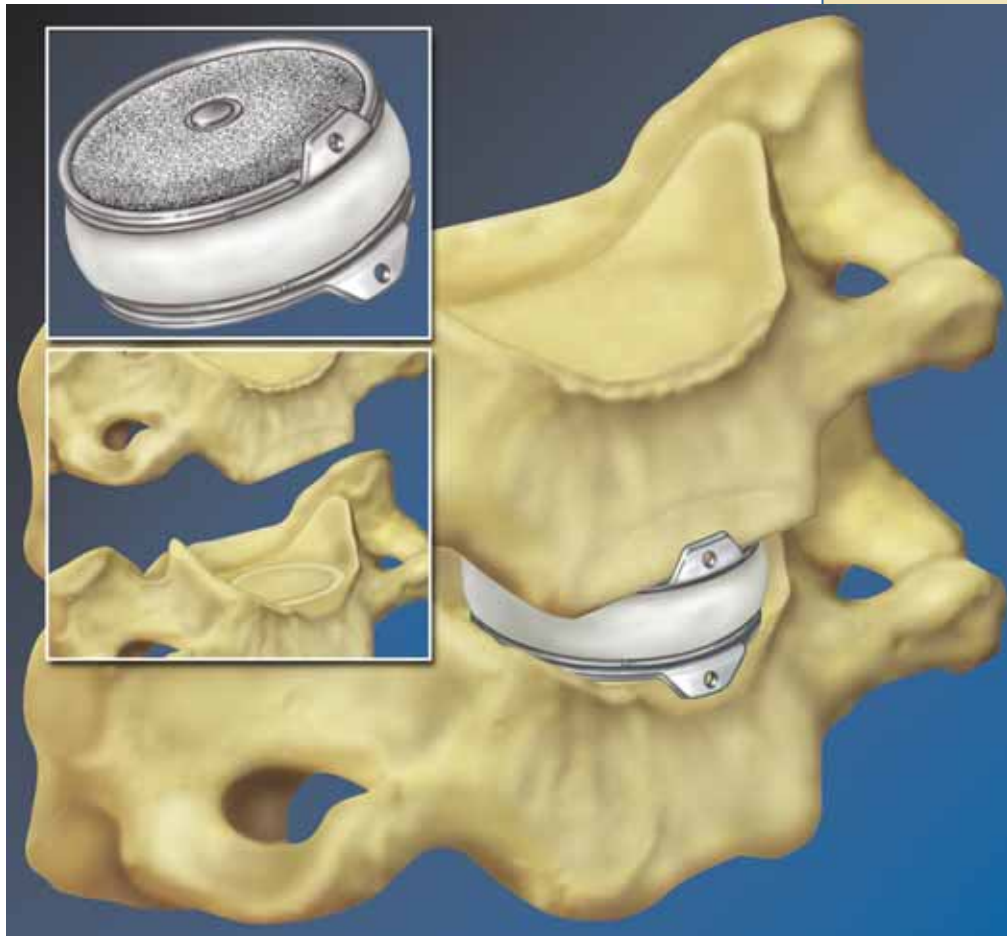


Bryan[®]
Cervical Disc System

INTERMEDIATE CLINICAL EXPERIENCE

Single and Bi-level
Indications



Medtronic
SOFAMOR DANEK

Accelerated Degeneration at Adjacent Levels

- Hilibrand *et al.* (1999) Reported symptomatic adjacent segment disease in 2.9% per year in 374 fused patients, two-thirds requiring surgical intervention
- Goffin *et al.* (2000) 92% of 180 consecutive fused patients showed radiographic evidence of adjacent DDD at 8.5 years postoperatively, equal incidence in trauma and DDD
- Brumley *et al.* (2000) Measured cervical motion using dynamic fluoroscopy and reported abnormal kinematic results at levels adjacent to fusions

European Clinical Study-Single Level

- Approximately 100 single-level patients were enrolled in the study in six countries in Europe (Belgium, Italy, Germany, Sweden, UK, France)
- Approximately 40 bi-level patients were enrolled in the study in three centers in two countries in Europe (Belgium, France)
- Designed to show relief of signs and symptoms including pain, equivalent to ACDF

