Specialists, Charlotte, NC, USA; [2]Center for Spinal Disorders, Thornton, CO, USA; [3]The Spine Institute at St John's Health Center, Santa Monica, CA, USA; [4]New York University Medical Center/Hospital for Joint Diseases, New York, NY, USA; [5]New York University Medical Center/Hospital for Joint Diseases Spine, New York, NY, USA; [6]Texas Back Institute, Plano, TX, USA; [7]University of California San Francisco, Department of Orthopaedic Surgery, San Francisco, CA, USA; [8]Harborview Medical Center, Seattle, WA, USA; [9]Yale Physicians Bldg/Yale University, New Haven, CT, USA; [10]University of Texas Southwestern Medical Center at Dallas, Dallas, TX, USA; [11]Booth, Bartolozzi, Balderston Orthopaedics/ Pennsylvania Hospital, Philadelphia, PA, USA; [12]Hospital for Special Surgery, New York, NY, USA; [13]Rothman Institute/Thomas Jefferson University, Philadelphia, PA, USA; [14]CORE Orthopaedics Medical Center, Encinitas, CA, USA

BACKGROUND CONTEXT: Cervical total disc deplacement (TDR) is intended to address discogenic pain and preserve physiologic motion between two vertebral bodies in patients with symptomatic cervical disc disease (SCDD). TDR may thus prevent long-term subsequent accelerated degeneration at adjacent disc levels.
PURPOSE: The purpose of this trial was to compare the safety and efficacy of the TDR, ProDisc-C (Synthes Spine, L.P., West Chester, PA) for the treatment of one level disease between C3-C7 to anterior cervical discectomy and fusion (ACDF) surgery.
STUDY DESIGN/SETTING: A non-inferiority design with a 1:1 randomization was utilized.
PATIENT SAMPLE: The study was conducted at 14 sites. 209 patients were randomized (106 ACDF, 103 ProDisc-C), enrolled and treated in accordance with the protocol.
OUTCOME MEASURES: Patients were evaluated by Visual Analog Scale (VAS) Pain and Intensity (Neck and Arm), and VAS Satisfaction, Neck Disability Index (NDI) and SF-36 standardized questionairres.
METHODS: Patients were assessed pre-operatively and post-operatively at prior to discharge, 6 weeks, 3, 6, 12, 18 and 24 months.
RESULTS: Demographics were similiar between the two patient groups (ProDisc-C: 42.1 ¡À 8.4 years, 45% males; Fusion: 43.5 ¡À 7.2 years, 46% males). The most commonly treated level was C5-C6 (ProDisc-C=56%; Fusion=58%). There was a statistically significant difference in intra-operative data (operative time and estimated blood loss) in favor of the ACDF group, although the magnitude of difference was not clinically significant. NDI and SF-36 scores were significantly less compared to pre-surgery scores at all follow-up visits for both treatment groups ($p<0.0001$). VAS neck pain intensity and frequency as well as VAS arm pain intensity and frequency were statistically lower at all follow-up time points compared to pre-operative levels ($p<0.0001$) but were not different between treatments. Neurologic success (improvement or maintainence) was achieved at 24 months in 90.9% of ProDisc-C and 88.0% of ACDF patients. Results show that at 24 months post-operatively, 84.4% of ProDisc-C patients achieved ¡Ý 4 degrees of motion or maintained motion relative to pre-operative baseline at the operated level.
CONCLUSIONS: At the 24 month follow-up, the ProDisc-C is not inferior to ACDF. ProDisc-C is therefore effective in the treatment of discogenic pain associated with SCDD in the cervical spine in the C3-C7 vertebral segments in properly selected patients.
FDA DEVICE/DRUG STATUS: ProDisc-C: Investigational/ Not approved.

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63. The Subarticular Pedicle Screw: A New Trajectory for the C2 Pedicle Screw

Jin Sup Yeom, MD[1], Kun Woo Park, MD[1], Bong-Soon Chang, MD[1], Choon-Ki Lee, MD[1], K. Daniel Riew, MD[2]; [1]Seoul National University, Seoul, South Korea; [2]Washington University in St. Louis, St. Louis, MO, USA

