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ORIGINAL RESEARCH

Five-year durability of stand-alone interspinous process decompression for lumbar spinal stenosis

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Background: Lumbar spinal stenosis is the most common indication for spine surgery in older adults. Interspinous process decompression (IPD) using a stand-alone spacer that functions as an extension blocker offers a minimally invasive treatment option for intermittent neurogenic claudication associated with spinal stenosis.

Methods: This study evaluated the 5-year clinical outcomes for IPD (Superion®) from a randomized controlled US Food and Drug Administration (FDA) noninferiority trial. Outcomes included Zurich Claudication Questionnaire (ZCQ) symptom severity (ss), physical function (pf), and patient satisfaction (ps) subdomains, leg and back pain visual analog scale (VAS), and Oswestry Disability Index (ODI).

Results: At 5 years, 84% of patients (74 of 88) demonstrated clinical success on at least two of three ZCQ domains. Individual ZCQ domain success rates were 75% (66 of 88), 81% (71 of 88), and 90% (79 of 88) for ZCQss, ZCQpf, and ZCQps, respectively. Leg and back pain success rates were 80% (68 of 85) and 65% (55 of 85), respectively, and the success rate for ODI was 65% (57 of 88). Percentage improvements over baseline were 42%, 39%, 75%, 66%, and 58% for ZCQss, ZCQpf, leg and back pain VAS, and ODI, respectively (all $P<0.001$). Within-group effect sizes were classified as very large for four of five clinical outcomes (ie, >1.0; all $P<0.0001$). Seventy-five percent of IPD patients were free from reoperation, revision, or supplemental fixation at their index level at 5 years.

Conclusion: After 5 years of follow-up, IPD with a stand-alone spacer provides sustained clinical benefit.

Keywords: interspinous spacer, lumbar spinal stenosis, Superion, neurogenic claudication, decompression

Introduction

Within 10 years, it is estimated that 64 million older adults will be afflicted with lumbar spinal stenosis, making it the most common indication for spine surgery in individuals older than 65 years.[1,2] This expanding population of patients requires a greater range of treatment options throughout the continuum of care, particularly in the elderly who may not be appropriate candidates for open surgical procedures with the associated risks of general anesthesia.[3] Interspinous process decompression (IPD) is a minimally invasive procedure that can be performed under monitored anesthesia care in an ambulatory surgery center and has been shown to provide comparable clinical performance to decompressive laminectomy for management of symptoms of spinal stenosis.[4,5]

Neurogenic claudication is the cardinal clinical feature of lumbar spinal stenosis, as it limits patients' walking ability and causes a major impact on their quality of life.[6] Intermittent neurogenic claudication is defined as unilateral or bilateral radicular pain

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during walking or standing that is relieved by sitting down or flexing the lumbar spine.[7] Stenotic arthritic degeneration of the lumbar spine causes bony and ligamentous compression of neural structures axially and laterally. Indeed, constriction and impingement of nerves traversing the lateral recess and exiting the foraminal aperture are highly contributory to the most pronounced and aggravating radicular symptoms of stenosis.[8]

IPD employs a stand-alone spacer that functions as an extension blocker to minimize the extent of compression of neural elements, particularly in the lateral recess and foramina.[9] Importantly, insertion of the spacer is performed percutaneously without surgical removal of tissue adjacent to the dura or exiting nerves. There is only one Food and Drug Administration (FDA)-approved stand-alone spacer commercially available in the USA. Herein, we provide the 5-year clinical outcomes for patients with moderate lumbar spinal stenosis treated with this IPD device.

Materials and methods

Clinical outcomes at the 5-year follow-up interval were obtained from the Superion® (VertiFlex, Inc., Carlsbad, CA, USA) treatment arm of a randomized controlled FDA noninferiority trial comparing two interspinous spacers. Methodological details of the study have been published previously.[10,11] This multicenter trial evaluated the use of stand-alone IPD in the treatment of subjects aged 45 or older with moderate symptoms of intermittent neurogenic claudication, secondary to a diagnosis of moderate degenerative lumbar spinal stenosis at one or two contiguous levels from L1 to L5. Three hundred ninety-one subjects met the trial eligibility criteria and were randomized to treatment. The comparative effectiveness of these two spacers and the FDA-approved indications for use for IPD have been reported previously.[12] The current 5-year analysis was restricted exclusively to the Superion arm of the trial.

