

## Supplemental Online Content

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This supplemental material has been provided by the authors to give readers additional information about their work.

**eTable 1.** List of Investigators and Participating Centers.

Site Name	Principal Investigator
LKH Graz (Graz, Austria)	Sandro Eustacchio
ZNA Middelheim (Antwerp, Belgium)	Robert Hes*
OLVG-location West (Amsterdam, The Netherlands)	Gerrit J. Bouma
St. Bonifatius Hospital GmbH (Lingen, Germany)	Peter Douglas Klassen
Klinikum Augsburg (Augsburg, Germany)	Volkmar Heidecke
Charite-Virchow-Klinikum (Berlin, Germany)	Peter Vajkoczy
University Medical Center Schleswig-Holstein (Kiel, Germany)	Hubertus Mehdorn ** Senol Jadik Charlotte Flüh
OLV Ziekenhuis (Aalst, Belgium)	Frederic Martens
Universitätsmedizin Mannheim (Mannheim, Germany)	Martin Barth †
University Hospital Düsseldorf (Düsseldorf, Germany)	Richard Bostelmann
Donausar Klinikum Deggendorf (Deggendorf, Germany)	Stefan Rath
Asklepios Westklinikum Hamburg (Hamburg, Germany)	Hans-Peter Köhler
Isala Ziekenhuis (Zwolle, The Netherlands)	Willem Art van den Brink
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Site Name	Principal Investigator
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Knappschafts-Krankenhaus Bochum-Langendreer (Bochum, Germany)	Martin Barth ‡
Centre Hospitalier Régional Universitaire de Lille (CHRU), Hôpital Roger Salengro (Lille, France)	Richard Assaker
Orthopädische Klinik und Poliklinik Universitätsmedizin Rostock (Rostock, Germany)	Susanne Fröhlich

\* PI moved to AZ Klina, Brasschaat, Belgium. EC approval at this site to follow patients enrolled at original site. PI at ZNA Middleheim now Guido Dua.

\*\* PI Mehdorn retired. Former Co-Investigator Flüh now PI.

† PI moved to Bochum, Germany, Perrin now PI.

‡ PI moved to Frankfurt, Germany, Brenke now PI.

**eTable 2.** Inclusion and Exclusion Criteria.

<b>Inclusion Criteria</b>
1. Age 21 to 75 years and skeletally mature (male or female)
2. Posterior or posterolateral disc herniations at one level between L1 and S1 with confirmation of neural compression using MRI.[Note: Intraoperatively, only post-discectomy annular defects between 4 and 6 mm tall and 6 and 10 mm wide shall qualify]
3. At least six weeks of failed, conservative treatment prior to surgery, including physical therapy, use of anti-inflammatory medications at maximum-specified dosage, and/or administration of epidural/facet injections
4. Minimum posterior disc height of 5mm at the index level
5. Radiculopathy (with or without back pain) with positive straight leg raise (0 –60 degrees) (L4/5, L5/S1) or femoral stretch test (L1/2, L2/3, L3/4 only)
6. Oswestry Disability Index score of at least 40/100 at baseline
7. Visual analog scale leg pain (one or both legs) score of at least 40/100 at baseline
8. Psychosocially, mentally, and physically able to fully comply with the clinical protocol and willing to adhere to follow-up schedule and requirements
<b>Exclusion Criteria</b>
1. Spondylolisthesis grade II or higher (25% slip or greater)
2. Requires spinal surgery other than a discectomy (with or without laminotomy) to treat leg/back pain (scar tissue and osteophyte removal is allowed)
3. Back or non-radicular leg pain of unknown etiology
4. Prior surgery at the index lumbar vertebral level
5. Patients with a SCORE of 6 or greater and a subsequent spine DXA T-score less than -2.0 at the index level. For herniations at L5/S1, the average T-score of L1-L4 shall be used
6. Clinically compromised vertebral bodies in the lumbosacral region due to any traumatic, neoplastic, metabolic, or infectious pathology
7. Pathologic fractures of the vertebra or multiple fractures of the vertebra or hip
8. Scoliosis of greater than 10 degrees (both angular and rotational)
9. Any metabolic bone disease
10. Active infection, either systemic or local
11. Cauda equina syndrome or neurogenic bowel/bladder dysfunction

12. Severe arterial insufficiency of the legs or other peripheral vascular disease (Screening on physical examination for subjects with diminution or absence of dorsalis pedis or posterior tibialis pulses. If diminished or absent by palpation, then an arterial ultrasound is required with vascular plethysmography. Absolute arterial pressure below 50mm Hg at the calf or ankle level results in exclusion.)
13. Significant peripheral neuropathy, defined as Type I or II diabetes or similar systemic metabolic condition causing decreased sensation in a stocking-like or non-radicular and non-dermatomal distribution in the lower extremities
14. Insulin-dependent diabetes mellitus
15. Morbidly obese, defined as a body mass index > 40 or weighing more than 100 lbs over ideal body weight
16. Active hepatitis, AIDS, or HIV
17. Rheumatoid arthritis or other autoimmune disease
18. Known allergy to titanium, polyethylene, or polyester materials
19. Baseline MRI cannot be obtained
20. Pregnant or interested in becoming pregnant in the next three years
21. Active tuberculosis or history of tuberculosis in the past three years
22. History of active malignancy, defined as any invasive malignancy, except non-melanoma skin cancer, unless treated with curative intent with no signs or symptoms of malignancy for at least two years
23. Immunologically suppressed, defined as receiving steroids for more than one month over the past year
24. Current anticoagulation therapy other than aspirin, unless anticoagulation therapy may be suspended for surgery
25. Current chemical/alcohol dependency or significant psychosocial disturbance
26. Life expectancy of less than three years
27. Current involvement in active spinal litigation
28. Current involvement in another investigational study
29. Incarceration
30. Any contraindication for MRI or CT scan (e.g., claustrophobia, contrast allergy)

**eTable 3.** Study Assessments at each Follow-up Interval.

Assessment	Preop	Surgery	6 weeks	3 months	6 months	1 year	2 years	3 years	4 years	5 years
Informed consent	■									
Demographics/medical history	■									
Pain medication	■	■	■	■	■	■	■	■	■	■
Clinical/neurologic exam	■	■	■	■	■	■	■	■	■	■
Neutral lateral/anteroposterior x-ray	■	■	■	■	■	■	■	■	■	■
Flexion-extension x-ray	■					■	■	■	■	■
Computed tomography	■					■	■	■	■	■
Magnetic resonance imaging	■					■	■	■	■	■
Randomization		■								
Adverse events *		→	→	→	→	→	→	→	→	→

\* Adverse events continuously monitored throughout the study.

