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Rigid segmental cervical spine instrumentation is safe and efficacious in younger children

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Rigid Segmental Cervical Spine Instrumentation is Safe and Efficacious in Younger Children --Manuscript Draft--

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Abstract:	<p>Background: The utilization of cervical spine instrumentation in the young pediatric patient is not well reported. This study presents outcomes and complications of cervical spine instrumentation in patients who underwent cervical spine fusion surgery before age 10.</p> <p>Methods: Radiographic and clinical data were collected on all patients who underwent cervical spine surgery with instrumentation at a single institution between January 1, 2006 and March 31, 2015. Patients were ≤ 10 years of age at the time of surgery with any cervical spine deformity/injury diagnosis. Patient demographics, details on cervical spine diagnosis, procedural data, imaging data, and post-operative follow up data were collected.</p> <p>Results: Twenty children met the criteria and were included in the study with a mean follow-up of 10.6 months (3 mo to 2 years). Initial indication for cervical spine correction surgery included: deformity (7 cases), trauma (6 cases), instability (3 cases), stenosis (2 cases), rotary subluxation (1 case), and infection (1 case). Fifteen cases were treated with adult 3.5mm cervical spine instrumentation, 3 with wiring (1 sublaminar and 2 spinous process), and 2 with cannulated screws. Postop immobilization included 16 Halo fixation, 3 collars, and 1 CTO. Overall there were 5 complications related to the surgery. Two patients who had wiring (1 sublaminar and 1 spinous process) developed a non-union and required revision surgery (1 with cannulated screws and 1 with 3.5mm segmental cervical spine instrumentation). One patient developed a postop infection that required incision and drainage. Five patients developed superficial pin infections for their Halo. Two deformity patients experienced neurological complications that were likely unrelated to the cervical instrumentation.</p>

Conclusions: Rigid segmental fixation can be safe and efficacious when used in pediatric cervical spine patients. Whether used with Halo or orthosis, patients experience minimal to no complications from the instrumentation and achieve successful fusion. Cervical spine wiring had a high risk of non-union requiring revision surgery. The incidence of wound infection was low with one in 20 cases.

Level of Evidence: Therapeutic-IV

To: Journal of Pediatric Orthopaedics

We are submitting an original manuscript for review entitled “Rigid Segmental Cervical Spine Instrumentation is Safe and Efficacious in Younger Children”. This manuscript is not under review elsewhere and all authors meet the authorship requirements as stated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals.

Thank you for the opportunity to submit our work to the Journal of Pediatric Orthopaedics.

Best Regards,

Burt Yaszay, MD

Rigid Segmental Cervical Spine Instrumentation is Safe and Efficacious in Younger Children

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*IRB approval was obtained for this study.

1 **Rigid Cervical Spine Instrumentation is Safe and Efficacious in Younger Children**

2 **Abstract**

3
4 **Background:** The utilization of cervical spine instrumentation in the young pediatric patient in
5 not well reported. This study presents outcomes and complications of cervical spine
6 instrumentation in patients who underwent cervical spine fusion surgery before age 10.
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8 **Methods:** Radiographic and clinical data were collected on all patients who underwent cervical
9 spine surgery with instrumentation at a single institution between January 1, 2006 and March 31,
10 2015. Patients were ≤ 10 years of age at the time of surgery with any cervical spine
11 deformity/injury diagnosis. Patient demographics, details on cervical spine diagnosis, procedural
12 data, imaging data, and post-operative follow up data were collected.
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14 **Results:** Twenty children met the criteria and were included in the study with a mean follow-up
15 of 10.6 months (3 mo to 2 years). Initial indication for cervical spine correction surgery included:
16 deformity (7 cases), trauma (6 cases), instability (3 cases), stenosis (2 cases), rotary subluxation
17 (1 case), and infection (1 case). Fifteen cases were treated with adult 3.5mm cervical spine
18 instrumentation, 3 with wiring (1 sublaminar and 2 spinous process), and 2 with cannulated
19 screws. Postop immobilization included 16 Halo fixation, 3 collars, and 1 CTO. Overall there
20 were 5 complications related to the surgery. Two patients who had wiring (1 sublaminar and 1
21 spinous process) developed a non-union and required revision surgery (1 with cannulated screws
22 and 1 with 3.5mm segmental cervical spine instrumentation). One patient developed a postop
23 infection that required incision and drainage. Five patients developed superficial pin infections
24 for their Halo. Two deformity patients experienced neurological complications that were likely
25 unrelated to the cervical instrumentation.
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27 **Conclusions:** Rigid segmental fixation can be safe and efficacious when used in pediatric
28 cervical spine patients. Whether used with Halo or orthosis, patients experience minimal to no
29 complications from the instrumentation and achieve successful fusion. Cervical spine wiring had
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34

35 **Introduction**

36 Pediatric cervical spine injuries account for up to 80% of pediatric vertebral injuries (1).
37 Major trauma to the head or neck is the most common mechanism of injury and includes motor
38 vehicle crashes, sports-related injuries, falls, and other sources of blunt trauma (2,3). Other
39 conditions may also predispose certain children to cervical spine deformity, including Torticollis,
40 Down Syndrome, Klippel-Feil Syndrome, Neurofibromatosis, and other cervical spine
41 syndromes (4). Surgical intervention may be required to stabilize the cervical spine or repair
42 injuries (4).