This trial complied with all US regulatory requirements and was approved by the Institutional Review Board at each participating site (Table S1), and patients provided written informed consent before any study-related procedures were performed. The trial was prospectively registered at ClinicalTrials.gov (NCT00692276).

At the 5-year follow-up interval, 127 patients were free from reoperation (n=48) and/or epidural steroid injection (n=33), and there were 6 deaths, leaving 121 (64%) spacer patients actively participating in the post-market period of this study. Eighty-eight of 121 active spacer patients (73%) provided complete 5-year clinical outcome assessments by the Zurich Claudication Questionnaire (ZCQ), leg and back pain severity by visual analog scale (VAS), and the Oswestry Disability Index (ODI).

Clinical outcome data were analyzed in several ways. Success rates were calculated based on a priori definitions of the minimal clinically important difference: ≥0.5-point change for ZCQ symptom severity (ss) and physical function (pf), ≤2.5 points for ZCQ patient satisfaction (ps), ≥20 mm for pain VAS, and ≥15% points for ODI. Additionally, we computed the percentage improvement in each outcome measure at 5 years compared to preoperative values and displayed these results graphically.

The within-group effect sizes at the 5-year postoperative interval were computed and compared to baseline for each clinical outcome separately using Cohen's formula and thresholds.[13,14] Effect sizes were reported in the range from 0.0 (no effect) to >1.0 (very large effects) with the following thresholds: 0.2 (small effect), 0.5 (medium effect), 0.8 (large effect), and >1.0 (very large effect).

Results

Five years after the index procedure, 74 of 88 patients (84%) demonstrated clinical success on at least two of three ZCQ domains. The success rates for the individual ZCQ domains were 75% (66 of 88), 81% (71 of 88), and 90% (79 of 88) for ZCQss, ZCQpf, and ZCQps, respectively. For leg and back pain VAS, the success rates were 80% (68 of 85) and 65% (55 of 85), respectively, and the rate was 65% (57 of 88) for ODI.

There was substantial improvement at each annual follow-up interval compared to baseline for the ZCQ (Figure 1), leg and back pain VAS (Figure 2), and ODI (Figure 3). Spacer patients demonstrated percentage improvements over baseline

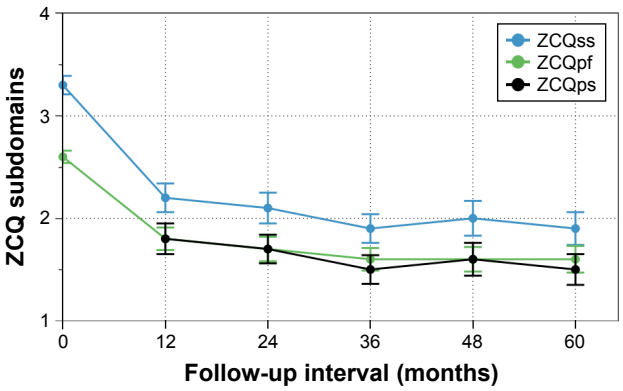

Figure 1 Time course of results for each subdomain of the ZCQ: ss, pf, ps.
Note: Results reported as mean (95% CI).
Abbreviations: pf, physical function; ps, patient satisfaction; ss, symptom severity; ZCQ, Zurich Claudication Questionnaire.

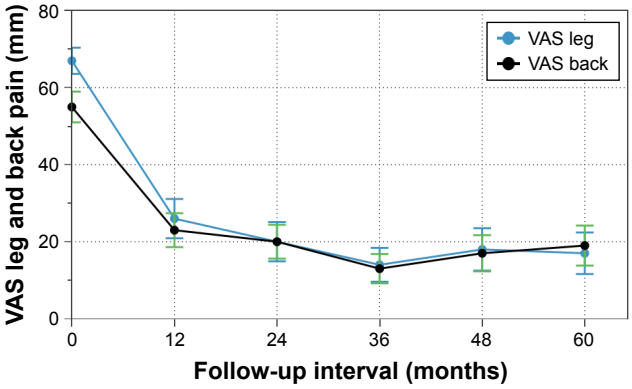

Figure 2 Time course of results for leg and back pain severity by VAS.
Note: Results reported as mean (95% CI).
Abbreviation: VAS, visual analog scale.