BACKGROUND CONTEXT: C2 pedicle screws have gained popularity in the recent past. To our knowledge, there has not been a large series investigating the incidence of anatomical variations that preclude the use of such screws, or the optimal trajectory of a C2 pedicle screw, using CT scan images and surgical simulation software.
PURPOSE: To determine a new trajectory for the C2 screw, and to evaluate its safety and accuracy.
STUDY DESIGN/SETTING: Simulation using computer software and 1 mm-sliced CT scan images.
PATIENT SAMPLE: 1 mm-sliced CT scan images of 158 continuous patients.
OUTCOME MEASURES: Vertebral foraminal violation detected during computer simulation using CT scan images.
METHODS: We used 1 mm-sliced CT scans and 3D reconstruction and screw trajectory simulation software, to simulate the insertion of a 4.0 mm pedicle screw. We then sought to determine the trajectory that minimized cortical breaches and compared this to the standard pedicle screw trajectory.
RESULTS: The pedicles of 158 patients were evaluated bilaterally, for a total of 316 pedicles. Using the standard trajectory, 6.0% (19/316) of the pedicle screws breached the lateral cortex of the pedicle, an area which has been called the vertebral artery groove of C2. The trajectory that produced the least number of cortical violations had the following trajectory: Medial angulation was the same as for the standard pedicle screw, between 30 and 40 degrees. The sagittal direction was toward a point 0-1 mm below the anterior-superior corner of the C2 superior articular facet under lateral fluoroscopy. The entry point was 3 mm caudal to the C1-2 joint, and 3–4 mm lateral to the medial border of the pars. This allows for screw insertion close to the superomedial border of the superior C2 facet with 30–40 degrees of convergence. We termed this trajectory for the C2 screw, ''subarticular pedicle screw''. We found that 2.5% (8/316) of these screws breached the vertebral grooves, which was significantly lower than for the standard technique ($p=0.030$, chi-square test). The average screw lengths of subarticular and standard screws were 25.6 mm (SD 2.9) and 29.1 mm (SD 3.4), respectively.
CONCLUSIONS: To our knowledge, this is the first description of a new trajectory for a C2 pedicle screw, that we term, the subarticular pedicle screw. We found that in this large population of patients, it has improved safety compared to the standard pedicle screw trajectory. However, even with this technique, there are some cases where these screws can not be inserted without breaching the vertebral groove.
FDA DEVICE/DRUG STATUS: This abstract does not discuss or include any applicable devices or drugs.

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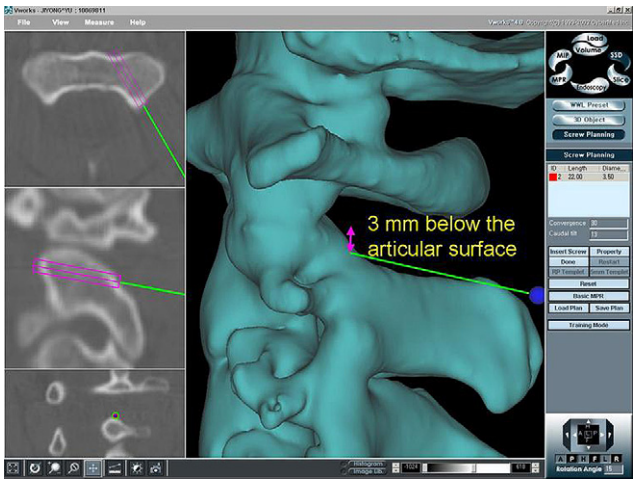
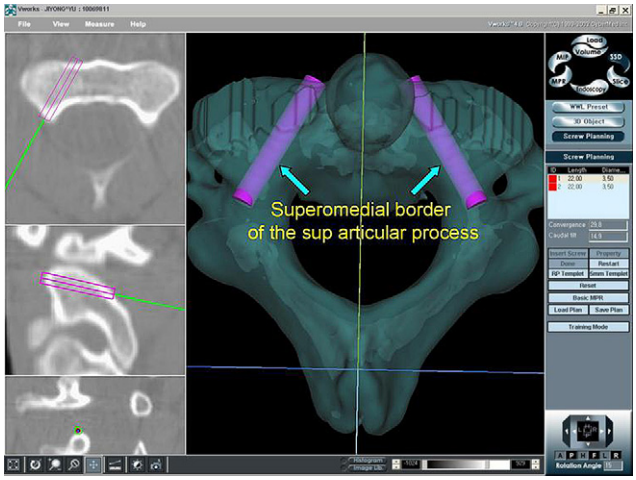
64. Cervical Disc Replacement: Over 3-4 year Prospective Randomized Clinical Outcomes and Range of Motion Follow-up with the Prodisc-C Prosthesis

Rick B. Delamarter, MD[1], Ben B. Pradhan, MD, MSE[1], Lea Kanim, MA[1], Michael A. Kropf, MD[1], Hyun W. Bae, MD[1]; [1]The Spine Institute at Santa Monica, Santa Monica, CA, USA

BACKGROUND CONTEXT: This paper represents the longest follow-up outcomes study with cervical disc replacements in the US with the ProDisc-C prosthesis (Synthes Spine, West Chester, PA), single-level, 2-levels, and 3-levels. The United States clinical trials for this device have been completed for over a year, and final FDA review of the results are taking place before formal approval.
PURPOSE: Longer term follow-up of cervical disc replacement at a single instititute.
STUDY DESIGN/SETTING: A prospective randomized controlled USFDA Clinical Trial of ProDisc-C intervertebral arthroplasty versus anterior cervical discectomy and fusion.
PATIENT SAMPLE: Thirty patients were enrolled in the study. There were more patients added into the continued access and compassionate use categories (total 1-level=41, 2-level=14, 3-level=9).

