

Clinical Study

The safety of spinal pedicle screws in children ages 1 to 12

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Abstract

BACKGROUND CONTEXT: Pedicle screws have shown to be a safe and effective method of spinal fixation, offering superior multiplanar correction compared with hooks or sublaminar wires in selected situations. Though only food and drug administration (FDA) approved in the adolescent population, they are commonly used in an off-label manner in the preadolescent population.

PURPOSE: To determine if the complication rate of the off-label use of pedicle screws for spinal fixation in the preadolescent 0- to 12-year-old population is comparable with the complication rate in the FDA-approved 13- to 18-year-old population.

STUDY DESIGN/SETTING: Retrospective medical record and radiograph review.

PATIENT SAMPLE: A total of 726 pediatric patients who underwent a spinal fusion procedure at a single tertiary institution between January 2003 and December 2008 were reviewed.

OUTCOME MEASURES: Incidence of instrumentation failure, infection, neurological complication, and total complications.

METHODS: The study population was divided into two groups based on age: the younger group included 0- to 12-year olds and the older group included 13- to 18-year olds at the time of surgery. Groups were further subdivided based on diagnosis: "A," neuromuscular scoliosis; "B," idiopathic scoliosis, and "C," other spinal deformities. Rates of neurovascular complications, infections, and instrumentation complications were compared statistically between the younger and the older groups. Only patients with greater than or equal to 1-year follow-up and greater than or equal to 2-year follow-up were included in the calculations for infection and instrumentation complication rates, respectively.

RESULTS: There were 206 patients (33% males, 67% females) in the younger group (0 to 12 years) and 520 (41% males, 59% females) in the older group (13 to 18 years). Overall, younger group had a 13.6% complication rate compared with 16.9% in the older group. Younger subjects showed a 13.4% complication rate because of instrumentation-related complications, 0.5% for neurovascular complications, and an infection rate of 9.2%. The older group showed a 15.4% complication rate because of instrumentation-related complications, 1.92% for neurovascular complications, and an infection rate of 11.0%. Complication rates were statistically insignificant between the two groups. Other complications in the younger group included one patient with aspiration pneumonia, two with ileus, and one with pulmonary and other complications in the older group included one patient with aspiration pneumonia, two with ileus, three with superior mesenteric artery syndrome, and three with wound dehiscence.

CONCLUSIONS: The complication rates in the young pediatric population associated with the off-label use of pedicle screws for spinal fusions are not statistically different from the complication

FDA device/drug status: Not approved for this indication (lumbar and thoracic pedicle screws for subjects less than 13 years of age); Approved (lumbar and thoracic pedicle screws for subjects 13+ years of age).

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Approval was obtained from the Colorado Multiple Institutional Review Board before the initiation of this study.

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rates associated with the FDA-approved adolescent population. © 2013 Elsevier Inc. All rights reserved.

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Introduction

Transpedicular instrumentation was first introduced by Roy-Camille who pioneered the use of lumbar pedicle screws in the 1960s, later expanding their use to the thoracic spine for trauma and tumor fixation [1]. Harrington and Tullos [2] in 1969 were among the first to report on the use of pedicle screws in two children with symptomatic spondylolisthesis in the lumbosacral region. The use of pedicle screws in the adult and adolescent lumbar spine has gained quick popularity; however, inherent risks involved with their use in the thoracic spine have been the focus of the recent studies. Collectively, results have shown that there is no increase in neurological or vascular complications when comparing the use of pedicle screws with hooks or sublaminar wires in the thoracic spine, even in the treatment of large magnitude curves; however, rare but major risks are associated with pedicle screw use such as aortic compromise and impingement of the spinal canal because of malpositioned screws [3–12]. Other less serious but more commonly reported complications associated with pedicle screw use include fractured pedicles; malposition resulting in pedicle breach, aortic abutment, canal intrusion with the potential for dural tears with or without neurological detriments; infection; required revision; and screw pullout and/or instrumentation pain/prominence [4,6,9,11,12]. Preliminary data have provided the evidence that pedicle screws may offer a safer alternative to hooks and sublaminar wires because with less freedom to move they do not intrude on the spinal canal [10,11]. For the treatment of spinal deformities in both the adult and the adolescent patients, selective evidence supports the claim that pedicle screws may offer superior multiplanar correction (coronal, sagittal, and rotational), potentially shorter fusions, and a lower rate of decompensation and implant failure or pullout compared with traditional hooks and sublaminar wires [3,7,8,10,12–19].

In the pediatric population, pedicle screws for spinal fixation procedures are currently only food and drug administration (FDA) approved in the adolescent group (13 to 18 years old), an arbitrarily assigned designation based on little empirical evidence because of the lack of data. However, they are commonly used in the preadolescent group (0 to 12 years old) in an off-label manner, the safety and effectiveness of which have been supported by several recent studies [20–23]. The purpose of this study is to compare the rate of complications associated with the use of pedicle screws in the thoracic and lumbar spine in the adolescent population with their off-label use in the preadolescent population in an effort to evaluate the FDA's current designations.

Materials and methods

This is a retrospective medical record review of patients less than 19 years old who underwent thoracic, thoracolumbar, and lumbar spinal fusion procedures (anterior, posterior, or anterior/posterior) between January 2003 and December 2008 for the treatment of spinal deformities and traumatic injuries at a single tertiary institution. In this study group, all surgeries were performed by senior-level spine surgeons with extensive experience in pediatric spinal deformity. Free-hand technique was applied for pedicle screw placement, and intraoperative fluoroscopy was used to assess the accuracy of screw placement. Patients were only excluded if their surgical procedure did not use pedicle screws. Approval was obtained from the local institutional review board before study initiation.

The population was divided into two groups: the younger group included patients 0 to 12 years old at the time of surgery and the older group included patients 13 to 18 years old at the time of surgery. Each group was further subdivided based on diagnosis: “A,” neuromuscular scoliosis; “B,” idiopathic scoliosis; and “C,” other spinal deformities including congenital scoliosis, kyphosis, syndromic scoliosis, and trauma-related cases, as these individual populations did not reach statistical significance on their own.

Medical records were reviewed for neurovascular complications, evidence of infection, complaints of pain or instrumentation prominence, and other complications (pulmonary, gastrointestinal, noninfection wound related, or other complications attributable to surgery), in addition to diagnosis, procedure type, age at time of surgery, length of stay, time of follow-up, and estimated blood loss. Existing anteroposterior and lateral radiographs of the thoracolumbar spine (taken routinely as part of the standard of care during clinical follow-ups) were reviewed for the evidence of instrumentation failure (loosening, pullout, and/or breakage), the number of levels fused, and the instrumentation type and counts (wires, hooks, rods, screws, and cross-links). Patient data were deidentified.

Complications were categorized as instrumentation related, neurovascular, or wound infection. Instrumentation complications included complaints of pain/prominence and instrumentation failure, which were further divided into one of the following categories: hook failure, sacral screw failure, pain/prominence, broken rod, wire failure, or disconnected screw. Only patients who had at least a 2-year follow-up were included when calculating instrumentation failure rates. Neurovascular complications included intraoperative motor loss, postoperative deficits, dural tears, strokes, or excessive bleeding. Both superficial and deep wound infections were taken into account when evaluating

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