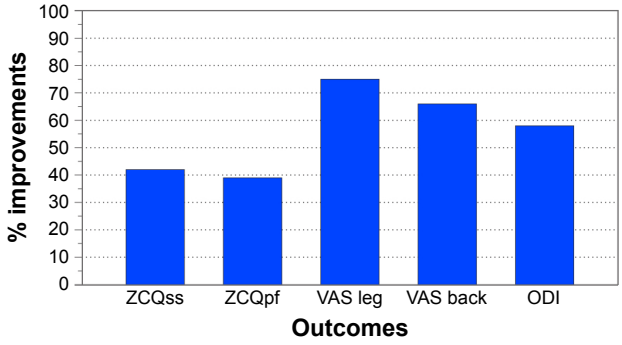

Figure 4 Percentage improvement for each outcome at 5 years compared to preoperative levels.
Note: All changes were statistically significant ($P<0.001$).
Abbreviations: ODI, Oswestry Disability Index; pf, physical function; ss, symptom severity; VAS, visual analog scale; ZCQ, Zurich Claudication Questionnaire.

of 42%, 39%, 75%, 66%, and 58% for ZCQss, ZCQpf, leg and back pain VAS, and ODI, respectively (all $P<0.001$), as shown in Figure 4. Within-group effect sizes were classified as very large for four of five clinical outcomes (ie, >1.0): 1.35, 1.40, 1.32, 0.97, and 1.37 for ZCQss, ZCQpf, leg and back pain VAS, and ODI, respectively (all $P<0.0001$), as shown in Figure 5.

Of the 190 patients randomized to receive treatment, 142 (75%) were free from reoperation, revision, or supplemental fixation at their index level at 5 years. Notably, there was a discernible trend toward decreasing risk of reoperation over time with the majority of revisions occurring during the initial 2 years of observation with annual percentage increments as follows: 27 (14.2%), 11 (5.8%), 3 (1.6%), 6 (3.2%), and 1 (0.5%) during years 1, 2, 3, 4, and 5, respectively.

Discussion

It has been estimated that ~40% of patients with lumbar spinal stenosis become refractory to conservative care and will ultimately require decompression surgery within 10 years to manage persistently worsening symptoms.[15] Moreover, while laminectomy effectively decompresses the offended neural elements providing symptom relief, it can destabilize the spine, eventually leading to re-emergence of symptoms requiring reoperation with instrumented fusion. A recent randomized controlled trial reported that one-third of laminectomy patients required reoperation with fusion within 4 years.[16] This rate of reoperation rate after laminectomy is comparable to a 28% rate reported from a large Washington state administrative database.[17] Treatment of recalcitrant symptoms of neurogenic claudication with an interspinous spacer may significantly delay or obviate completely the need for decompressive laminectomy as well as the downstream risk of revision surgery with instrumented fusion.

This is the first report to document the long-term clinical durability of stand-alone interspinous spacer decompression for lumbar spinal stenosis through 5 years of monitored follow-up. For the 75% of spacer patients who have remained free of reoperation with an intact implant, the clinical results

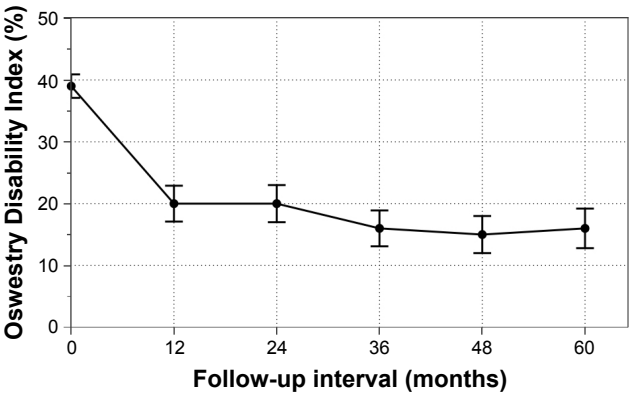

Figure 3 Time course results for the Oswestry Disability Index.
Note: Results reported as mean (95% CI).