Inclusion Criteria

- Disc herniation with radiculopathy and/or myelopathy which has not responded to conservative treatment
- Spondylotic radiculopathy and/or myelopathy which has not responded to conservative treatment
- One level, or two adjacent levels
- ≥ 21 years of age

Exclusion Criteria

- Active infection
- Previous spine surgery
- Radiographic instability
- Axial neck pain as only symptom
- Metabolic bone disease

Not Investigated

- Adjacent to a surgical fusion
- No motion on preoperative F/E films
- More than two levels implanted

Study Design

Follow-up assessments

- Neurological assessment by physician
- Function and pain assessment by patient
- Radiographic assessment by independent radiologist
 - ✓ Motion
 - ✓ Device stability

Data Analysis

- Results from the surgeon examination and the patient questionnaire were averaged to determine relief of neurological symptoms and signs, results were categorized into classifications by a computer using a scoring algorithm
- Radiographs were analyzed separately to determine if motion was present at the operative level and the device was stable (i.e., not migrating or subsiding)

Classification Definitions: Neurological Symptoms and Patient Function

- Excellent: improvement in most (80%) of the preoperative signs and symptoms, with little deterioration (not more than 10%)
- Good: improvement in some (70%) of the preoperative signs and symptoms, with some deterioration (not more than 15%)
- Fair: improvement in half (50%) of the preoperative signs and symptoms, with some deterioration (not more than 20%)
- Poor: improvement in few (less than 50%) of the preoperative signs and symptoms, or significant deterioration (more than 20%)

Disease State

Clinical Diagnosis		
	Single-Level	Bi-Level
Radiculopathy	86%	77%
Myelopathy	7%	14%
Multiple	7%	9%
Primary Etiology		
	Single-Level	Bi-Level
Herniation	67%	16%
Spondylosis	21%	77%
Multiple	12%	7%
Duration of Symptoms		
	Single-Level	Bi-Level
One year or less	64%	60%
Greater than 1 year	36%	40%

Demographic Comparison

- The distribution of gender, age, levels treated, and sizes are the same in each study
- The difference in clinical diagnosis is not statistically significant, the difference in primary etiology is highly significant ($P < .001$)

Clinical Outcomes: One-level Study

49 Patients Scored	Excellent at 1 Year	Good at 1 Year	Fair at 1 Year	Poor at 1 Year
Excellent at 2 Years	42	2	1	1
Good at 2 Years	3	2	1	0
Fair at 2 Years	4	2	4	3
Poor at 2 Years	1	0	1	6

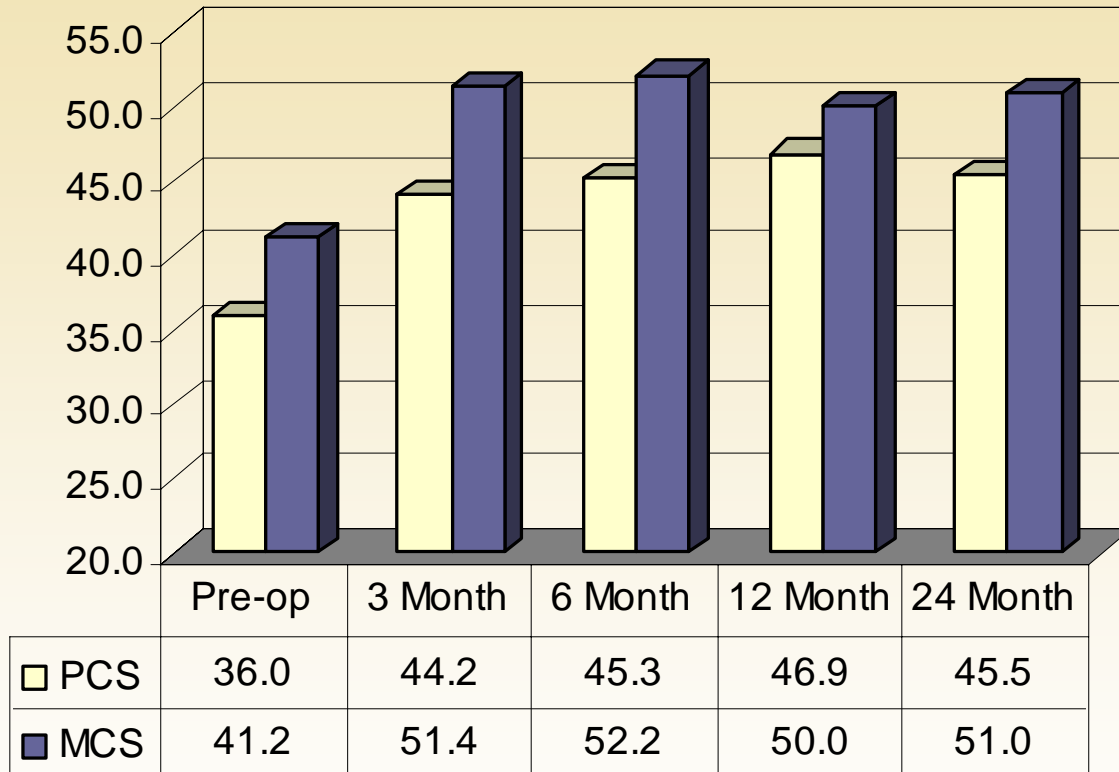
Study enrollment initiated January 2000 and concluded June 2002.