**eTable 4.** Reoperations by Type and Timeframe through 5 Years.

Reoperation Type	Year 0-1		Year 1-2		Year 2-3		Year 3-4		Year 4-5		Total	
	Device	Control	Device	Control	Device	Control	Device	Control	Device	Control	Device	Control
Discectomy / decompression	10	24	5	9	2	10	5	5	1	2	23	50
Lumbar fusion	6	6	3	4	5	4	5	1	3	2	22	17
Wound complication	-	5	-	1	1	-	-	-	-	-	1	6
Device removal	4	-	-	-	1	-	-	-	-	-	5	0
Device implant	-	3	-	1	-	-	-	-	-	1	0	5
Hematoma	-	3	-	-	-	-	-	-	-	-	0	3
Instrumentation removal	-	-	-	-	-	-	1	1	-	-	1	1
Dural tear	1	-	-	-	-	-	-	-	-	-	1	0
	<b>21</b>	<b>41</b>	<b>8</b>	<b>15</b>	<b>9</b>	<b>14</b>	<b>11</b>	<b>7</b>	<b>4</b>	<b>5</b>	<b>53</b>	<b>82</b>

**eTable 5.** Serious Adverse Events through 5 Years.<sup>a</sup>

Group	Device			Control			Significance	
	Events	Subjects	%	Events	Subjects	%	Difference	P
<b>ANY SERIOUS ADVERSE EVENT</b>	<b>209</b>	<b>115</b>	<b>43.1%</b>	<b>237</b>	<b>132</b>	<b>46.6%</b>	<b>-3.6%</b>	<b>.440</b>
<b>Benign soft tissue masses/tumors</b>	2	2	0.7%	2	2	0.7%	0.0%	> .99
<b>Cancer</b>	5	5	1.9%	4	3	1.1%	0.8%	.493
<b>Cardiac and Vascular</b>	20	18	6.7%	10	10	3.5%	3.2%	.119
<i>Bleeding</i>	0	0	0.0%	0	0	0.0%		
<i>Other</i>	20	18	6.7%	10	10	3.5%		
<b>Death</b>	1	1	0.4%	1	1	0.4%	0.0%	> .99
<b>Dermatologic</b>	0	0	0.0%	1	1	0.4%	-0.4%	> .99
<b>Device Deficiency</b>	12	12	4.5%	0	0	0.0%	4.5%	< .001
<i>Anchor (whole device) migration</i>	3	3	1.1%	0	0	0.0%		
<i>Mesh Migration - Extradiscal</i>	4	4	1.5%	0	0	0.0%		
<i>Mesh Migration - Intradiscal</i>	1	1	0.4%	0	0	0.0%		
<i>Mesh Subsidence - no Detachment</i>	0	0	0.0%	0	0	0.0%		
<i>Mesh Subsidence - with Detachment</i>	0	0	0.0%	0	0	0.0%		
<i>Mesh Detachment - Extradiscal</i>	2	2	0.7%	0	0	0.0%		
<i>Mesh Detachment - Intradiscal</i>	1	1	0.4%	0	0	0.0%		
<i>Anchor Fracture</i>	1	1	0.4%	0	0	0.0%		
<i>Other</i>	0	0	0.0%	0	0	0.0%		
<b>Disc Herniation</b>	37	31	11.6%	75	59	20.8%	-9.2%	.004
<i>Herniation - Index Level</i>	23	20	7.5%	67	55	19.4%		
<i>Residual herniation - Index Level</i>	2	2	0.7%	0	0	0.0%		
<i>Disc Herniation - Adjacent Level</i>	5	4	1.5%	7	6	2.1%		
<i>Disc Herniation - Non-Adjacent Level</i>	7	6	2.2%	1	1	0.4%		
<b>Endocrine</b>	4	4	1.5%	1	1	0.4%	1.1%	.204
<b>Eyes/Ears/Nose/Throat (EENT)</b>	3	3	1.1%	10	10	3.5%	-2.4%	.090
<b>Gastrointestinal</b>	16	12	4.5%	20	18	6.4%	-1.9%	.354
<b>Genitourinary</b>	8	8	3.0%	10	9	3.2%	-0.2%	> .99
<b>OB/GYN</b>	9	7	2.6%	7	7	2.5%	0.1%	> .99



