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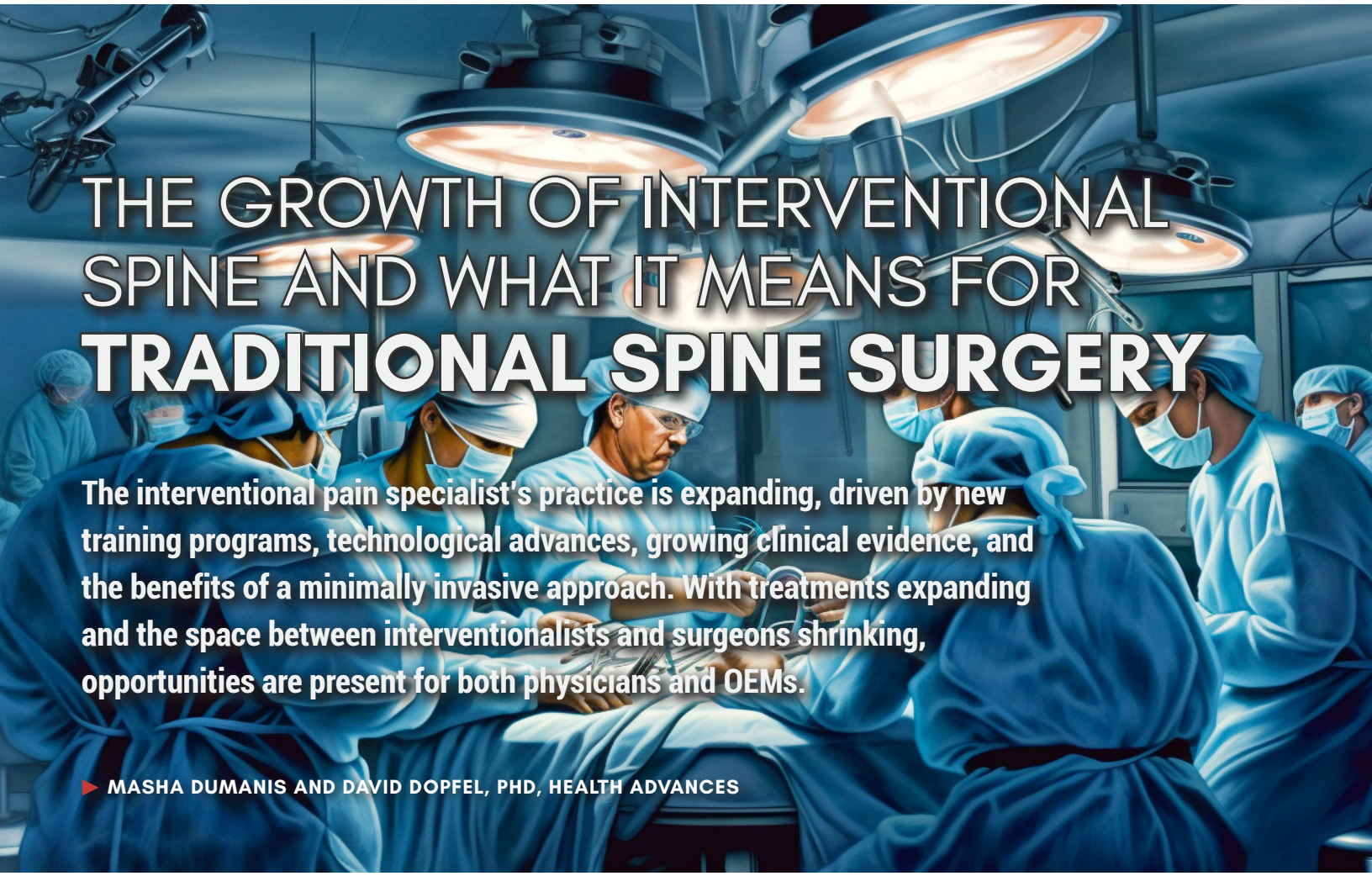


THE GROWTH OF INTERVENTIONAL SPINE AND WHAT IT MEANS FOR TRADITIONAL SPINE SURGERY

The interventional pain specialist's practice is expanding, driven by new training programs, technological advances, growing clinical evidence, and the benefits of a minimally invasive approach. With treatments expanding and the space between interventionalists and surgeons shrinking, opportunities are present for both physicians and OEMs.

