The Most Recent Evidence for the Radiographic Diagnosis of Cervical Arthrodesis – When will the Food and Drug Administration Change the Spinal Investigational Device Exemptions Guidelines.

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Introduction

Medical device trials rely on the Food and Drug Administration (FDA) Investigational Device Exemptions document as a guide for fusion assessment. Unfortunately, the methodology of grading cervical spinal arthrodesis suggested by this fourteen-year-old document is flawed and antiquated according to more recent data. Lax fusion thresholds can potentially have a significant impact on reported rates of fusion and pseudoarthrosis. The purpose of this abstract is to review the current literature for assessing cervical segmental fusion and provide a new perspective on the current FDA requirements.

Methods

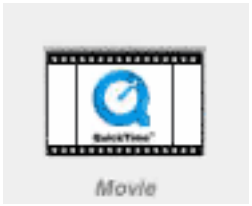
A literature review was undertaken to elucidate new guidelines for what constitutes a fused cervical segment based upon the most recent scientific literature.

Results

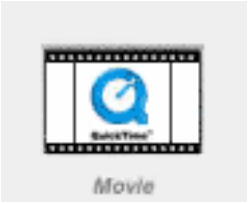
The current FDA guidelines state that cervical arthrodesis can be identified by: evidence of bridging, trabecular bone, translational motion less than three millimeters, and angular motion less than five degrees on flexion-extension imaging. In 2009, Kaiser et al concluded that pseudoarthrosis is best detected by intra-spinous process motion of greater than two millimeters. In addition, they suggested that all fusion assessments be performed by blinded observers as radiographic diagnoses diverge between the operating surgeon and a blinded radiologist when patients show clinical improvement.

Results (CONTINUED)

More recent data has shown that with validated computerized measurement systems, intervertebral motion less than or equal to one millimeter has been shown to be as reliable as thin-slice CT scans in assessing arthrodesis.



Fused cervical level after a one level anterior cervical discectomy and fusion. Note the paucity of movement between the spinous processes at the fused levels.



Pseudoarthrosis demonstrated by greater than 2 mm of motion between spinous processes at instrumented levels seen with software stabilization of the caudal instrumentation level.

Conclusions

Recent studies have set forth new criteria by which cervical segmental fusion should be assessed: interspinous process motion less than two millimeters and/or intervertebral motion less than one degree measured by a computerized system. Radiologists assessing attempted fusion should be blinded to the clinical results. Also, bone trabeculation is neither as sensitive nor specific as interspinous or intervetebral motion in assessing fusion. When will the FDA change its guidelines to match the current scientific evidence?

Learning Objectives

By the conclusion of this session participants should be able to: 1) Understand the current FDA guidelines for radiographically assessing cervical arthrodesis. 2) Describe the criteria recommended by the most recent literature for radiographically assessing fusion/pseudoarthrosis.