<b>Infectious Disease</b>	3	3	1.1%	4	4	1.4%	-0.3%	> .99
<b>Immunological</b>	1	1	0.4%	1	1	0.4%	0.0%	> .99
<b>Metabolic/Hematologic/Electrolytes</b>	0	0	0.0%	1	1	0.4%	-0.4%	> .99
<b>Musculoskeletal - Lumbar</b>	6	5	1.9%	5	5	1.8%	0.1%	> .99
<i>Spinal Instability</i>	1	1	0.4%	0	0	0.0%		
<i>Scoliosis</i>	0	0	0.0%	0	0	0.0%		
<i>Radiographic Finding</i>	0	0	0.0%	0	0	0.0%		
<i>Facet Syndrome</i>	4	3	1.1%	2	2	0.7%		
<i>Other</i>	1	1	0.4%	3	3	1.1%		
<b>Musculoskeletal - Non-Lumbar</b>	23	20	7.5%	20	16	5.7%	1.8%	.395
<b>Neurological - Lumbar and Lower Extremity</b>	2	2	0.7%	4	4	1.4%	-0.7%	.687
<i>Nerve or Spinal Root Injury: Index Surgery</i>	0	0	0.0%	1	1	0.4%		
<i>Nerve Root or Spinal cord Impingement</i>	1	1	0.4%	0	0	0.0%		
<i>Musculoskeletal Spasms of the Back or Legs</i>	1	1	0.4%	1	1	0.4%		
<i>Neurological Deterioration</i>	0	0	0.0%	2	2	0.7%		
<i>Other</i>	0	0	0.0%	0	0	0.0%		
<b>Neurological - Non-Lumbar/Lower Extremity</b>	10	9	3.4%	11	9	3.2%	0.2%	> .99
<b>Pain - Lumbar and Lower Extremity</b>	26	20	7.5%	21	15	5.3%	2.2%	.301
<i>Lower Extremity Only</i>	8	8	3.0%	5	4	1.4%		
<i>Lumbar</i>	10	10	3.7%	8	7	2.5%		
<i>Lumbar and Lower Extremity</i>	8	7	2.6%	8	5	1.8%		
<i>Non-specific</i>	0	0	0.0%	0	0	0.0%		
<b>Psychological</b>	4	4	1.5%	5	5	1.8%	-0.3%	> .99
<b>Respiratory/Pulmonary</b>	2	2	0.7%	7	7	2.5%	-1.7%	.178
<b>Trauma</b>	12	11	4.1%	8	8	2.8%	1.3%	.487
<b>Wound Issue- Index or Secondary Surgery at Index Level</b>	3	3	1.1%	9	7	2.5%	-1.3%	.341

<i>Dural Injury/Tear or CSF Leak</i>	1	1	0.4%	2	2	0.7%		
<i>Infection</i>	1	1	0.4%	3	2	0.7%		
<i>Hematoma</i>	0	0	0.0%	1	1	0.4%		
<i>Delayed Wound Healing</i>	1	1	0.4%	0	0	0.0%		
<i>Dehiscence</i>	0	0	0.0%	1	1	0.4%		
<i>Deep</i>	0	0	0.0%	2	2	0.7%		
<b>Necrosis of Bone or Resorption</b>	0	0	0.0%	0	0	0.0%	0.0%	—

<sup>a</sup> Adverse events reported in the as-treated population consisting of 267 patients receiving ACD and 283 receiving Control. In the as-treated population, failed implantation in 5 ACD patients (including 1 with nerve root injury) resulted in assignment to the Control group.

**eTable 6.** Serious Device- and Procedure-related Adverse Events through 5 Years.<sup>a</sup>

Group	Device			Control			Significance	
	Events	Subjects	%	Events	Subjects	%	Difference	P
<b>ANY DEVICE OR PROCEDURE RELATED SERIOUS ADVERSE EVENT</b>	<b>41</b>	<b>32</b>	<b>12.0%</b>	<b>80</b>	<b>58</b>	<b>20.5%</b>	<b>-8.5%</b>	<b>.008</b>
<b>Benign soft tissue masses/tumors</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Cancer</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Cardiac and Vascular</b>	0	0	0.0%	2	2	0.7%	-0.7%	.500
<i>Bleeding</i>	0	0	0.0%	0	0	0.0%		
<i>Other</i>	0	0	0.0%	2	2	0.7%		
<b>Death</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Dermatologic</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Device Deficiency</b>	11	11	4.1%	0	0	0.0%	4.1%	< .001
<i>Anchor (whole device) migration</i>	2	2	0.7%	0	0	0.0%		
<i>Mesh Migration - Extradiscal</i>	4	4	1.5%	0	0	0.0%		
<i>Mesh Migration - Intradiscal</i>	1	1	0.4%	0	0	0.0%		
<i>Mesh Subsidence - no Detachment</i>	0	0	0.0%	0	0	0.0%		
<i>Mesh Subsidence - with Detachment</i>	0	0	0.0%	0	0	0.0%		
<i>Mesh Detachment - Extradiscal</i>	2	2	0.7%	0	0	0.0%		
<i>Mesh Detachment - Intradiscal</i>	1	1	0.4%	0	0	0.0%		
<i>Anchor Fracture</i>	1	1	0.4%	0	0	0.0%		
<i>Other</i>	0	0	0.0%	0	0	0.0%		
<b>Disc Herniation</b>	24	21	7.9%	60	49	17.3%	-9.4%	.001
<i>Herniation - Index Level</i>	21	18	6.7%	60	49	17.3%		
<i>Residual herniation - Index Level</i>	2	2	0.7%	0	0	0.0%		
<i>Disc Herniation - Adjacent Level</i>	1	1	0.4%	0	0	0.0%		
<i>Disc Herniation - Non-Adjacent Level</i>	0	0	0.0%	0	0	0.0%		
<b>Endocrine</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Eyes/Ears/Nose/Throat (EENT)</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Gastrointestinal</b>	0	0	0.0%	1	1	0.4%	-0.4%	> .99

<b>Genitourinary</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>OB/GYN</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Infectious Disease</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Immunological</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Metabolic/Hematologic/Electrolytes</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Musculoskeletal - Lumbar</b>	0	0	0.0%	1	1	0.4%	-0.4%	> .99
<i>Spinal Instability</i>	0	0	0.0%	0	0	0.0%		
<i>Scoliosis</i>	0	0	0.0%	0	0	0.0%		
<i>Radiographic Finding</i>	0	0	0.0%	0	0	0.0%		
<i>Facet Syndrome</i>	0	0	0.0%	0	0	0.0%		
<i>Other</i>	0	0	0.0%	1	1	0.4%		
<b>Musculoskeletal - Non-Lumbar</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Neurological - Lumbar and Lower Extremity</b>	0	0	0.0%	2	2	0.7%	-0.7%	.500
<i>Nerve or Spinal Root Injury: Index Surgery</i>	0	0	0.0%	1	1	0.4%		
<i>Nerve Root or Spinal cord Impingement</i>	0	0	0.0%	0	0	0.0%		
<i>Musculoskeletal Spasms of the Back or Legs</i>	0	0	0.0%	0	0	0.0%		
<i>Neurological Deterioration</i>	0	0	0.0%	1	1	0.4%		
<i>Other</i>	0	0	0.0%	0	0	0.0%		
<b>Neurological - Non-Lumbar/Lower Extremity</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Pain - Lumbar and Lower Extremity</b>	3	3	1.1%	5	3	1.1%	0.1%	> .99
<i>Lower Extremity Only</i>	1	1	0.4%	4	3	1.1%		
<i>Lumbar</i>	1	1	0.4%	0	0	0.0%		
<i>Lumbar and Lower Extremity</i>	1	1	0.4%	1	1	0.4%		
<i>Non-specific</i>	0	0	0.0%	0	0	0.0%		
<b>Psychological</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Respiratory/Pulmonary</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Trauma</b>	0	0	0.0%	0	0	0.0%	0.0%	—