MASHA DUMANIS AND DAVID DOPFEL, PHD, HEALTH ADVANCES

Back pain patients have for many decades followed a common referral flow, starting at the primary care provider (PCP) and ending at the spine surgeon, with just a stint of care provided by the pain management specialist. That is partly because until recently, the armamentarium of the pain management doctor, commonly an anesthesiologist, has been limited to a script for physical therapy (PT), epidural injections, and/or spinal cord stimulation when surgery is contraindicated.

Throughout the last decade, however, new interventional devices and techniques have emerged, allowing pain management specialists, and, specifically, an emerging specialty called interventional pain management, to treat back pain patients more effectively and for longer durations. Even with the advent of minimally invasive implants for pain management, the interventional pain physician and the spine surgeon have largely found room to coexist and treat mutually exclusive groups of patients. Surgeons are trained to operate and are reimbursed significantly more for surgeries than they are for interventional procedures (*see Figure 1*). This has discouraged surgeons from adopting non-surgical, interventional techniques.

Technological Explosion

The interventionalist's toolkit has expanded as novel technologies have evolved. No longer are interventional clinicians relegated to just ablating facet nerves. The growing options at their disposal may, depending on

the etiology of the pain (for instance, with vertebrogenic pain), help certain patients avoid progressing to the spine surgeon.

Let's examine, for example, the case of **Relievant Medsystem**'s *Intracept*—a basivertebral nerve ablation interventional procedure for relief of chronic, vertebrogenic pain. Despite initial challenges, Relievant now has completed two randomized controlled trials (RCTs) and amassed five-year follow-up data demonstrating the sustained effect of pain relief in treated patients. (*See "Can Relievant Medsystems Crack the Code for Chronic Lower Back Pain?"* MedTech Strategist, *September 24, 2020*.) After more than 10 years from trial initiation, and five and a half years from launch, in January 2022, *Intracept* received two permanent category 1 CPT codes. These codes have begun to pave the way for positive coverage decisions from payors (*see Figure 2*).

Recently, the American Society of Pain and Neuroscience (ASPN) developed an extensive evidence-based "Back Guidelines" guidance document for all existing marketed technologies. Relievant's *Intracept* was one of several technologies to receive the highest rating of Grade A Quality of Evidence and High Level of Certainty Regarding Net Benefit. Also relevant to the interdisciplinary themes of this article, in February 2023, the North American Spine Society (NASS) announced a positive coverage recommendation of basivertebral nerve ablation for chronic vertebrogenic nerve pain. Access to many technologies has been challenging historically due to limited payor coverage, but this resounding support from several clinical communities, backed by comprehensive documentation, has the potential to positively impact payor coverage and policy review.

It might only be a matter of time before the potential of more interventional products is realized and trajectories accelerated, as an increasing number of companies and investors take notice of this space. Over the last decade, we have seen a rise in the number of single-product companies geared toward the interventional spine clinician (*see Figure 3*). Recently, for example, **Companion Spine** has emerged as a new company dedicated entirely to servicing the interventional spine specialist and solving back pain through non-surgical and minimally invasive interventions. A French company backed by the Viscogliosi Brothers, veteran investors in the musculoskeletal space, it raised a $60 million Series A in March 2023. (*See "An Investor's Perspective on Creating Value in a Tough Spine Market," this issue.*)

Figure 1

Reimbursement Rates per Procedure Correlate with the Invasiveness of the Procedure and Show an Apparent Incentive for Surgeon Focus on Highly Reimbursed Procedures

Average 2023 CMS Reimbursement Rates
Representative CPT Codes

		INJECTION		NEUROLYSIS	MINIMALLY INVASIVE SURGERY		NEUROSTIMULATION			SPINE SURGERY			
		Epidural	Nerve Block	RFA & Cryoneurolysis	Non-Implant	Implant	PNS	SCS	Open Electrode Implant	Laminotomy/ectomy	Arthrodesis/Fusion (*Select Codes*)		Disc Arthroplasty
	CPT Code	64483	64461	64635	22510	22869	64555	63650	636550	63045	22630	22633	22856
FACILITY FEE IN	Interventional Pain	$110	$80	$190	$440	$440	$330	$420	$860	N/A	N/A	N/A	N/A
	Spine Surgeon	$110	$80	$190	$440	$440	$330	$420	$860	$1,320	$1,590	$1,840	$1,650