Data presented as of June 2003.

Clinical Outcomes: One-level Study

- The previous chart summarizes the clinical results for 73 patients with complete data at the 2 year follow-up visit
- 54 of 73 patients (74%) maintained their clinical status from 1 year to the 2 year follow-up visit (diagonal line)
- 8 of 73 patients improved their clinical status from 1 year to the 2 year follow-up visit (above diagonal line)
- 11 of 73 patients did worse at the 2 year follow-up when compared to the 1 year follow-up visit (below diagonal line)

SF-36 Summary Results: One-level



SF-36 Physical Component Summary (PCS)
and Mental Component Summary (MCS) scores.

Clinical Outcomes: Two-level Study

23 Patients Scored	Excellent at 6 Mo.	Good at 6 Mo.	Fair at 6 Mo.	Poor at 6 Mo.
Excellent at 1 Year	14	4	3	0
Good at 1 Year	2	0	0	1
Fair at 1 Year	0	1	1	3
Poor at 1 Year	0	0	0	1

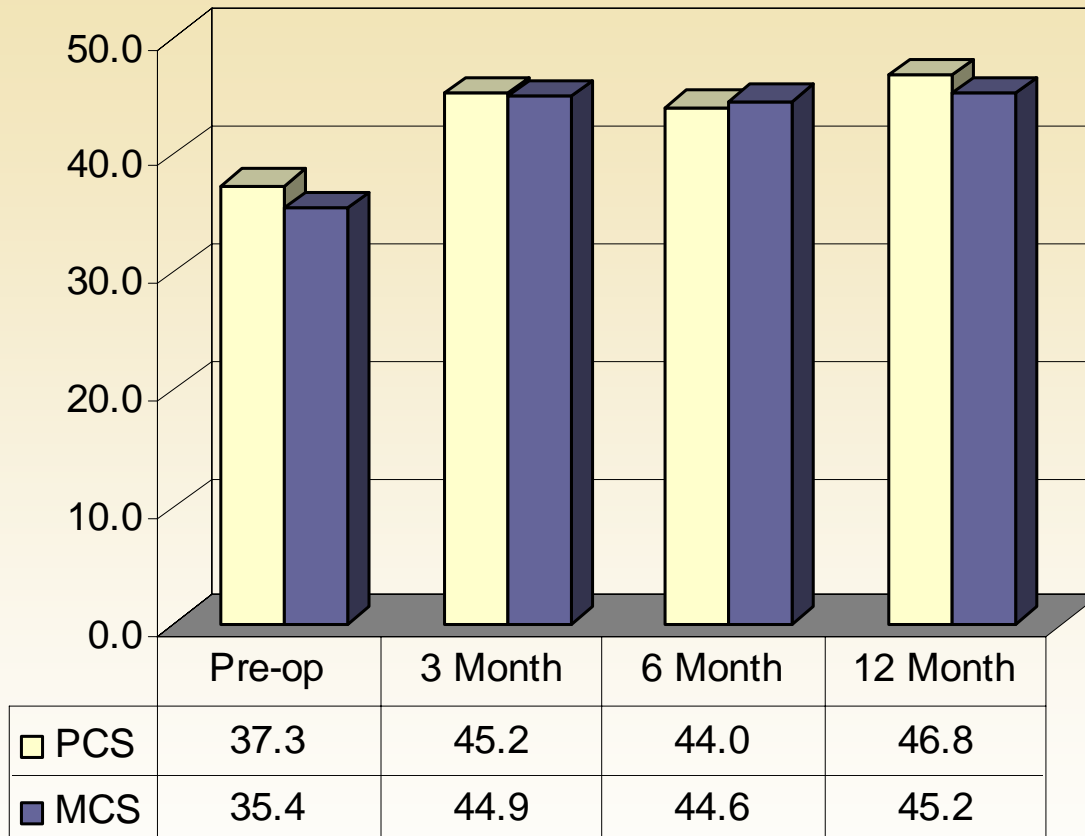
Study enrollment initiated January 2001 and concluded April 2002.