<b>Wound Issue- Index or Secondary Surgery at Index Level</b>	3	3	1.1%	9	7	2.5%	-1.3%	.341
<i>Dural Injury/Tear or CSF Leak</i>	1	1	0.4%	2	2	0.7%		
<i>Infection</i>	1	1	0.4%	3	2	0.7%		
<i>Hematoma</i>	0	0	0.0%	1	1	0.4%		
<i>Delayed Wound Healing</i>	1	1	0.4%	0	0	0.0%		
<i>Dehiscence</i>	0	0	0.0%	1	1	0.4%		
<i>Deep</i>	0	0	0.0%	2	2	0.7%		
<b>Necrosis of Bone or Resorption</b>	0	0	0.0%	0	0	0.0%	0.0%	—

<sup>a</sup> Adverse events reported in the as-treated population consisting of 267 patients receiving ACD and 283 receiving Control. In the as-treated population, failed implantation in 5 ACD patients (including 1 with nerve root injury) resulted in assignment to the Control group.

eTable 7. All Adverse Events through 5 Years.<sup>a</sup>

Group	Device			Control			Significance	
	Events	Subjects	%	Events	Subjects	%	Difference	P
<b>ANY ADVERSE EVENT</b>	<b>680</b>	<b>228</b>	<b>85.4%</b>	<b>662</b>	<b>232</b>	<b>82.0%</b>	<b>3.4%</b>	<b>.301</b>
<b>Benign soft tissue masses/tumors</b>	3	3	1.1%	2	2	0.7%	0.4%	.678
<b>Cancer</b>	8	8	3.0%	5	4	1.4%	1.6%	.250
<b>Cardiac and Vascular</b>	27	24	9.0%	25	23	8.1%	0.9%	.762
<i>Bleeding</i>	2	2	0.7%	0	0	0.0%		
<i>Other</i>	25	22	8.2%	25	23	8.1%		
<b>Death</b>	1	1	0.4%	1	1	0.4%	0.0%	> .99
<b>Dermatologic</b>	3	3	1.1%	5	5	1.8%	-0.6%	.725
<b>Device Deficiency</b>	34	33	12.4%	1	1	0.4%	12.0%	< .001
<i>Anchor (whole device) migration</i>	3	3	1.1%	0	0	0.0%		
<i>Mesh Migration - Extradiscal</i>	8	8	3.0%	0	0	0.0%		
<i>Mesh Migration - Intradiscal</i>	4	4	1.5%	0	0	0.0%		
<i>Mesh Subsidence - no Detachment</i>	4	4	1.5%	0	0	0.0%		
<i>Mesh Subsidence - with Detachment</i>	3	3	1.1%	0	0	0.0%		
<i>Mesh Detachment - Extradiscal</i>	7	7	2.6%	0	0	0.0%		
<i>Mesh Detachment - Intradiscal</i>	2	2	0.7%	1	1	0.4%		
<i>Anchor Fracture</i>	2	2	0.7%	0	0	0.0%		
<i>Other</i>	1	1	0.4%	0	0	0.0%		
<b>Disc Herniation</b>	69	55	20.6%	122	93	32.9%	-12.3%	.001
<i>Herniation - Index Level</i>	38	34	12.7%	102	85	30.0%		
<i>Residual herniation - Index Level</i>	2	2	0.7%	0	0	0.0%		
<i>Disc Herniation - Adjacent Level</i>	19	17	6.4%	16	14	4.9%		
<i>Disc Herniation - Non-Adjacent Level</i>	10	9	3.4%	4	4	1.4%		
<b>Endocrine</b>	8	8	3.0%	4	4	1.4%	1.6%	.250
<b>Eyes/Ears/Nose/Throat (EENT)</b>	13	13	4.9%	23	23	8.1%	-3.3%	.167
<b>Gastrointestinal</b>	28	22	8.2%	40	32	11.3%	-3.1%	.253
<b>Genitourinary</b>	18	18	6.7%	17	15	5.3%	1.4%	.591
<b>OB/GYN</b>	12	10	3.7%	9	9	3.2%	0.6%	.817