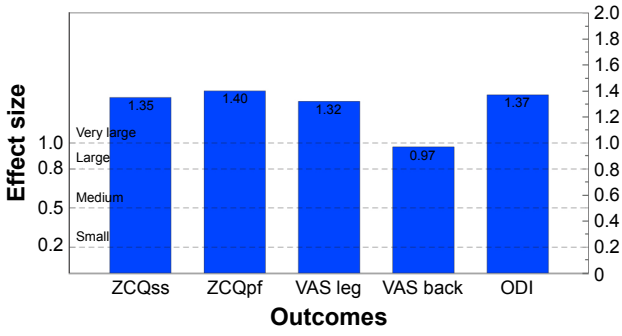

Figure 5 Within-group effect sizes for each outcome at 5 years.
Note: Effect sizes for four of five outcomes exceeded the very large threshold and all effect sizes were highly statistically significant ($P<0.0001$).
Abbreviations: ODI, Oswestry Disability Index; pf, physical function; ss, symptom severity; VAS, visual analog scale; ZCQ, Zurich Claudication Questionnaire.

continue to be impressive, with almost 85% of patients achieving success on at least two of three ZCQ domains. Leg pain symptom amelioration remains most notable with an average improvement of 75% at 5 years over preoperative values. This suggests that the spacer continues to offer sufficient indirect decompression of neural structures in the lateral recesses and foramina to suppress claudicant and radicular symptoms.

Thirty-eight of 48 (79%) spacer patients underwent reoperation within the initial 2 years of postoperative observation. Of the remaining 10 reoperations, only 1 occurred during the fifth year of observation, suggesting a decreasing risk of revision surgery with time. This implies that patients who demonstrate early clinical improvement with spacer implantation will maintain that benefit over time. Clinical failures after spacer treatment can be identified early in the postoperative time course and these patients can be offered other surgical options. In contrast, reoperation rates after laminectomy tend to increase with time.[16] Consequently, early clinical success may not be sustained in the long term, as outcomes eventually deteriorate due to the untoward effects of laminectomy-induced spinal instability, necessitating a complex instrumented fusion procedure to provide stabilization.

Because the IPD implantation procedure is performed in a minimally invasive fashion and causes only minor anatomic disruption, the full range of surgical options remains available if a revision becomes necessary to manage re-emergence of symptoms. Thus, with simplicity of the operative procedure, rapid patient recovery, low surgical risk of complications, and long-term clinical durability, IPD remains a viable treatment option for stenosis patients.

Conclusion

After 5 years of postoperative follow-up, IPD with a standalone spacer provides sustained clinical benefit. Its use is indicated for patients with intermittent neurogenic claudication associated with moderate lumbar spinal stenosis.

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Author contributions

All authors contributed toward data analysis, drafting and critically revising the paper and agree to be accountable for all aspects of the work.

Disclosure

JB is an independent advisor to VertiFlex. The authors report no other conflicts of interest in this work.