Data presented as of June 2003.

Clinical Outcomes: Two-level Study

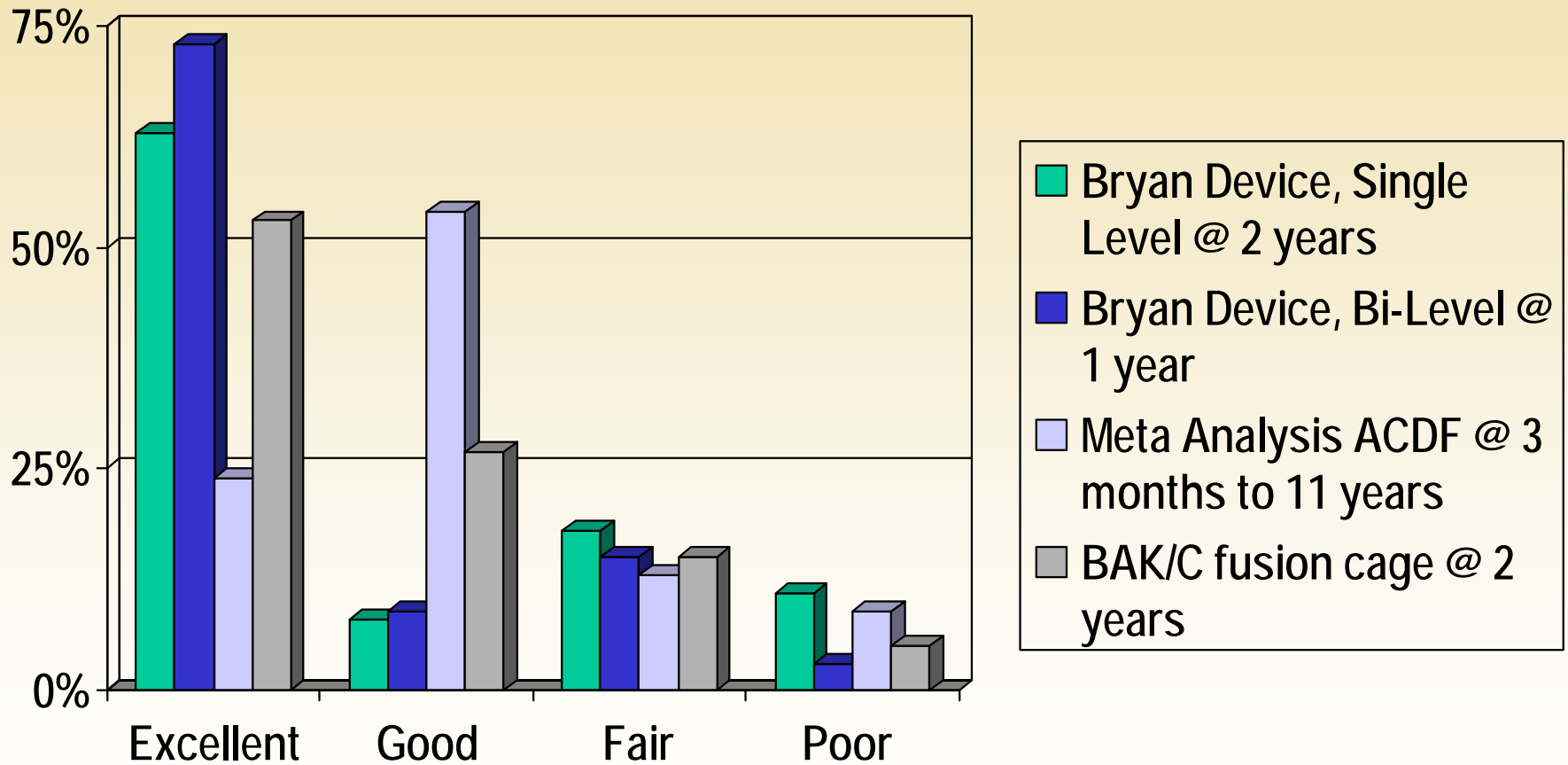
- The previous chart summarizes the clinical results for 30 patients with complete data at the 1 year follow-up visit
- 16 of 30 patients (53%) maintained their clinical status from 6 month to the 1 year follow-up visit (diagonal line)
- 11 of 30 patients improved their clinical status from 6 month to the 1 year follow-up visit (above diagonal line)
- 3 of 30 patients did worse at the 1 year follow-up when compared to the 6 month follow-up visit (below diagonal line)