OUTCOME MEASURES: Visual Analog Scale (VAS) for both neck and arm pain, and Oswestry disability questionnaires.
METHODS: Pre-op and follow up flexion-extension and side bending radiographs were studied and measured. Clinical outcomes were recorded with the Visual Analog Scale (VAS) for both neck and arm pain, and Oswestry disability questionnaires. This paper includes follow-up now of over 3 years.





Figures 1 and 2.

RESULTS: Average flexion-extension motion went from 10 degrees preoperatively to essentially no motion at the last follow-up postoperatively in the fusion group, but was well-preserved at over 10 degrees in the disc replacement group. Side-bending went from 6 degrees to preoperatively to essentially no motion in the fusion group, versus 6 to 5 degrees in disc replacement patients. Clinical outcome scores revealed significant improvements in VAS and Oswestry scores for both groups, which has been sustained over 3 years to 4 years after surgery. By six months, VAS (neck) was down from approximately 7 to about 2 in disc replacement patients, and 6 to just under 3 in fusion patients. VAS (arm) was down from over 6 to under 3 and from over 6 to under 3 in disc replacement and fusion patients respectively. Oswestry scores similarly decreased from about 50 to 25 and from 50 to 24 at over 12 months in disc replacement and fusion patients respectively. VAS and Oswestry improvements have been maintained at up to 4 years. Thus far there has been no evidence of degenerative breakdown at segments adjacent to fusion or disc replacement. There have been no device related complications in this cohort of patients.
CONCLUSIONS: Our results suggest that cervical disc replacement is a viable alternative for preservation of motion at affected vertebral levels without compromising clinical outcomes, and with the additional upside of possible prevention of accelerated adjacent segment degeneration. This report contains the longest follow-up in a prospective randomized controlled trial for the ProDisc-C device. Long-term safety and efficacy studies are in progress.
FDA DEVICE/DRUG STATUS: ProDisc-C: Approved for this indication.

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65. Reliability of Diagnosis and Treatment Decisions for Traumatic Cervical Dislocation

Ahmed Nassr[1], Joon Y. Lee, MD[2], Paul Arnold, MD[3], Darrel Brodke, MD[4], Andrew Dailey, MD[4], David G. Schwartz, MD[5], Jonathan Grauer, MD[6], Raja Rampersaud, MD[7], Alexander Vaccaro, MD[8]; [1]PA, USA; [2]University of Pittsburgh, PIttsburgh, PA, USA; [3]University of Kansas, Kansas City, KS, USA; [4]University of Utah, Salt Lake City, UT, USA; [5]Orthopaedics Indianapolis, LLC, Indianapolis, IN, USA; [6]Yale University, New Haven, CT, USA; [7]University of Toronto, Toronto, Ontario, Canada; [8]Thomas Jefferson University, Philadelphia, PA, USA

BACKGROUND CONTEXT: There is considerable controversy with respect to the assessment, diagnosis, and treatment of traumatic cervical dislocations. In particular, whether MRI is performed before an attempted closed reduction is controversial, as some argue that presence of a herniated disk increases the risk of iatrogenic spinal cord injury. In addition, the method of reduction and fixation vary widely, as some may advocate anterior fixation when others are in favor of posterior fixation or combined anterior and posterior approach.
PURPOSE: The purpose of this study was to ascertain the degree of agreement or disagreement in assessment, diagnosis, and treatment of traumatic cervical dislocations among international group of spine trauma surgeons.
STUDY DESIGN/SETTING: A survey analysis of the Spine Trauma Study Group.
PATIENT SAMPLE: Selected patients who were admitted to a level-1 trauma center with diagnosis of sub-axial cervical facet dislocation.
OUTCOME MEASURES: Inter-/intra-observer variablity and agreement/disagreement analysis of selected patients presented to the Spine Trauma Study Group.
METHODS: Comprehensive sets of imaging studies from 10 cases of cervical trauma were distributed to members of the Spine Trauma Study Group, an organization of surgeon-scientists from North America, Europe, and Asia. Each case included CT, MRI, and X-ray images. Twenty-nine surgeons answered a series of questions about how they would diagnose and treat each case. These questions included: (1) How would you classify this injury based on the X-rays and/or CT (before having access to MRI results)? (2) After evaluating the plain x-rays and/or CT images, would you proceed with a closed skeletal traction reduction or would you obtain a MRI of the cervical spine prior to open or closed reduction? (3) Assuming that a MRI was obtained prior to reduction, after evaluating the provided MRI, do you believe a disk herniation is present at the level of injury? (4) Assuming you decided to get a MRI prior to performing a reduction, after evaluating the MRI would you now proceed with a closed or an open reduction? (5) Following review of all imaging studies, what type of surgical approach would you recommend as the treatment of this injury if a closed reduction was NOT performed or, if attempted, was NOT SUCCESSFUL? (6) If a successful closed reduction was performed, what would be your definitive surgical procedure in light of the imaging studies for this case (assume appearance of disk is not altered from the images provided)? For surgical approach questions, surgeons chose from an anterior