Note: RFA = radiofrequency ablation, PNS = peripheral nerve stimulation, SCS = spinal cord stimulation.
Source: Health Advances

Highest Reimbursement
Moderate Reimbursement
Lowest Reimbursement

Original equipment manufacturers (OEMs) entering this space through acquisitions will be competing with spine OEMs that are already well positioned for growth in interventional spine. **Stryker**, for example, has a portfolio of interventional spine products made up of the more traditional kypho/vertebroplasty solutions for vertebral compression fractures, radiofrequency ablation, and discography probes. With an established channel and sales force, the company is now well positioned as an acquirer of single-product companies.

It still remains to be seen whether spine and neuromodulation giant **Medtronic** will jump into this market. Rumors swirled in 2022 that the company might be looking to spin off its spine business, which would lessen the potential synergy an acquisition in this space could create.

The proverbial "technology of tomorrow" offers even more tools for interventionalists, giving them the potential to address the nagging and enormous problem of back pain associated with degenerative disc disease (DDD). Products in the pipeline include both device- and cell-based regenerative approaches (*see Figure 4*).

Building, Not Burning, Bridges

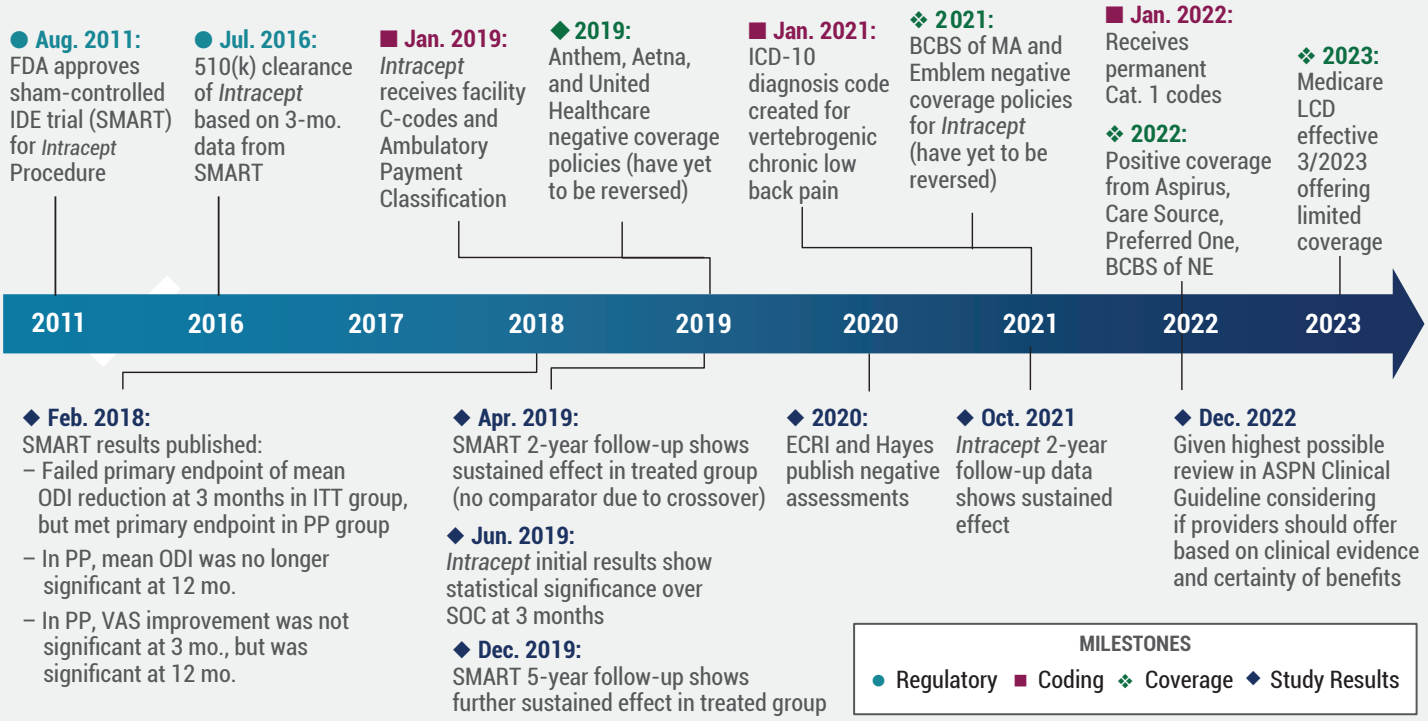
So, what does this mean for spine surgeons and for the OEMs focused on them?