SF-36 Summary Results: Two-level



SF-36 Physical Component Summary (PCS)
and Mental Component Summary (MCS) scores.

Clinical Outcome Comparison



Complications

- One report of temporary dysphonia in single-level study
- Four re-interventions at the treatment level in single-level study:
 - ✓ Removal of postoperative hematoma
 - ✓ Complete decompression (fragment remaining from 1st surgery)
 - ✓ Perform posterior decompression to treat residual myelopathic symptoms in a patient with over 2 years duration of symptoms
 - ✓ One explant at 20 months postoperative to remove posterior osteophytes
- One CSF leakage while decompressing posteriorly in the disc space in bi-level study
- Four re-interventions at the treatment in the bi-level study:
 - ✓ Repair of pharyngeal tear/esophageal wound
 - ✓ Removal of postoperative hematoma (2 cases)
 - ✓ Removal of post operative hematoma associated with temporary paralysis (no residual symptoms)
- One report severe dysphonia due to distraction occurred when implanting a second Bryan at an adjacent level 20 months following first implant

Single-Level Flexion/Extension ROM

Follow-up	Number of Patients with Radiographic Results	Number of Patients with Radiographic Evidence of Motion	Average \pm Std. Dev. (degrees)
Six Month	90	88	8 \pm 4
One Year	94	84	8 \pm 5
Two Year	71	63	8 \pm 6

- *Two degrees is considered the minimum to establish motion*
- *ROM measured by Cobb angle of the outer endplates of the FSU*

Single-level Radiographic Success

Follow-up Period	Number of Patients with Radiographic Results	ROM $\geq 2^\circ$	ROM $< 2^\circ$
12 Month	94	84 (89%)	10 (11%)
24 Month	71	63 (89%)	8 (11%)

