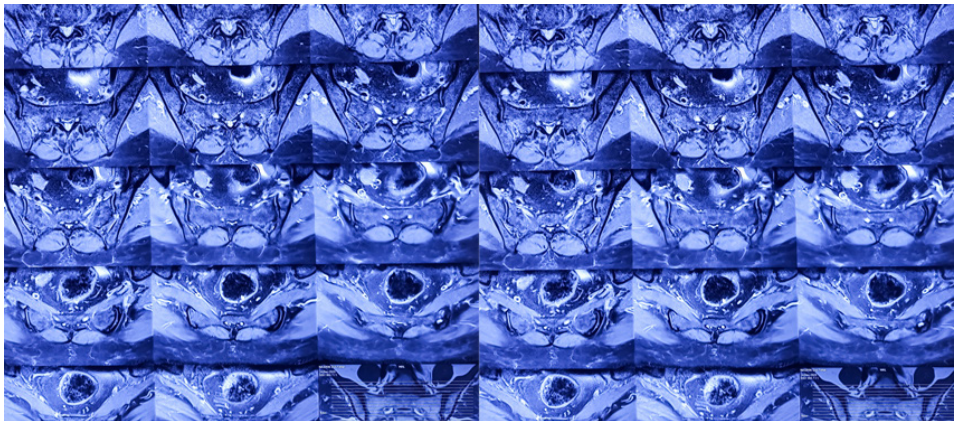
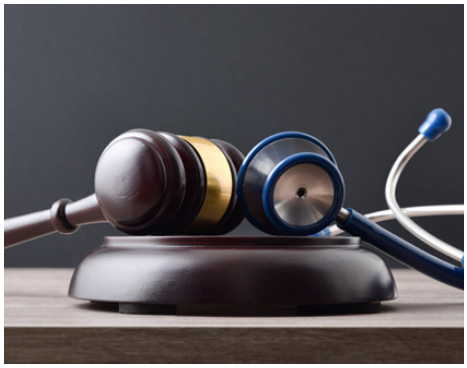
VOLUME 20, ISSUE 23 | DECEMBER 17, 2024

Orthopedics This Week

WEEK IN REVIEW





BREAKING NEWS

For all news that is ortho, read on.