<b>Infectious Disease</b>	5	4	1.5%	4	4	1.4%	0.1%	> .99
<b>Immunological</b>	3	3	1.1%	7	7	2.5%	-1.3%	.341
<b>Metabolic/Hematologic/Electrolytes</b>	4	4	1.5%	8	8	2.8%	-1.3%	.385
<b>Musculoskeletal - Lumbar</b>	17	15	5.6%	17	14	4.9%	0.7%	.849
<i>Spinal Instability</i>	2	2	0.7%	0	0	0.0%		
<i>Scoliosis</i>	0	0	0.0%	3	3	1.1%		
<i>Radiographic Finding</i>	4	4	1.5%	0	0	0.0%		
<i>Facet Syndrome</i>	10	9	3.4%	9	7	2.5%		
<i>Other</i>	1	1	0.4%	5	5	1.8%		
<b>Musculoskeletal - Non-Lumbar</b>	89	66	24.7%	84	64	22.6%	2.1%	.616
<b>Neurological - Lumbar and Lower Extremity</b>	44	37	13.9%	33	30	10.6%	3.3%	.297
<i>Nerve or Spinal Root Injury: Index Surgery</i>	2	2	0.7%	4	4	1.4%		
<i>Nerve Root or Spinal cord Impingement</i>	4	4	1.5%	3	2	0.7%		
<i>Muskuloskeletal Spasms of the Back or Legs</i>	9	9	3.4%	1	1	0.4%		
<i>Neurological Deterioration</i>	28	23	8.6%	25	23	8.1%		
<i>Other</i>	1	1	0.4%	0	0	0.0%		
<b>Neurological - Non-Lumbar/Lower Extremity</b>	24	19	7.1%	20	15	5.3%	1.8%	.383
<b>Pain - Lumbar and Lower Extremity</b>	139	97	36.3%	148	111	39.2%	-2.9%	.538
<i>Lower Extremity Only</i>	41	37	13.9%	53	46	16.3%		
<i>Lumbar</i>	68	59	22.1%	75	65	23.0%		
<i>Lumbar and Lower Extremity</i>	29	26	9.7%	20	16	5.7%		
<i>Non-specific</i>	1	1	0.4%	0	0	0.0%		
<b>Psychological</b>	15	15	5.6%	15	15	5.3%	0.3%	> .99
<b>Respiratory/Pulmonary</b>	6	6	2.2%	17	17	6.0%	-3.8%	.033
<b>Trauma</b>	27	26	9.7%	26	24	8.5%	1.3%	.658
<b>Wound Issue- Index or Secondary Surgery at Index Level</b>	26	22	8.2%	25	22	7.8%	0.5%	.876

<i>Dural Injury/Tear or CSF Leak</i>	19	18	6.7%	15	15	5.3%		
<i>Infection</i>	2	2	0.7%	5	4	1.4%		
<i>Hematoma</i>	3	3	1.1%	2	2	0.7%		
<i>Delayed Wound Healing</i>	1	1	0.4%	0	0	0.0%		
<i>Dehiscence</i>	0	0	0.0%	1	1	0.4%		
<i>Deep</i>	1	1	0.4%	2	2	0.7%		
<b>Necrosis of Bone or Resorption</b>	57	54	20.2%	4	4	1.4%	18.8%	< .001

<sup>a</sup> Adverse events reported in the as-treated population consisting of 267 patients receiving ACD and 283 receiving Control. In the as-treated population, failed implantation in 5 ACD patients (including 1 with nerve root injury) resulted in assignment to the Control group.



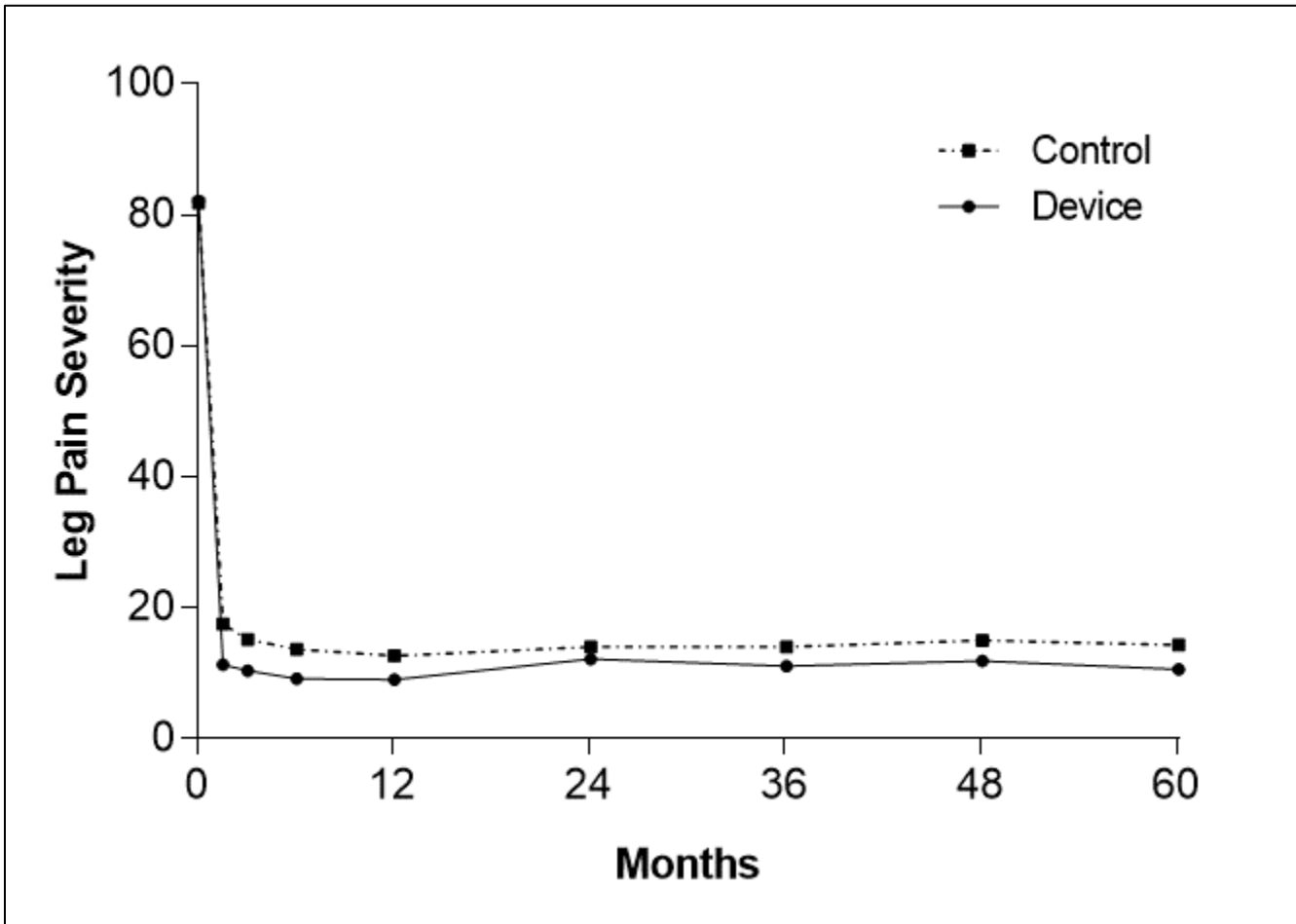
**eTable 8.** All Device- and Procedure-related Adverse Events through 5 Years.<sup>a</sup>