Scope of practice has, at times, become a contested subject between the interventionalist and surgeon communities.

ASPN, a multi-disciplinary group consisting of both surgeon and non-surgeon practitioners, recently put out a position statement

Figure 2

Relievant Is Beginning to Break Ground with Some Commercial Coverage and a Medicare LCD Being Enacted in 2023



Notes: List of regional payors included in timeline is not all inclusive. Additional positive or negative coverage policies likely exist.
RCT = randomized control trial, IDE = investigational device exemption, ODI = Oswestry Disability Index, ITT = intention to treat, PP = per-protocol, VAS = visual analog scale.

Source: Health Advances

on what procedures it deems minimally invasive enough to be performed by an interventionalist not trained in traditional open surgical techniques. The society believes that interventional physicians coming from specialties including anesthesiology, physiatry, and radiology, when properly fellowship trained in interventional techniques, can safely preform many MIS procedures and are thought to be "practicing within the scope of their skill set."

While some may perceive that previously non-interventional clinicians are suddenly taking on surgery, the "interventional implantology" community is not positioning itself in this way. As noted above, these clinicians complete a fellowship program. And as part of their fellowship rotation, they shadow and train with orthopedic surgeons and neurosurgeons. Hands-on procedural training is also a part of these clinicians' continuing medical education. In fact, CMS distinguishes between pain medicine and interventional pain medicine in physician specialty coding associated with its payments data.

The reality is that many of these spine conditions are degenerative, and ASPN highlights the need for a collaborative cross-specialty approach. Indeed, building bridges between interventionalists and spine surgeons may be critical for the future of spine care and potentially a big opportunity for OEMs in this space.

Fortunately, many of the emerging spine pain/chronic lower back pain (CLBP) interventions have a "leave nothing behind" approach that does not burn a bridge to the spine surgeon's historic standard of care (SOC), spine fusion. Similarly, motion preserving technologies, such as some interspinous spacers, also

Figure 3

MIS Products Are Increasingly at the Interventional Spine Doctor's Disposal, Driven by the Improving Clinical Evidence and Refinement-of-Use Cases

COMPANY/PRODUCT	PRODUCT	TREATMENT TYPE	INDICATION	LAUNCH YEAR
relievant medsystems	*Intracept*	Basivertebral Nerve Ablation	Vertebrogenic Pain	2016
Vertos MEDICAL	*MILD*	Decompression	Spinal Stenosis	2006
carevature MEDICAL	*Dreal*	Decompression	Spinal Stenosis	2017
COMPANION SPINE / BACK BONE	*LISA*	Interspinous Spacer	Spinal Stenosis/DDD	2018
Boston Scientific	*Vertiflex*	Interspinous Spacer	Spinal Stenosis	2015
Spinal Simplicity	*Minuteman*	Interspinous Spacer/ Fusion (Interbody)	Spinal Stenosis/DDD	2015
PAINTEQ™	*LinQ*	Fusion (Sacroiliac)	Sacroiliac Joint Pain/Instability	510K not required
stryker®	*Spine Jack*	Vertebral Augmentation	Vertebral Compression Fracture	2018
hyprevention®	*V-STRUT*	Vertebral Augmentation	Vertebral Compression Fracture	2020

Source: Health Advances

Figure 4

Representative Injectable Pipeline Products for DDD and Interventional Pain Development Activity Illustrate the Potential of Additional Interventional Products