43 Cervical spinal instrumentation is now commonly used in pediatric spinal deformity
44 correction surgery (4,5,6). Despite its widespread use, a paucity of research exists regarding the
45 safety and efficacy of spinal implants in the pediatric population (4,5,6). Previously, Hedequist
46 et al. reported on the safety of modern cervical spine implants in children greater than 6 years of
47 age (5). In a series of 25 cases, three complications were reported (1 deep infection, 1 superficial
48 wound infection, and 1 transient radiculopathy) (5). No implant related complications were
49 reported and there were no revisions or reoperations related to the implants.

50 Hwang et al. reviewed literature on pediatric cervical spine fusion and analyzed 914
51 patients with a mean age of 8.3 years (7). In 285 occipitocervical fusions, screw instrumentation
52 had a 99% fusion rate, whereas wiring had a 95% fusion rate ($p < 0.05$) (7). In 181 cervical
53 fusions below the occipitocervical junction, screw instrumentation had a 99% fusion rate and
54 wiring had an 83% fusion rate ($p < 0.05$) (7). Wiring was associated with a higher complication
55 rate in both groups ($p < 0.05$) (7).

56 Mazur et al. reported on 127 occipitocervical fusions in patients with a mean age of 7.7
57 years (range 1.2 – 17.9 years) (8). 84.3% of the cases achieved successful fusion after one

58 procedure, whereas 15.7% involved surgical failure and required revision surgeries (8). Four
59 cases involved immediate failure and required immediate reoperation within the first 48hrs
60 postoperatively (8).

61 To date, no literature exists regarding the safety and efficacy of modern spine
62 instrumentation in children under 10 years of age. The purpose of this study was to evaluate
63 current surgical techniques used to correct cervical spinal pathologies in the pediatric population
64 and to identify the most common complications associated with cervical spinal implants. The
65 study presents an in-depth analysis of patients' surgical outcomes based on the type of spinal
66 deformity, peri- and post-operative complications, and loss of correction over time. This
67 institutional review provides new information on the use of spinal implants in the young
68 pediatric population (under 10 years of age) and adds to the evidence in support of the safety of
69 pediatric cervical spinal implants.

70 **Materials and Methods**

71 Institutional Review Board approval was obtained for this study. A retrospective review
72 of all patients who underwent cervical spine surgery with instrumentation at a single pediatric
73 institution between January 1, 2006 and March 31, 2015 was conducted. The electronic medical
74 record system and the ICD-9 codes 733.82, 756.19, 805.00, 805.02, 805.07, 806.00, 839.00,
75 839.01 and 996.49 were employed to identify eligible patients. Initial indication for cervical
76 spine correction surgery was consolidated into 1) trauma, 2) deformity, 3) rotary subluxation, 4)
77 stenosis, and 5) infection. Patients were ≤ 10 years of age at the time of surgery with any
78 cervical spine deformity/injury diagnosis. Patients who underwent surgery without
79 instrumentation or only in the thoracic or lumbar spine were excluded. The patient
80 demographics, details on cervical spine diagnosis, procedural approach data, fusion levels, size

81 and type of instrumentation, neuromonitoring data, imaging obtained, post-op immobilization
82 data, and post-op follow up data was collected. Reports of complications were collected and
83 included halo pin infections, surgical site infections, instrumentation failure-related
84 complications, and neurological complications. Instrumentation failure-related complications
85 were defined as a complication associated with an implanted screw or wire, such as breakage of
86 wire or incomplete fusion requiring revision surgery. Reports of any failed initial surgery and
87 reoperations were also recorded.

88 **Results**

89 Twenty patients who underwent cervical spine surgery with instrumentation at a single
90 institution between January 1, 2006 and March 31, 2015 were identified. There were 12 female
91 and 8 male patients. Mean age at time of surgery was 5.25 ± 2.47 years (range 1.5 to 9 years).
92 Initial indication for cervical spine correction surgery included: deformity (7 cases), trauma (6
93 cases), instability (3 cases), stenosis (2 cases), rotary subluxation (1 case), and infection (1 case).
94 The mean follow-up for all 20 cases was 10.6 months (3 mo to 2 years). Two patients underwent
95 revision surgery, which included repeat cervical fusion with reduction and replacement of screws
96 or wires for breakage.

97 *Procedural Data*

98 There were 19 posterior approaches, one anterior approach, two combined anterior and
99 posterior approaches. Fifteen cases were treated with adult 3.5mm cervical spine
100 instrumentation, three with wiring (one sublaminar and two spinous process), and two with
101 cannulated screws. There were a total of 107 vertebrae fused (fusion level ranged from occiput
102 to L2). The average number of levels fused per surgery was 4.84 (range 2 – 16). Seventeen
103 cases included a decompression. Ten cases included a laminectomy.