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Supplementary material

Table S1 Site list of institutional review board (IRB) information

Investigators/investigational sites				
Site	**Doctor**	**IRB site approved address**	**IRB address**	**IRB Chairman**
01	Pierce Nunley, MD 318-629-5555 (Site inactive)	Spine Institute of Louisiana 1500 Line Avenue, Suite 200 Shreveport, LA 71101 *Specialist Hospital of Shreveport 1500 Line Avenue, Suite 206 Shreveport, LA 71101	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Viveca Burnette 800-562-4789
02	Robert Jackson, MD 949-588-5800 (Site inactive)	Orange County Neurosurgical Associates 23961 Calle de la Magdalena, Suite 504 Laguna Hills, CA 92563 *Saddleback Memorial Medical Center 24451 Health Center Drive Laguna Hills, CA 92563	Office of Research Administration Van Camp Center 2625 Pasadena Ave Long Beach, CA 90806 MHS Research Council-Mailing Address 2801 Atlantic Avenue Long Beach, CA 90806	Edward Quilligan, MD 562-933-9574
04	Warren Yu, MD 202-498-2105 (Site inactive)	George Washington University 2150 Pennsylvania Avenue, NW Suite 7-416 Washington, DC 20037	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Paul Newton 800-562-4789
08	Vikas Patel, MD 720-848-1980 (Site inactive)	Anschutz Outpatient Pavilion 1635 North Ursula Street MS F722, Box 6510 Aurora, CO 80045 *University of Colorado Hospital Anschutz Medical Campus 12605 East 16th Avenue Aurora, CO 80045 Lone Tree Health Center 9548 Park Meadows Drive Lone Tree, CO 80124	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Viveca Burnette 800-562-4789
10	Vito Loguidice, MD 610-252-1600 (Site inactive)	Coordinated Health Inc., 3100 Emrick Blvd., Bethlehem, PA 18020 Orthopedic Associates of Greater Lehigh Valley 755 Memorial Parkway Phillipsburg, NJ 08865 *Warren Hospital 185 Roseberry Street Phillipsburg, NJ 08865	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115 Warren Hospital IRB 185 Roseberry Street Phillipsburg, NJ 08865 (IRB inactive)	Currien MacDonald 800-562-4789 Dr Frank Gilly 908-859-6700 inactive
11	Richard Ozuna, MD 978-818-6350 (Site inactive)	Sports Medicine North One Orthopedics Drive, 2nd Floor Peabody, MA 01960 *Orthopedic Surgical Center of the North Shore One Orthopedics Drive Peabody, MA 01960	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Viveca Burnette 800-562-4789
13	Richard Tallarico, MD 315-464-8622 (Site inactive)	Upstate Bone and Joint Center 6620 Fly Road, Suite 200 East Syracuse, NY 13057 SUNY University of New York 750 East Adams Street, Syracuse, NY 13210-2375 *Upstate Orthopedics Ambulatory Surgery Center 6620 Fly Road, Suite 300 Syracuse, NY 13057	SUNY University of New York Institutional Review Board Office 750 East Adams Street, Syracuse, NY 13210-2375	Stephen L Graziano, MD 315-464-4317
14	Ralph Liebelt, MD 919-220-5255 (Site inactive)	Triangle Orthopedics Associates, PA 120 William Penn Plaza Durham, NC 27704 *Granville Medical Center 1010 College Street Oxford, NC 27565 North Carolina Specialty Hospital 3916 Ben Franklin Blvd., Durham, NC 27704 Triangle Orthopedic Associates, PA 103 Professional Park Drive Oxford, NC 27565	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Viveca Burnette 800-562-4789
15	Thomas Haley, DO 610-275-7013 (Site inactive)	Performance Spine and Sports Physicians, PC 1603 East High Street, Suite C Pottstown, PA 19464 2 Lawnton Road, East Norriton, PA 19401	Pottstown Memorial Medical Center IRB 1600 East High Street, Pottstown, PA 19464	James T Guille, MD 610-327-7000 Main contact below

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Investigators/investigational sites				
Site	**Doctor**	**IRB site approved address**	**IRB address**	**IRB Chairman**
		*Pottstown Memorial Medical 1600 East High Street, Pottstown, PA 19464		Courtney Clemente IRB Coordinator 610-327-7000
17	Michael Hisey, MD 940-382-2204 (Current; Site inactive) William Bradley, MD 972-608-5000 (Previous)	Texas Back Institute 2817 South Mayhill Road, Suite 100 Denton, TX 76208 *Texas Back Institute, Plano 6020 West Parker Road, Suite 200 Plano, TX 75093 Texas Back Institute, Rockwall 1005 West Ralph Hall Parkway, Suite 227 Rockwall, TX 75032 Texas Back Institute 400 West Arbrook Arlington, TX 76014 Texas Back Institute, Mansfield 2800 East Broad Street, Suite 522 Mansfield, TX 76063 Texas Health Center for Diagnostics and Surgery 6020 West Parker Road, Plano, TX 75093	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Currien MacDonald 800-562-4789
18	Scott Kitchel, MD 541-284-0530 (Site inactive)	NeuroSpine Institute, LLC 74-B Centennial Loop, Suite 300 Eugene, OR 97401 *NeuroSpine Institute, LLC 74-B Centennial Loop, Suite 100 Eugene, OR 97401 NorthWest NeuroSpine Institute 74-B Centennial Loop, Suite 200 Eugene, OR 97401	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Viveca Burnette 800-562-4789
19	Carl Lauryssen, MD 310-358-2490 (Site inactive)	Neurosurgical Spine Institute 8201 Beverly Hills Blvd., Suite 405 Los Angeles, CA 90048 *Olympia Medical Center 5900 West Olympic Boulevard Los Angeles, CA 90036	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Lucille Broberg 800-562-4789
20	Jeffery Roh, MD 206-302-0702 (Site inactive)	ProOrtho 901 Boren Avenue, Suite 900 Seattle, WA 98104 ProOrtho 12333 NE 130th Lane, Suite 400 Kirkland, WA 98104 Evergreen Medical Center 12040 Northeast 128th Street, Kirkland, WA 98034 *Orthopedics Intl. Ambulatory Surgery Center 600 Broadway, Suite 460 Seattle, WA 98122	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Currien MacDonald 800-562-4789
23	Reginald Davis, MD 443-849-4270 (Site inactive)	Greater Baltimore Neurosurgical Associates Physicians Pavilion North 6535 N Charles Street, Suite 600 Baltimore, MD 21204 *Greater Baltimore Medical Center Institutional Review Board 6701 North Charles Street Baltimore, MD 21704	Greater Baltimore Medical Center Institutional Review Board 6701 North Charles Street, Baltimore, MD 21704	Philip Levin, MD 443-849-2379
24	Bernard Guiot, MD 720-638-7500 (Site inactive)	Neurosurgery One 7780 S Broadway, Suite 350 Littleton, CO 80122 *Porter, Littleton, and Parker Adventist Hospital 2525 South Downing Street, Denver, CO 80210	Porter, Littleton, and Parker Adventist Hospital Joint IRB 2525 South Downing Street, Denver, CO 80210	Nathaniel Hibbs, DO 303-778-2554
26	Kevin Shrock, MD 954-764-8033 (Site inactive)	Shrock Orthopedic Research, LLC 1414 Southeast 3rd Avenue Ft. Lauderdale, FL 33316 Behnam Myers, DO 3850 Sheridan Street Hollywood, FL 33021	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Paul Newton 800-562-4789