CLICK HERE TO DOWNLOAD A PDF VERSION OF THIS WEEK'S NEWSLETTER

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Could musculoskeletal sales someday be cleared using block chain or bitcoin? If the stock market is any indication, the answer's "yes." Digital currency is this morning's #1 driver of shareholder wealth as (BTC-USD) sets a fresh record. Investor's expecting another 0.25% rate cut at the FED's final meeting of the year this week. Bigger question is 2025. Will the FED scale back its planned cuts given sticky inflation and potential Trump Tarrifs? Personal Consumption Expenditures (PCE) data—the Fed's preferred inflation gauge—comes this week. Rising costs remain the #1 economic issue in MSK and the economy overall.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Pacira Biosciences	13.02%	20.75%	Major shareholder, DOMA Capital, demands PCRX start buying back stock with cash on hand. Nominates 4 (!) new directors to PCRX's board. PCRX is the #1 most undervalued stock in MSK.
2	5	Integra LifeSciences	6.60	3.09	New economic study concludes that IART's DuraSeal cuts healthcare costs—more than it costs to buy. Journal of Comparative Effectiveness.
3	6	Globus Medical	17.67	(0.15)	GMED, which is the most Warren Buffet-type stock in ortho, is up 3 spots on the Power Rankings by virtue of its price and profits: one is low, one is very high.
4	2	Orthofix	(10.99)	(3.65)	Last month, in a sign of confidence and organizational stability, management announced 3-year financial targets to its employees and shareholders. Strong sign for OFIX equity.
5	10	Bioventus	4.78	(1.16)	Wall Street's consensus that BVS could rise 26% over the next 12 months. That's over optomistic, but it's based on solid operational gains and a still low valuation
6	4	Zimmer Biomet	20.70	(2.94)	ZBH scores two key FDA clearances: OsseoFit™ stemless shoulder replacement and Persona® SoluTion PPS Femur. Good blocking and tackling. Need more offense.
7	3	ConMed	12.22	(4.10)	CNMD's key virtue is a comparatively cheap stock. With a leadership transition in process, investors wondering what the new growth strategy might be.
8	7	Medtronic	19.17	(6.24)	Multi-national suppliers like MDT and JNJ will bear the brunt of any tarriff moves in 2025. Investors are re-jiggering portfolios to hedge against tariffs.
9	NR	Axogen	(0.65)	(12.92)	New CEO Dale, with Paul Thomas supporting as the new Chairman of the Board, has investors encouraged and buying AXGN.
10	NR	Alphatec	(20.35)	5.37%	ATEC's absolute blow out of the 3rd quarter will be reinforced at the JP Morgan and other upcoming investors conferences. Hot spine company right now.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	SINTX Technologies	SINT	$3.10	$4	42.86%
2	Pacira Biosciences	PCRX	$19.86	$917	20.73%
3	Dynatronics Corp	DYNT	$0.14	$1	13.92%
4	AxoGen	AXGN	$14.16	$623	12.92%
5	Alphatec Holdings	ATEC	$9.62	$1,364	5.37%
6	Smith & Nephew	SNN	$25.53	$11,161	3.70%
7	Integra LifeSciences	IART	$24.03	$1,854	3.09%
8	SI-BONE, Inc	SIBN	$13.42	$563	2.13%
9	MicroPort Scientific	0853	$0.85	$1,563	1.61%
10	Paragon 28	FNA	$10.42	$872	1.17%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Aclarion	ACON	$0.11	$1	-39.66%
2	Xtant Medical Hldgs	XTNT	$0.37	$51	-22.05%
3	OrthoPediatrics Corp	KIDS	$22.12	$536	-8.82%
4	Nevro Corp	NVRO	$4.07	$153	-8.54%
5	Medtronic	MDT	$82.48	$105,763	-6.24%
6	Aurora Spine	ASG.V	$0.31	$24	-5.02%
7	ConMed	CNMD	$72.55	$2,241	-4.10%
8	Orthofix	OFIX	$17.96	$686	-3.65%
9	Johnson & Johnson	JNJ	$146.62	$353,006	-3.55%
10	Stryker	SYK	$374.60	$142,803	-3.54%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Pacira Biosciences	PCRX	$19.86	$917	14.30
2	Johnson & Johnson	JNJ	$146.62	$353,006	19.14
3	Medtronic	MDT	$82.48	$105,763	19.77
4	ConMed	CNMD	$72.55	$2,241	24.57
5	Zimmer Biomet	ZBH	$106.74	$21,249	26.21

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Xtant Medical Hldgs	XTNT	$0.37	$51	76.90
2	Globus Medical	GMED	$82.42	$11,223	56.41
3	Smith & Nephew	SNN	$25.53	$11,161	42.44
4	Medacta	MOVE	$123.92	$2,478	40.62
5	Stryker	SYK	$374.60	$142,803	36.25

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Integra LifeSciences	IART	$24.03	$1,854	-7.60
2	ConMed	CNMD	$72.55	$2,241	1.28
3	Pacira Biosciences	PCRX	$19.86	$917	1.32
4	Medacta	MOVE	$123.92	$2,478	1.46
5	Stryker	SYK	$374.60	$142,803	3.13

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Johnson & Johnson	JNJ	$146.62	$353,006	6.38
2	Xtant Medical Hldgs	XTNT	$0.37	$51	3.84
3	Zimmer Biomet	ZBH	$106.74	$21,249	3.82
4	Smith & Nephew	SNN	$25.53	$11,161	3.76
5	Medtronic	MDT	$82.48	$105,763	3.59

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Dynatronics Corp	DYNT	$0.14	$1	0.03
2	Nevro Corp	NVRO	$4.07	$153	0.36
3	Xtant Medical Hldgs	XTNT	$0.37	$51	0.56
4	Orthofix	OFIX	$17.96	$686	0.92
5	Aurora Spine	ASG.V	$0.31	$24	1.20

