pooled estimate of the effect size demonstrated significantly **greater ROM** on flexion and extension **at 1 year** postoperatively **than with long-term follow-up** *(p = .004)*

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Long-Term Mean</th>
<th>SD</th>
<th>Total</th>
<th>1-Year Mean</th>
<th>SD</th>
<th>Total</th>
<th>Weight</th>
<th>IV, Fixed, 95% CI</th>
<th>Mean Difference</th>
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<tr>
<td>Cornet et al. 2019</td>
<td>6.85</td>
<td>4.96</td>
<td>230</td>
<td>7.85</td>
<td>4.32</td>
<td>280</td>
<td>40.8%</td>
<td>-1.00 [-1.82, -0.18]</td>
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<tr>
<td>Phillips et al. 2015</td>
<td>5.2</td>
<td>3.8</td>
<td>163</td>
<td>5.8</td>
<td>3.9</td>
<td>218</td>
<td>44.7%</td>
<td>-0.60 [-1.38, 0.18]</td>
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<tr>
<td>Radcliff et al. 2017</td>
<td>10.2</td>
<td>6.3</td>
<td>141</td>
<td>10.82</td>
<td>5.853</td>
<td>164</td>
<td>14.4%</td>
<td>-0.62 [-1.99, 0.75]</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>534</strong></td>
<td></td>
<td><strong>662</strong></td>
<td><strong>100.0%</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>-0.77 [-1.29, -0.24]</strong></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Chi² = 0.53, df = 2 *(P = 0.77)*; I² = 0%

Test for overall effect: Z = 2.88 *(P = 0.004)*

Favours 1-Year vs. Long-Term
CONCLUSION

This study found that range of motion on flexion and extension at the operative level significantly decreased with long-term follow-up when compared to the early postoperative period.

However, range of motion over the long-term remained comparable to baseline function.

Given the young average demographics of patients undergoing cervical TDA, additional studies investigating device-specific range of motion and outcomes with further longitudinal follow-up are necessary.
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