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Investigators/investigational sites				
Site	**Doctor**	**IRB site approved address**	**IRB address**	**IRB Chairman**
		Anthony Hall, MD 1222 South University Drive Plantation, FL 33324 *University Hospital and Medical Center 7201 North University Drive Tamarac, FL 33321		
27	Guy Lee, MD 215-588-1510 (Site inactive)	Abington Orthopedic Specialists, PC Rothman Institute (current) 2400 Maryland Road, Suite 20 Willow Grove, PA 19090 *Abington Memorial Hospital 1200 Old York Road, Abington, PA 19001-3788	Abington Memorial Hospital IRB 1200 Old York Road, Abington, PA 19001-3788	Chris Christensen III, DO. 215-481-7467
28	David Wiles, MD 423-232-8301 (Site inactive)	*East Tennessee Brain & Spine Center 701 Med Tech Parkway, Suite 300 Johnson City, TN 37604	East Tennessee State University VA Office for the Protection of Human Research Box 70565 Johnson City, TN 37614	George Youngbery, MD 423-439-6053
29	Edward Dohring, MD 602-953-9500 (Current; Site inactive) Daniel Lieberman, MD 602-256-2525 (Previous)	The Spine Institute of Arizona 9735 North 90th Place Scottsdale, AZ 85258 Arizona Center for Neurosurgery 3300 N. Central Avenue, Suite 2550 Phoenix, AZ 85020 Ali Araghi, DO The CORE Institute-North Phoenix 18444 North 25th Ave, Suite 210 Phoenix, AZ 85023 CORE Institute 14520 West Granite Valley Drive Sun City West, AZ 85375 *Surgical Specialty Hospital of Arizona 6501 North 19th Avenue Phoenix, AZ 85015	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Viveca Burnnette 800-562-4789
30	George Rappard, MD 232-913-4718 (Site inactive)	Brain and Spine Institute 6200 Wilshire Blvd., Suite 806 Los Angeles, CA 90048 *California Spine Institute 1001 Newbury Road Newbury Park, CA 91320 Glendale Adventist Medical Center 1509 Wilson Terrace Glendale, CA 91206 *Olympia Medical Center 5900 West Olympic Blvd., Los Angeles, CA 90036	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Viveca Burnette 800-562-4789
31	Harold Hess, MD 913-491-3344 (Site inactive)	Johnson County Spine 8575 West 110th Street, Suite 205 Overland Park, KS 66210 *Menorah Medical Center 119th and Nall Overland Park, KS 66204	Patient Advocacy Council, Inc. 601 Bel Air Blvd., Suite 315 Mobile, AL 36606 251-479-5472	James V Roberts, Jr Attorney at Law Ph 251-479-5472
32	Peter Whang, MD 203-785-7132 (Site inactive)	Yale University Yale Physicians Building PO Box 208071 New Haven, CT 06520-8047 *Yale University 800 Howard Avenue New Haven, CT 06520-8071 48 Wellington Road, Milford, CT 06471	Human Investigational Committee 55 College Street, New Haven, CT 06510	Maurice Mahoney, MD, JD 230-785-4688
33	Douglas Orndorff, MD 970-882-9500 (Site inactive)	Durango Orthopedic Associates, PC Spine Colorado 1 Mercado Street, Suite 200 Durango, CO 81301 *Mercy Regional Medical Center 1010 Three Springs Blvd., Durango, CO 81301	Mercy Regional Medical Center 1010 Three Springs Blvd, Durango, CO 81301	John AK Boyd, MD
34	Mark Hollmann, MD 386-734-3710 (Site inactive)	Florida Research Associates, PA 740 West Plymouth Avenue Deland, FL 32720 Florida Orthopaedic Associates, PA 1053 Medical Center Drive, Suite 101 Orange City, FL 32763	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Viveca Burnette 800-562-4789