Group	Device			Control			Significance	
	Events	Subjects	%	Events	Subjects	%	Difference	P
<b>ANY DEVICE OR PROCEDURE RELATED ADVERSE EVENT</b>	<b>168</b>	<b>121</b>	<b>45.3%</b>	<b>146</b>	<b>105</b>	<b>37.1%</b>	<b>8.2%</b>	<b>.057</b>
<b>Benign soft tissue masses/tumors</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Cancer</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Cardiac and Vascular</b>	2	2	0.7%	4	4	1.4%	-0.7%	.687
<i>Bleeding</i>	2	2	0.7%	0	0	0.0%		
<i>Other</i>	0	0	0.0%	4	4	1.4%		
<b>Death</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Dermatologic</b>	0	0	0.0%	1	1	0.4%	-0.4%	> .99
<b>Device Deficiency</b>	33	32	12.0%	1	1	0.4%	11.6%	< .001
<i>Anchor (whole device) migration</i>	2	2	0.7%	0	0	0.0%		
<i>Mesh Migration - Extradiscal</i>	8	8	3.0%	0	0	0.0%		
<i>Mesh Migration - Intradiscal</i>	4	4	1.5%	0	0	0.0%		
<i>Mesh Subsidence - no Detachment</i>	4	4	1.5%	0	0	0.0%		
<i>Mesh Subsidence - with Detachment</i>	3	3	1.1%	0	0	0.0%		
<i>Mesh Detachment - Extradiscal</i>	7	7	2.6%	0	0	0.0%		
<i>Mesh Detachment - Intradiscal</i>	2	2	0.7%	1	1	0.4%		
<i>Anchor Fracture</i>	2	2	0.7%	0	0	0.0%		
<i>Other</i>	1	1	0.4%	0	0	0.0%		
<b>Disc Herniation</b>	38	34	12.7%	91	77	27.2%	-14.5%	< .001
<i>Herniation - Index Level</i>	35	31	11.6%	91	77	27.2%		
<i>Residual herniation - Index Level</i>	2	2	0.7%	0	0	0.0%		
<i>Disc Herniation - Adjacent Level</i>	1	1	0.4%	0	0	0.0%		
<i>Disc Herniation - Non-Adjacent Level</i>	0	0	0.0%	0	0	0.0%		
<b>Endocrine</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Eyes/Ears/Nose/Throat (EENT)</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Gastrointestinal</b>	1	1	0.4%	3	3	1.1%	-0.7%	.624
<b>Genitourinary</b>	1	1	0.4%	1	1	0.4%	0.0%	> .99

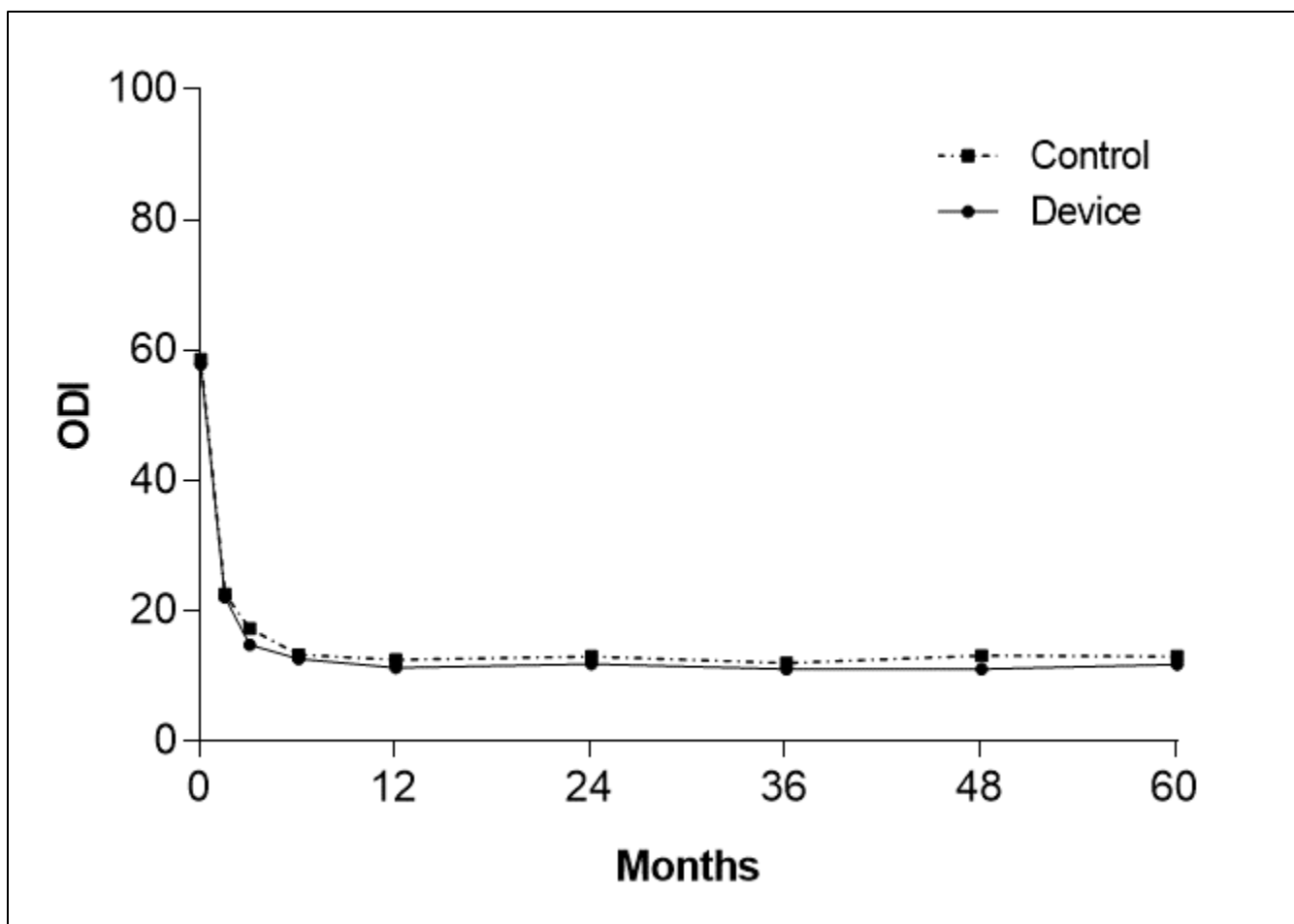
<b>OB/GYN</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Infectious Disease</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Immunological</b>	0	0	0.0%	1	1	0.4%	-0.4%	> .99
<b>Metabolic/Hematologic/Electrolytes</b>	0	0	0.0%	1	1	0.4%	-0.4%	> .99
<b>Musculoskeletal - Lumbar</b>	1	1	0.4%	1	1	0.4%	0.0%	> .99
<i>Spinal Instability</i>	0	0	0.0%	0	0	0.0%		
<i>Scoliosis</i>	0	0	0.0%	0	0	0.0%		
<i>Radiographic Finding</i>	1	1	0.4%	0	0	0.0%		
<i>Facet Syndrome</i>	0	0	0.0%	0	0	0.0%		
<i>Other</i>	0	0	0.0%	1	1	0.4%		
<b>Musculoskeletal - Non-Lumbar</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Neurological - Lumbar and Lower Extremity</b>	3	3	1.1%	9	9	3.2%	-2.1%	.144
<i>Nerve or Spinal Root Injury: Index Surgery</i>	2	2	0.7%	4	4	1.4%		
<i>Nerve Root or Spinal cord Impingement</i>	0	0	0.0%	0	0	0.0%		
<i>Muskuloskeletal Spasms of the Back or Legs</i>	0	0	0.0%	0	0	0.0%		
<i>Neurological Deterioration</i>	1	1	0.4%	5	5	1.8%		
<i>Other</i>	0	0	0.0%	0	0	0.0%		
<b>Neurological - Non-Lumbar/Lower Extremity</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Pain - Lumbar and Lower Extremity</b>	9	9	3.4%	8	6	2.1%	1.3%	.438
<i>Lower Extremity Only</i>	3	3	1.1%	6	5	1.8%		
<i>Lumbar</i>	3	3	1.1%	1	1	0.4%		
<i>Lumbar and Lower Extremity</i>	2	2	0.7%	1	1	0.4%		
<i>Non-specific</i>	1	1	0.4%	0	0	0.0%		
<b>Psychological</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Respiratory/Pulmonary</b>	0	0	0.0%	0	0	0.0%	0.0%	—
<b>Trauma</b>	0	0	0.0%	1	1	0.4%	-0.4%	> .99