☐ FDA Designation

COMPANY	ASSET	PHASE OF DEVELOPMENT	PRODUCT DESCRIPTION
ReGelTec	HYDRAFIL	Pilot (Device)	Polymer-based structural support injectable in pilot study with FDA device breakthrough designation
DISCURE MEDICAL	Miniature Electrode	Pilot (Device)	Device that alters the electrical potential differential in the disc environment to treat DDD
SPINAL STABILIZATION TECHNOLOGIES™	PerQDisc Nucleus Replacement System	Planned US Trials	Lumbar nucleus replacement device that fills the enucleated space of a deteriorating spinal disc FDA breakthrough designation and CE Mark approval
SpineBiopharma	Remedisc	Phase III	Remedisc (SB-01) a synthetic peptide compound that modulates TGF-β1, an inflammatory cytokine implicated in DDD
FibroGenesis REGENERATIVE MEDICINE	CybroCell	Phase II	Allogeneic immune-neutral cell therapy with small Phase I/II study data showing clear benefit and granting FDA IND clearance for next phase of clinical trials
DiscGenics™	IDCT-001	Phase I/II	Allogeneic discogenic cell therapy platform current in Phase I/II for pain, with indication expansion to DDD Received FDA RMAT designation based on the positive results from the first-in-human study
AnGes	AMG0103	Phase Ib	The only clinical-stage oligonucleotide with unique mechanism of action with positive Phase Ib data
Gelmetix Transforming Individuals' Lives.	DXM	Preclinical	Polymer gel injectable focused on restoring water content and cell function

Note: RMAT = regenerative medicine advanced therapy.
Source: Health Advances

allow for spine fusion as a future treatment option. The intent is to address patients earlier in their patient journey, giving them a better quality of life (QoL) without cutting off critical treatment pathways and increasing the risk of revision back surgery.

Most surgeons believe that in the near future the rise in interventional procedures will have minimal impact on their spine surgery practices. Indications for spine surgery are well defined, and neither spondylolisthesis nor scoliosis can be corrected interventionally. Similarly, significant herniations are still best addressed with discectomies. But, as technology improves, data matures, and clinicians gain more experience, single-level lumbar fusions for stenosis, which used to live in the realm of the surgeon, may transition slowly to the interventional space, through alternative approaches.

Surgeons may be shortsighted on timing. Patient behavior is important for spine practices to keep in mind as patients tend to favor less invasive options due to the perception of faster recovery rates and reduced perioperative complications, even as high satisfaction rates have been reported by recipients of both MIS and open surgeries. Furthermore, upstream patients who are treated by the interventionalist may never present to the spine surgeon. The growing arsenal of treatment options opens the funnel to additional patients who currently have limited options and who might otherwise fall prey to opioids for pain relief.

Those who refute the possibility of these transitions may want to glance at the historic transitions from cardiothoracic surgery to interventional cardiology as an example. As interventional cardiology has become more advanced, many procedures that were once performed exclusively by cardiothoracic surgeons have now shifted to interventional cardiologists.

This shift has led to a decrease in the number of procedures performed by cardiothoracic surgeons, particularly in the areas of diagnostic and interventional procedures such as cardiac catheterization, balloon angioplasty, and stenting. Cardiothoracic surgeons still play a critical role in more complex procedures, such as coronary artery bypass grafting (CABG), valve repair or replacement, and heart transplant surgeries. But overall, the field has become more collaborative, with cardiothoracic surgeons and interventional cardiologists working together to provide the best possible care for their patients. In many cases, these two specialties work hand in hand to ensure that patients receive the most appropriate treatment for their specific heart condition.

As the interventional shift happens in spine care, the calculus may change for spine surgeons as to whether they should pursue injections and other interventional products as part of their practices. The challenge may be that the patient pathways may be established by then, so those who want to ensure that they have access to both the surgical patient of today and the non-surgical patient of tomorrow may consider offering these procedures soon, and also look to partner with interventionalists in their networks.

As the interventional shift happens in spine care...hardware-only OEMs should consider whether interventional products have a place in their portfolio since the treatments of tomorrow may not be surgical *per se*.

In a similar sense, spine surgeons will need to consider if the addition of interventional products will drive changes in surgical practice beyond patient access. Endoscopic spine, while still a small portion of all surgical procedures, can offer similar benefits to interventional procedures and become the natural stepping stone from the interventionalist to the spine surgeon.

And while chronic lower back pain is a massive, and unfortunately for patients, growing problem, hardware-only OEMs should consider whether interventional products have a place in their portfolio since the treatments of tomorrow may not be surgical *per se*.

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