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Investigators/investigational sites				
Site	**Doctor**	**IRB site approved address**	**IRB address**	**IRB Chairman**
		*Florida Hospital Fish Memorial 1053 Medical Center Drive Orange City, FL 32763		
35	Jeffery Baron, MD 520-784-60276 (Site inactive)	Tucson Orthopaedic Institute, PC 5301 East Grant Road, Tucson, AZ 85712	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Viveca Burnette 800-562-4789
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36	Harel Deutsch, MD 312-942-6644 (Site inactive)	RUSH University Medical Center University Neurosurgery 1725 West Harrison, Suite 970 Chicago, IL 60612	RUSH University Medical Center Research and Clinical Trials Administration 1653 West Congress Parkway Chicago, IL 60612-3833	Allen Korenblit, MD, CIP 312-942-5498
		*RUSH University Medical Center 1653 West Congress Parkway, Chicago, IL 60612		
37	Kenneth Kopacz, MD 973-226-2725 (Site inactive)	Spine Care and Rehabilitation, Inc. 556 Eagle Rock Avenue Roseland, NJ 07068	Department of Medical Education St Barnabas Medical Center 94 Old Short Hills Road, Livingston, NJ 07039	Gregory J Rokosz, DO, JD 973-322-5048
		*St Barnabas Medical Center 94 Old Short Hills Road, Livingston, NJ 07039		
38	Richard Salib, MD 952-814-6600 (Site inactive)	Institute for Low Back and Neck Care 3001 Metro Drive, Suite 330 Bloomington, MN 55425	Schulman Associates, IRB 4445 Lake Forest Drive, Suite 300 Cincinnati, OH 45242	Julie Blasingim 513-761-4100
		*Allina Health System 800 East 28th Street Minneapolis, MN 55407	Allina Hospital & Clinics IRB 2925 Chicago Avenue Minneapolis, MN 55440	Yvonne Rumsey 612-262-4927 inactive
39	Raphael Davis, MD 631-444-7925 (Site inactive)	*SUNY Stony Brook HSC 12-80 Neurosurgery Stony Brook, NY 11794-8122	CORIHS Stony Brook University Stony Brook, NY 11794B Stony	Prof Harold Carlson 631-632-9036
40	Casey O'Donnell, DO 401-490-7530 (Site inactive)	New England Center for Clinical Research, Inc. 1681 Cranston Street, Suite C Cranston, RI 02920	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Theodore Schultz 800-562-4789
		*Our Lady of Fatima Hospital 200 High Service Avenue North Providence, RI 02919		
41	Timothy Deer, MD 304-347-6120 (Site inactive)	The Center for Pain Relief, Inc. 400 Court Street, Suite 100 Charleston, WV 25301	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Lucille Broberg 800-562-4789
		*Saint Francis Hospital 333 Laidley Street Charleston, WV 25301		
42	Robert Wailes, MD 760-941-2600 (Site inactive)	Pacific Pain Medicine Consultants 3998 Vista Way, Suite 106 Oceanside, CA 92056	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Viveca Burnette 800-562-4789
		*Pacific Surgery Center 3998 Vista Way Oceanside, CA 92056		
43	John Regan, MD 310-881-3730 (Site inactive)	Spine Group of Beverly Hills 8929 Wilshire Blvd., Suite 302 Beverly Hills, CA 90211	Western Institutional Review Board (WIRB) 1019 39th Avenue, SE Suite 120 Puyallup, WA 98374-2115	Viveca Burnette 800-562-4789
		*Olympia Medical Center 5900 West Olympic Blvd., Los Angeles, CA 90036		

Notes: Primary treatment site, *denotes a secondary clinical site.