<b>Wound Issue- Index or Secondary Surgery at Index Level</b>	25	22	8.2%	23	21	7.4%	0.8%	.753
<i>Dural Injury/Tear or CSF Leak</i>	18	18	6.7%	14	14	4.9%		
<i>Infection</i>	2	2	0.7%	4	3	1.1%		
<i>Hematoma</i>	3	3	1.1%	2	2	0.7%		
<i>Delayed Wound Healing</i>	1	1	0.4%	0	0	0.0%		
<i>Dehiscence</i>	0	0	0.0%	1	1	0.4%		
<i>Deep</i>	1	1	0.4%	2	2	0.7%		
<b>Necrosis of Bone or Resorption</b>	55	53	19.9%	1	1	0.4%	19.5%	< .001

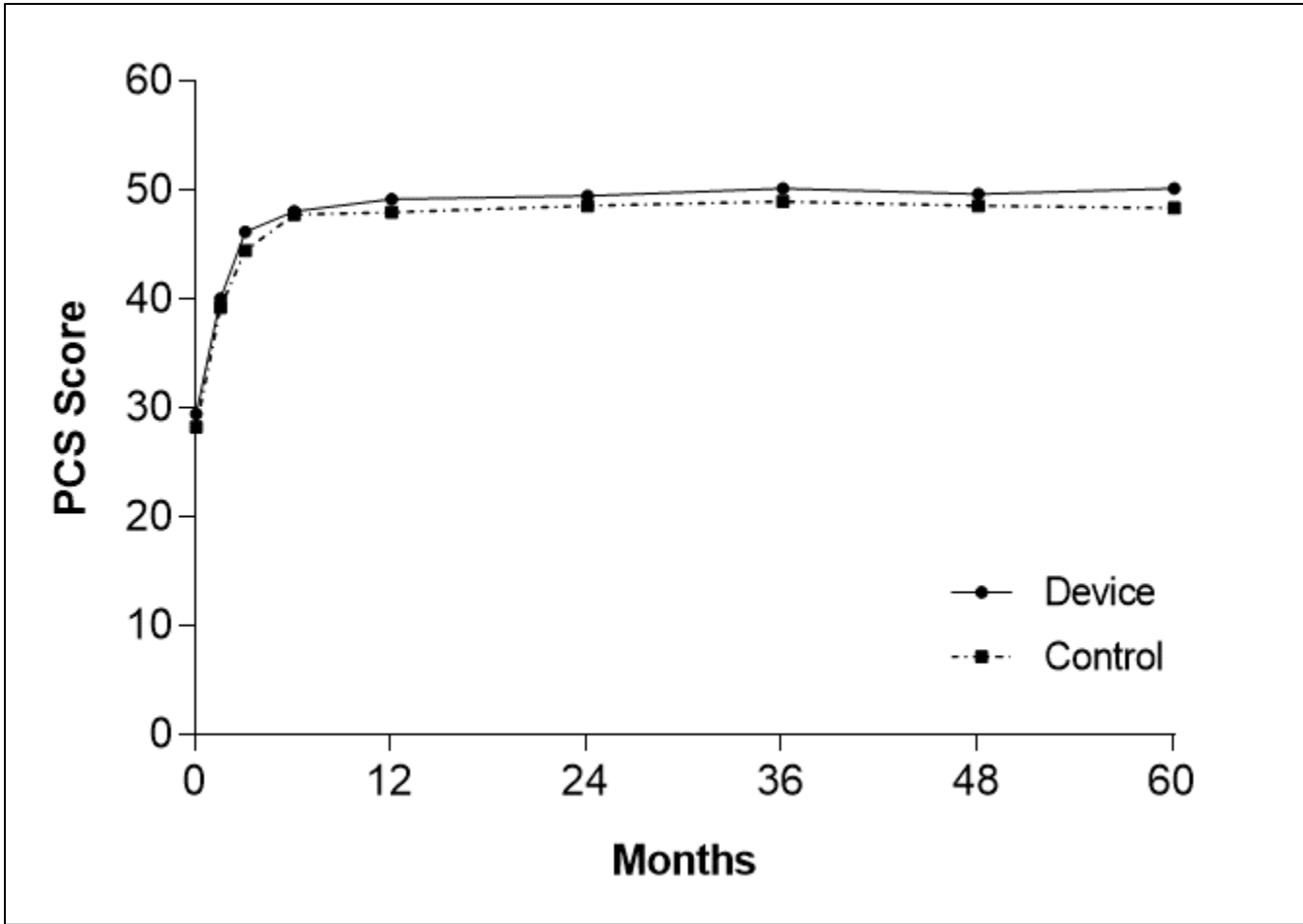
<sup>a</sup> Adverse events reported in the as-treated population consisting of 267 patients receiving ACD and 283 receiving Control. In the as-treated population, failed implantation in 5 ACD patients (including 1 with nerve root injury) resulted in assignment to the Control group.



