Department of Orthopedic Surgery

# Risk Benefit Assessment of Major versus Minor Osteotomies for Flexible and Rigid Cervical Deformity Correction

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# Introduction and Study Objective

ISSG INTERNATIONAL SPINE STUDY GROUP

- Cervical Deformity (CD)
  - Vast range of etiologies
- Surgeons continue to operate on more **challenging** cases and **higher risk** patients
  - Osteotomies are common for sagittal malalignment correction

**OBJECTIVE:**

**Investigate the risks and benefits of performing a major osteotomy for CD correction.**

# **Materials and Methods:** Design and Inclusion Criteria

- **Retrospective review of prospective, multicenter CD database** (2013-2017 at 13 centers)
  - Cervical deformity, defined radiographically as
    - C2-7 sagittal Cobb angle ≥ 10º
    - C2-7 coronal Cobb angle ≥ 10º
    - C2-7 SVA ≥ 4cm
    - Chin-brow vertical angle ≥ 25º

- **Inclusion criteria:**
  - Patients ≥ 18 years old
  - Patients had available preoperative and 1-year follow up radiographic sagittal imaging
  - **Excluded**: Patients with active tumors or infections


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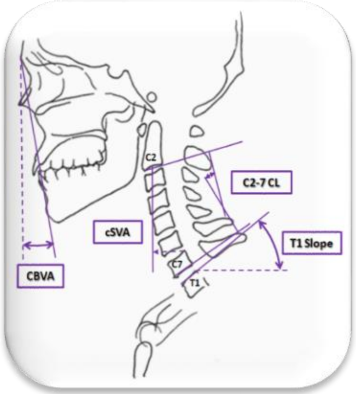
# **Methods:** Radiographic Parameters

- Cervical anterior-posterior and lateral images analyzed with SpineView®

- Alignment Targets of Interest Included:
  - **CERVICAL ALIGNMENT:** Cervical Sagittal Vertical Angle (**cSVA**), C-C7 Lordosis (**CL**), T1 Slope Minus CL (**TS-CL**) and **CBVA**
  - **GLOBAL RADIOGRAPHIC:** Sagittal Vertical Angle (**SVA**), Pelvic Incidence (**PI**), Lumbar Lordosis (**LL**), as well as mismatch (**PI-LL**), Pelvic Tilt (**PT**)



# **Methods:** Data collection and Patient Stratification

- Assessment of patient **demographics** including age, sex, BMI, prior cervical surgery and CCI
- **Surgical data collected**: Op time, EBL, Approach, BMP-2, osteotomy use and number of osteotomies, levels fused, and instrumentation used
- **Patient stratification**
  - Based on either
    - Major osteotomy (MAJ)
      1. Pedicle subtraction osteotomy
      2. Vertebral column
    - Minor osteotomy (MIN)

Flexibility of deformity was assessed with CL and T1S change greater than 10° between flexion and extension

# **Methods:** Statistical Analysis

- PSM controlling for baseline **cSVA** and **T1S** to generate two groups
    1. Major osteotomy
    2. Minor osteotomy
- **Independent t-tests** for continuous variables and **Chi-squared tests** for categorical variables were used to assess differences
- A sub-analysis was performed on patients with **fixed/rigid** (<10° difference between flexion and extension) and **non-fixed/flexible** (>10° change between flexion and extension) alignment for cervical lordosis for both major and minor deformities
- Two-sided p-values less than 0.05 were considered statistically significant. All analyses were performed using SPSS version 23.

# **Results:** Cohort Overview After PSM


| Baseline Demographics Factors | MAJ (N=19) Mean (SD) | MIN (N=19) Mean (SD) | P-Value |
|---|---|---|---|
| **Age (years)** | 60.5 (9.7) | 59.8 (12.0) | 0.844 |
| **Gender (% Female)** | 63.2% | 52.6% | 0.372 |
| **BMI (kg/m$^2$)** | 28.3 (7.1) | 31.6 (8.5) | 0.221 |
| **Frailty Score** | 0.417 (0.10) | 0.417 (0.11) | 0.997 |
| **Smoking Status** | 27.8% | 31.3% | 0.560 |
| **Diabetes** | 10.5% | 0.0% | 0.243 |
| **Osteoporosis** | 15.8% | 10.5% | 0.500 |
| **Depression** | 26.3% | 36.8% | 0.364 |

Similar Demographics $p>0.05$

# **Results:** Surgical factors compared between major (MAJ) and minor (MIN) osteotomy patients

| **Surgical Factors** | MAJ (N=19) | MIN (N=19) | P-Value |
|---|---|---|---|
| **Levels Fused** | 10.6 (3.1) | 7.1 (2.7) | **<0.001** |
| **Estimated Blood Loss (cc)** | 1442.1 (968.9) | 802.6 (837.2) | **0.036** |
| **Operative Time (min)** | 382.8 (185.6) | 415.1 (346.0) | 0.722 |
| **Intra-Operative Major Complication Rate** | 1 (5.3%) | 0 | 0.500 |
| **Intra-Operative Any Complication Rate** | 3 (15.8%) | 2 (10.5%) | 0.500 |
| **Major Complication Rate** | 4 (21.1%) | 4 (21.1%) | 0.654 |

