at L1/2 and L2/3 ($p<.04$). In specimens age 30-39, a higher prevalence of facet arthrosis vs. disc degeneration was noted at L4/5 ($p=.02$). The specimens' age 40-49, 50-59, 60-69, and >70 showed significantly higher degrees of end plate degeneration when compared with facet arthrosis at all levels ($p<.05$).

CONCLUSIONS: This study suggests that the bony evidence of facet arthrosis appears early in the degenerative process, preceding changes in the end plates of the intervertebral disc. Once the facets start to deteriorate with age, the discs rapidly degenerate, with end plate changes developing more rapidly than continued facet arthrosis. These results challenge the belief that the degenerative process begins in the disc; rather, it appears that disc degeneration progresses more rapidly in later years but that facet degeneration occurs first.

FDA DEVICE/DRUG STATUS: This abstract does not discuss or include any applicable devices or drugs.

CONFLICT OF INTEREST: No conflicts.

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Friday, September 29, 2006
3:51–4:34 PM
Concurrent Session 2: Cervical Motion Segment Replacement

3:51

123. Cervical Disc Replacement: 2 to 3-Year Range of Motion and Clinical Outcomes Follow-Up With the ProDisc-C Prosthesis

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BACKGROUND CONTEXT: As the surgical standard of care to date for intractable neck and arm pain due to cervical degenerative disc disease or disc herniation, anterior cervical discectomy and fusion (ACDF) has been very effective. However, the long-term effects of motion-eliminating surgery in the spine, especially at multiple levels, have come under scrutiny recently. Several studies have documented the accelerated degeneration of adjacent segments after cervical fusion surgery. On the heels of encouraging results with lumbar total disc arthroplasty, clinical trials for cervical spine total disc arthroplasty have begun in the U.S. The ProDisc-C artificial cervical disc has semiconstrained kinematics, with keels and porous coating for both immediate fixation and long-term bony ingrowth.

PURPOSE: This study represents the longest follow-up outcomes study with cervical disc replacements in the U.S. with the ProDisc-C prosthesis.

STUDY DESIGN/SETTING: A prospective, randomized, and controlled study.

PATIENT SAMPLE: Patients with intractably symptomatic degenerative disc disease or disc herniations causing neck or arm pain were randomized into the study.

OUTCOME MEASURES: Radiographic findings, visual analog scale scores for neck and arm pain, Oswestry Disability Index scores.

METHODS: This is a prospective randomized controlled USFDA clinical trial of ProDisc-C intervertebral arthroplasty versus anterior cervical discectomy and fusion. Forty patients were enrolled in the study. Preoperative 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. The average follow-up was 24 months postoperatively, with some completing 3 years and over.

RESULTS: 24 patients received ProDisc-C and 16 received fusion. Average flexion-extension motion went from 9 degrees preoperatively to approximately 1 degree (essentially no motion) at over 12 months postoperatively in the fusion group, but was well-preserved from 11 to 12.5 degrees in the disc replacement group. Side-bending went from 6 degrees to <2 degrees (essentially no motion) in the fusion group, versus 5.9 to 5 degrees in disc replacement patients. Clinical outcome scores revealed significant improvements in VAS and Oswestry scores for both groups. By 6 months, VAS (neck) was down from 6.6 to 2.4 in disc replacement patients, and 6.2 to 2.6 in fusion patients. VAS (arm) was down from 4.7 to 2.4 and 6.5 to 2.9 in disc replacement and fusion patients respectively. Oswestry scores similarly decreased from 25 to 9 and 24 to 13 at over 12 months in disc replacement and fusion patients respectively. VAS and Oswestry improvements have been maintained at over 2 years. There was no difference in complication rates between the groups, and the rates were low. Specifically there were no device-related complications with the ProDisc-C device, and there have been no revisions or salvage of the disc replacements.

CONCLUSIONS: Our results suggest that cervical disc replacement is a viable alternative to fusion for cervical disc degeneration or herniation, affording preservation of motion at affected vertebral levels without compromising clinical outcomes, and with the additional upside of prevention of adjacent segment degeneration. Longer-term safety and efficacy studies are in progress.

FDA DEVICE/DRUG STATUS: ProDisc-C: Investigational/not approved.

CONFLICT OF INTEREST: Authors (RBD, BBP) Grant/Research Support: Synthes Spine.

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3:57

124. Cervical Arthroplasty With the Bryan Disc: 4-Year Results

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BACKGROUND CONTEXT: Cervical arthroplasty is a new technology for treating degenerative diseases of the cervical spine. However, no long-term follow-up data are available at this time.

PURPOSE: To study the clinical and radiological outcome at 4-year follow-up.

STUDY DESIGN/SETTING: From 2000 to 2004 a European multi-center prospective clinical trial with the Bryan cervical artificial disc was carried out. One hundred and three patients were included in the single-level and 43 in the bi-level study. According to the protocol, the study was concluded after a 2-year follow-up period. Consequently a post-market prospective long-term study was initiated in Leuven, Belgium: this new study consisted of those Leuven patients who were already included in the first multi-center study, as well as a consecutive series of patients who were also operated upon in Leuven after termination of the inclusion period for the first trial. The eventual inclusion of patients in this post-market study was terminated at the end of December 2002.

PATIENT SAMPLE: Sixty-three patients passed their 4-year follow-up examination: 55 single-level and 8 bi-level patients.

OUTCOME MEASURES: Clinical outcome was assessed with the Odom score: good, excellent, fair, or poor. Radiologically mobility and paravertebral ossification were assessed at the operated level. Adjacent level degeneration at baseline and at 4 years were compared.

METHODS: Clinical examination was done with the Odom score. Radiological examination was performed with dynamic flexion-extension X-rays.

RESULTS: According to the Odoḿs criteria 34 of the single-level cases had an excellent outcome at 4 years, 15 good, 5 fair, and 1 poor: this last patient developed multiple sclerosis. Five of the bi-level patients had an excellent outcome, 3 had a good outcome. From a radiological viewpoint motion was preserved in 45 single-level patients (81.8%). For the bi-level group motion was preserved at the cranial level in all 8 patients and at the caudal level in 5 patients. At 4-year follow-up, paravertebral ossification was detected on plain X-rays in 13 patients of the single-level group