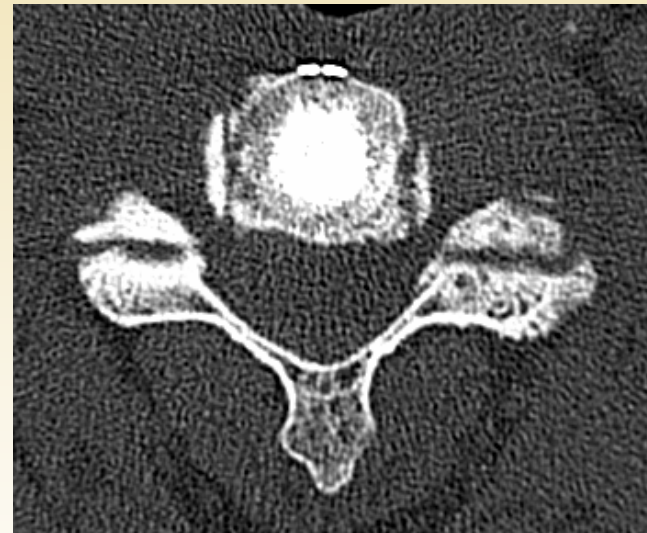
Paravertebral Ossification

- Discovered on routine follow-up CT scans
- Results from surgical procedure related trauma
- Usually develops during the early post-op period
- Has not had significant impact on clinical results
- A review of 40 CT scans demonstrated that the prevalence and degree of ossification was significantly less in patients that received NSAIDs

Postoperative CT Scans



Without NSAIDs



With NSAIDs

Single-Level Radiographic Summary

- No radiographic evidence of subsidence
- Motion equal to or greater than 2° present 89% of patients at one year and 89% of patients at two years as of June 2003.
- One early case of temporary anterior migration of the device (3.0 mm) was observed; this case was associated with a partially milled cavity

Bi-Level Flexion/Extension ROM

Follow-up	Number of Levels with Radiographic Results	Number of Levels with Radiographic Evidence of Motion	Average \pm Std. Dev. (degrees)
Six Month	76	75	7 \pm 4
One Year	61	51	8 \pm 5

- *Two degrees is considered the minimum to establish motion*
- *ROM measured by Cobb angle of the outer endplates of the FSU*

Bi-Level Radiographic Success

Follow-up Period	Number of Levels with Radiographic Results	ROM $\geq 2^\circ$	ROM $< 2^\circ$
6 months	76	75 (99%)	1 (1%)
12 Month	61	51 (84%)	10 (16%)

Bi-Level Radiographic Summary

- Motion equal to or greater than 2° present 84% of patients at one year as of June 2003.
- One case of temporary posterior migration of the device (less than 3 mm) was observed; this case was associated with a partially milled cavity
- No radiographic evidence of subsidence

Radiographic Findings - General

- In random follow-up CT scans, varying degrees of paravertebral ossification were observed. The cause and nature of this observation are being investigated.
- NSAIDs prescribed to reduce instances this ossification.

Radiographic Case Study – Single-level

- Male patient
- 44 years old
- Treated for disc herniation with radiculopathy
- Duration of symptoms > 2 years
- 2 year follow-up x-rays to follow