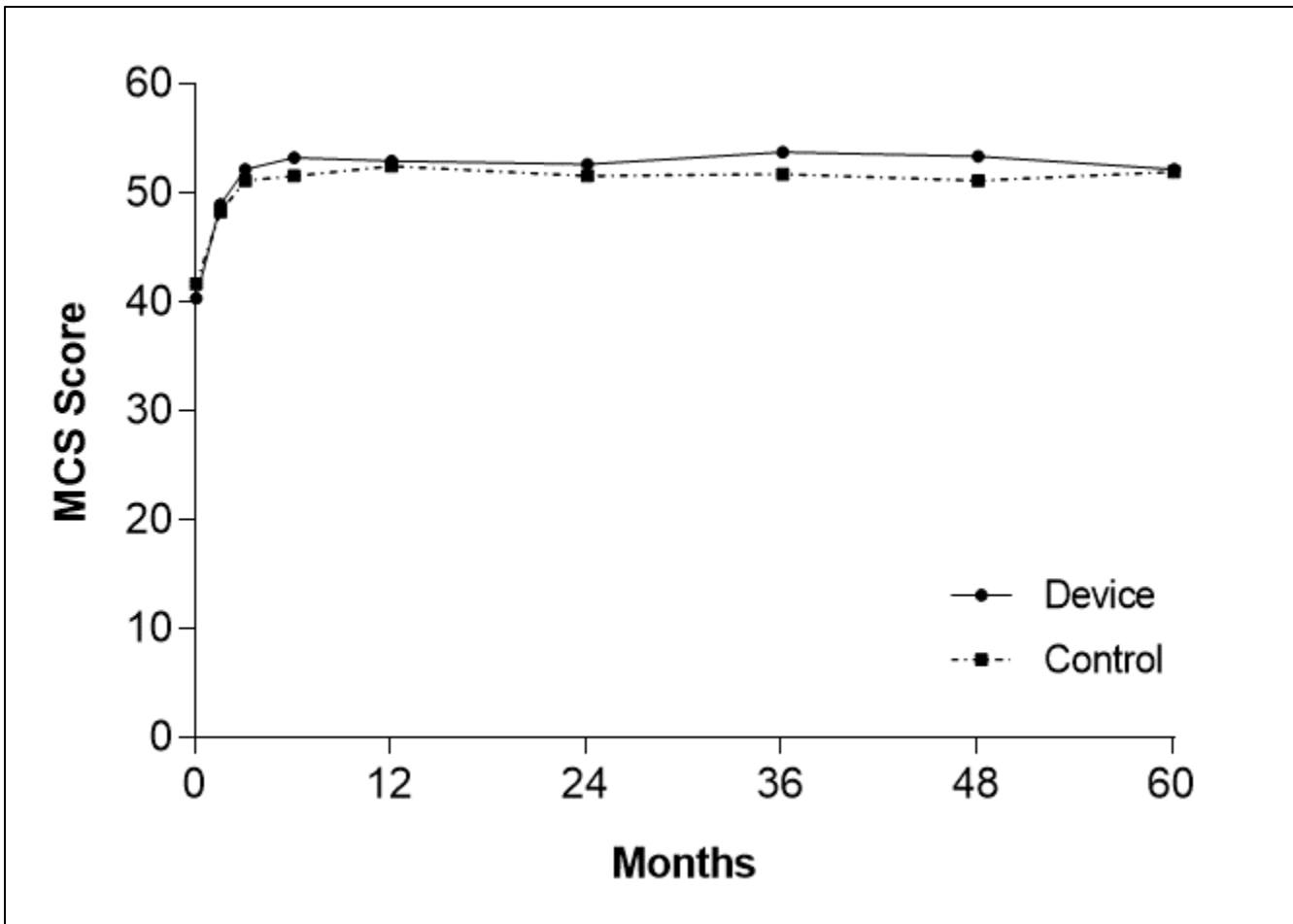
**eFigure 1.** Visual analogue Scale for Leg Pain Severity over 5 Years Follow-up.



**eFigure 2.** Oswestry Disability Index Score over 5 Years Follow-up.  
ODI=Oswestry Disability Index.



**eFigure 3.** SF-36 Physical Component Summary Score over 5 Years Follow-up. PCS=Physical Component Summary.



**eFigure 4.** SF-36 Mental Component Summary Score over 5 Years Follow-up. MCS=Mental Component Summary.