MAJ patients underwent more invasive surgeries with more levels fused and higher blood loss



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# **Results:** Health Related Quality of Life Scores MAJ vs MIN

**NDI**

MAJ had **lower rates of reaching 1Y MCID** for **NDI** (p=0.001)

**mJOA**

Similar rates of reaching 1Y MCID (p=0.346)

**EQ5D**

Similar rates of reaching 1Y MCID (p=0.346)

# **Results:** Radiographic Alignment between MAJ and MIN

| Radiographic Parameter | Pre-Operative | | | Post-Operative | | |
|---|---|---|---|---|---|---|
| | MAJ (N=19) | MIN (N=19) | P | MAJ (N=19) | MIN (N=19) | P |
| **Pelvic Tilt (°)** | 20.27 (15.09) | 19.21 (13.78) | 0.822 | 18.76 (12.69) | 20.06 (10.77) | 0.736 |
| **PI-LL (°)** | -1.39 (23.21) | -0.58 (21.42) | 0.912 | -2.83 (22.67) | 0.09 (15.04) | 0.643 |
| **T4-T12 Thoracic Kyphosis (°)** | -41.43 (22.9) | -42.69 (15.55) | 0.843 | -46.78 (19.43) | -47.72 (13.14) | 0.863 |
| **SVA (mm)** | -7.04 (68.82) | 2.44 (98.08) | 0.732 | 11.65 (82.54) | 18.86 (79.45) | 0.788 |
| **T1 Slope (°)** | 41.89 (18.9) | 34.87 (16.8) | 0.234 | 40.31 (14.8) | 38.78 (13.9) | 0.749 |
| **TS-CL (°)** | 38.31 (19.05) | 45.5 (18.94) | 0.251 | 32.92 (11.81) | 29.58 (15.32) | 0.469 |
| **C2-C7 Lordosis (°)** | 3.59 (22.72) | -10.62 (25.11) | 0.076 | 7.91 (20.8) | 9.21 (18.76) | 0.846 |
| **cSVA (mm)** | 59.26 (17.82) | 56.81 (17.52) | 0.672 | 49.65 (13.73) | 45.32 (13.02) | 0.339 |
| **C2-T3 Angle (°)** | -19.56 (24.79) | -24.16 (22.53) | 0.554 | -5.97 (23.63) | -1.58 (19.51) | 0.547 |
| **C2-T3 SVA (mm)** | 102.97 (32.91) | 93.67 (29.62) | 0.336 | 86.1 (21.35) | 86.36 (20.16) | 0.970 |
| **C2 Slope (°)** | 40.02 (21.79) | 46 (19.49) | 0.378 | 31.69 (13.75) | 29.96 (15.94) | 0.730 |

****No significance**

# **Results:** Flexible and Rigid Cervical Deformities

- **MAJ**: 9 (56.3%) patients with flexible deformity and 7 (43.8%) MAJ patients with rigid deformity
- **MIN**: 13 (81.3%) of patients had flexible deformities and 3 (18.3%) had rigid deformities

- **MAJ flexible** trended towards **higher complication** (78% vs 43%, p=0.182) and **higher reoperation** (44% vs 0%, p=0.069) than fixed deformities

- **Rigid MAJ** trended towards greater improvement in **mJOA** than MIN patients (57.1% improve vs 0.0%, p=0.167) and **NDI** (71.4% vs 66.7%, p=0.708)

- **MAJ rigid** trended towards **lower complication** (42.9% vs 100%, p=0.167) as well as **lower reoperation** (0% vs 33.3%, p=0.30) than MIN rigid

- **MIN rigid** more commonly developed **post-operative DJK** (12.5% vs 6.3%), p=0.563

# Conclusion

- Selecting the appropriate surgery for the appropriate patient is paramount for deformity surgery.
- Overall, the same correction was achieved with and without osteotomies
  - Those who did not receive osteotomies had improved NDI scores.
- While the clinical benefit of correction needs further investigation, some rigid deformities require osteotomy to obtain correction.

**This study suggests patients with rigid cervical deformity may benefit from osteotomies as part of their correction, while those with flexible cervical deformity may benefit from a correction without osteotomies.**

**Conflict of Interest Statement:**

Peter G Passias MD – Reports personal consulting fees for Spinewave, Zimmer Biomet and Medicrea outside the submitted work.

Virginie Lafage PhD - Depuy Synthes paid lectures; Nuvasive paid lectures; K2M paid lectures; Medtronic paid lectures; Nemaris Board member and shareholder.

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Chris Shaffrey
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