Lateral Neutral



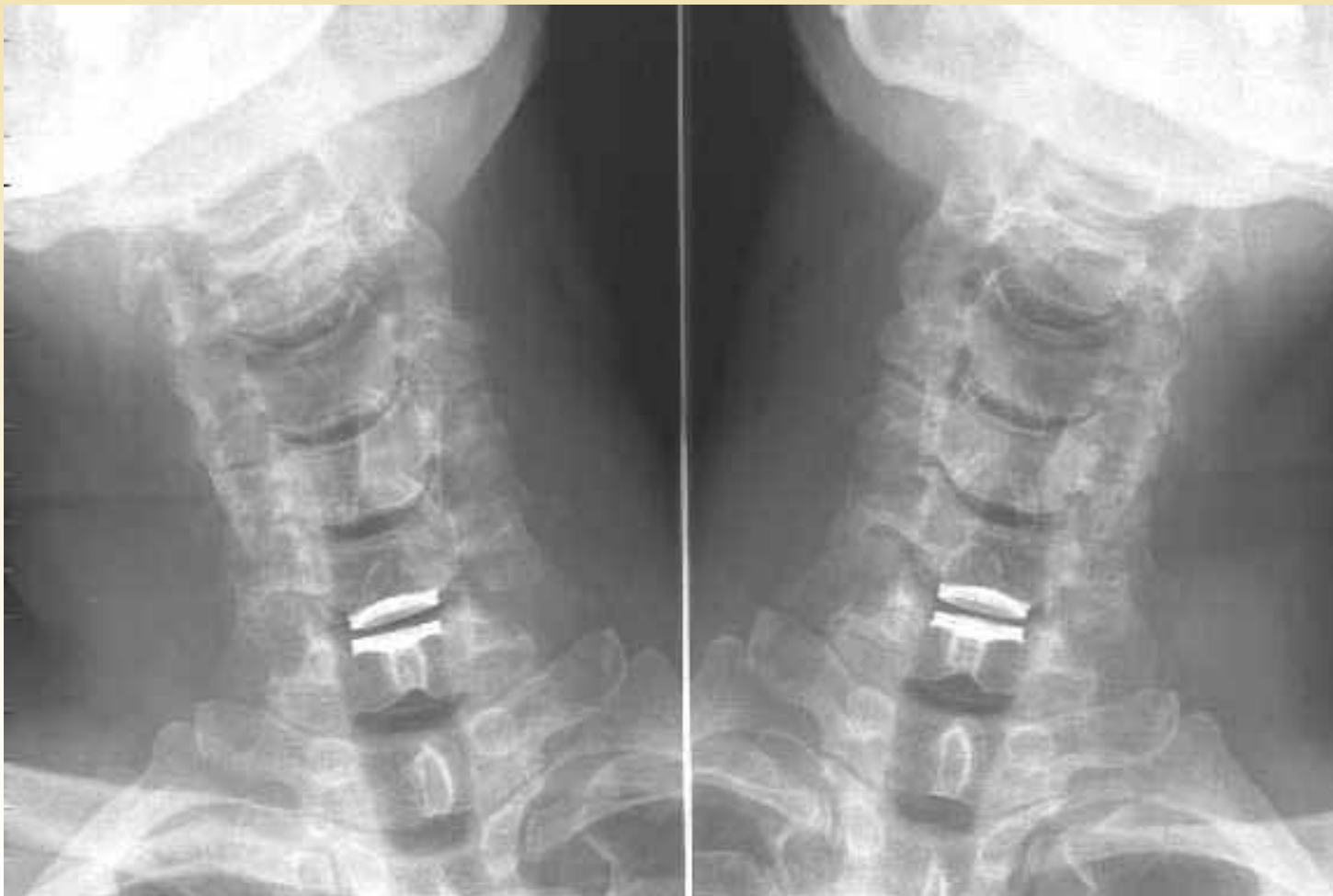
Flexion/Extension



A/P Neutral



Right/Left Lateral Bending



Right/Left Rotation



Radiographic Case Study – Bi-level

- Male patient
- 63 years old
- Treated for spondylosis with radiculopathy at both levels
- Duration of symptoms > 2 years
- Six month follow-up x-rays to follow

Flexion/Extension



Bryan Disc Clinical Observations

- Paravertebral Ossification may occur; the use of NSAIDs post-op appears to reduce ossification
- Shell angulation was an issue associated with 1st generation instruments
- Adequate decompression is necessary to relieve patient symptoms when maintaining motion

Shell Angulation

Significant shell angulation resulted in restricted ROM in several patients. Three causes for improperly aligned shells have been identified:

- An early version of the surgical technique and instrumentation could result in anterior closed angle alignment of shells. The instruments and procedure have since been revised
- Incorrect intra-operative patient positioning
- Patients with significant preoperative kyphosis may have sub-optimal shell alignment postoperatively

Outcomes Observations

- Inadequate decompression of the symptomatic level may result in ongoing symptoms
- Incorrect intra-operative positioning of the patient may lead to misaligned shells and restricted ROM
- Inadequate or incorrect milling of the vertebral endplates may lead to delayed shell stability
- Significant preoperative kyphosis or reversal of lordosis at the treatment level may lead to misaligned shells
- Lack of preoperative motion may be associated with low postoperative motion

Summary

- Good to excellent six-month, one-year and two-year clinical results were clearly demonstrated; initial comparison to ACDF results is favorable
- The device provided a clinically significant benefit for patients with objective neurological symptoms and signs with or without pain
- There was evidence of minimal post-op migration of two devices, subsidence was not observed
- There were no device-related surgical interventions