104 Postop immobilization included 16 Halo fixations, three collars, and one Cervical
105 Thoracic Orthosis (CTO). The average duration of wear for the Halo fixation was 11.8 weeks
106 (range 6 – 17 weeks). The average duration for the collars was 11 weeks (range 8 – 13 weeks).
107 The one CTO was worn for six weeks.

108 *Complications Data*

109 In total, there were 5 complications related to the surgery. Two patients (10%) required a
110 revision surgery, both of which had wiring (one sublaminar and one spinous process) and
111 developed a non-union. One patient developed a postop surgical site infection that required
112 incision and drainage. Five patients developed superficial pin infections for their Halo.

113 One deformity patient experienced a perioperative complication that involved a
114 traumatic duratomy. A lumbar drain was placed to manage the CSF leak, CSF cultures were
115 monitored, and the drain was discontinued after five days. Another deformity patient who
116 underwent a C7 to L2 fusion experienced a postoperative neurologic deficit of no motor or
117 sensory function in the lower extremities. Following revision surgery including thoracic screw
118 repositioning and a wide decompression was performed and the patient demonstrated recovery
119 with complete resolution of his neurologic deficit by 6 weeks postoperative.

120 A final neurological complication occurred postoperatively as persistent left arm
121 weakness and loss of finger intrinsic control. This likely resulted from some traction injury to
122 the brachial plexus following correction of a cervicothoracic congenital deformity. There was no
123 indication to suggest this results from the cervical spine instrumentation. At six month follow
124 up, the patient was undergoing occupational therapy and wearing a metacarpal phalangeal joint
125 blocking splint for some improvement in left hand function.

126 **Discussion**

127 Apart from this study, no other literature has been published on the safety and efficacy of
128 modern spinal instrumentation in children under 10 years of age. The most common indications
129 for surgery were deformity, trauma, instability, stenosis, rotary subluxation, and infection,
130 respectively. This was consistent with previous studies that also reported congenital anomalies
131 as the most common surgical indication (4,7). Hwang et al. reviewed pediatric cervical spine
132 fusion literature from 2007 to 2011 and reported 55% of cases had congenital abnormality as the
133 indication for surgery. Similarly, Mazur et al. reported congenital spinal anomaly as the most
134 common indication (29.1%) in a study population of 127 occipitocervical fusions (8). Chiari
135 malformation was the second most common indication (19.7%), followed by trauma (17.3%),
136 Down syndrome (16.5%), skeletal dysplasia (14.2%), and os odontoideum (3.1%) (8).
137 Interestingly, Mazur et al. performed a subgroup analysis and found that congenital vertebral
138 anomaly and skeletal dysplasia patients were at higher risk for instrumentation-related
139 complications and surgical failure (8). The diversity of diagnoses was also similar to previous
140 studies on pediatric cervical spine instrumentation surgeries (7, 8, 9, 10).

141 In our study of 20 cases, there were five complications related to surgery. Two patients,
142 both of whom had wiring, developed a non-union and subsequently underwent revision surgery.
143 One patient had a surgical site infection requiring incision and drainage, and five had superficial
144 Halo pin infections. These findings were consistent with prior studies that reported similar rates
145 and types of complications (5, 7, 8, 9). Hedequist et al. reviewed 25 cervical spine correction
146 surgeries in children greater than 6 years with an average patient age of 12 years and reported
147 complications in 3 cases (1 deep infection, 1 superficial wound infection, 1 transient
148 radiculopathy) (5). No cases of instrumentation failure requiring reoperation were reported (5).
149 Brockmeyer et al. reported two complications in 24 cases of pediatric cervical spine screw

150 fixation in patients 16 years or younger. One complication involved hardware failure and
151 reoperation (9). The other complication was a superficial wound site infection that resolved with
152 antibiotic treatment (9). Hwang et al. reported postsurgical complications in 26% of the 914
153 patients included in the literature they reviewed (7). Five percent of the 914 patients had
154 multiple complications (7).

155 Hwang et al. also reported surgeries involving wiring were associated with a significantly
156 higher complication rate (50%) than surgeries involving screws (14%). This was consistent with
157 our data, as both patients who had instrumentation failure and required repeat operation had
158 wiring placed in their initial surgery.

159 A limitation of this study was the lack of consistent long-term follow up. One patient
160 transferred care to a different pediatric hospital in the immediate postoperative period and did not
161 return for follow up at our institution. Two patients died of causes unrelated to their surgery at
162 thirteen months and four months after surgery. We expect some may have followed up in their
163 home locations, as our institution serves a vacationing population. The small number of patients
164 and the retrospective nature of this study also limited our analyses.

165 This analysis of twenty cervical spine fusion patients found that the use of rigid
166 segmental instrumentation was both safe and efficacious when used in the pediatric population.
167 Whether used with Halo or orthosis, patients experience minimal to no complications from the
168 instrumentation and achieve successful fusion. Cervical spine wiring on the other hand had a
169 high risk of non-union requiring revision surgery.

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