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Aclarion	ACON	$0.11	$1	14.53
2	Globus Medical	GMED	$82.42	$11,223	7.16
3	Stryker	SYK	$374.60	$142,803	6.97
4	Medacta	MOVE	$123.92	$2,478	4.85
5	Johnson & Johnson	JNJ	$146.62	$353,006	4.15

PSR: Aggregate current market capitalization divided by aggregate sales and the calculation excluded the companies for which sales figures are not available.

As SI Joint Treatment Options Grow, So Does Controversy

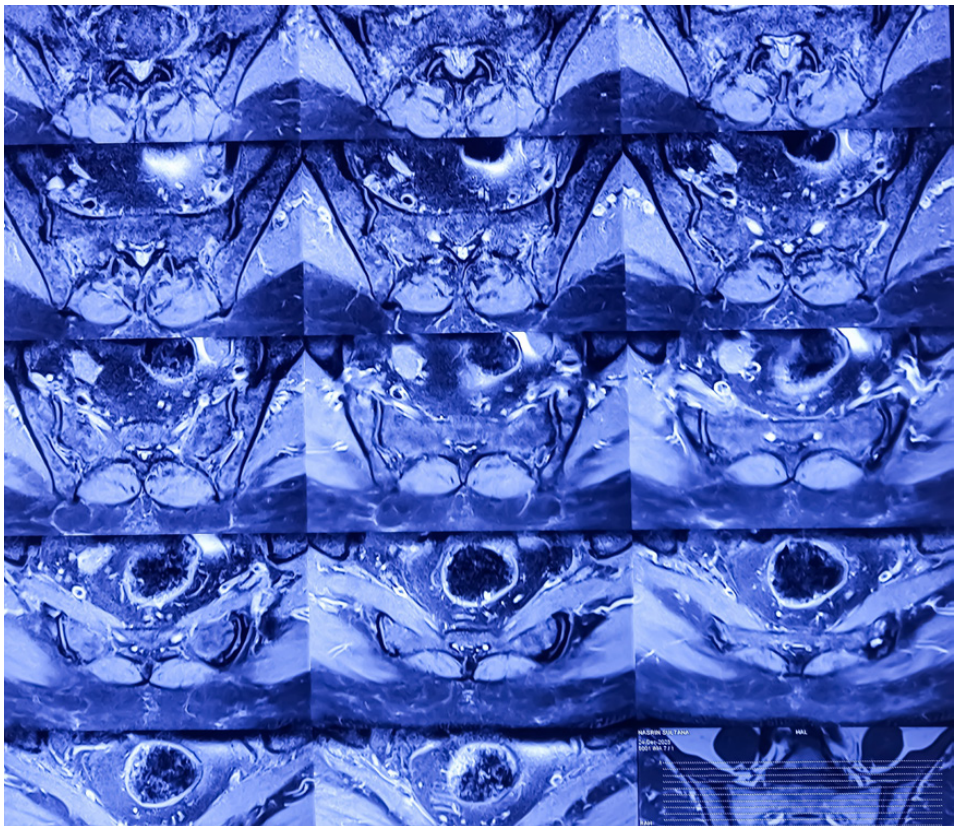
BY TRACEY ROMERO

Sacroiliac joint disease is inflammation or injury of the joint capsule, ligaments, or subchondral bone in the SI joint. About 15 to 25% of reported back pain is caused by pain in the sacroiliac joint. For some patients, the pain it causes can be severely debilitating, but it is a condition that is challenging to diagnose and treat.

Because back pain can be the result of a variety of conditions and there are no objective radiographic or objective examinations to diagnose SI joint diseases, physicians rely on certain clinical maneuvers and "diagnostic" injections to determine the cause of a patient's back pain.

As our understanding of SI joint disease continues to evolve, the experts still highly recommend conservative management of the disease, which includes a multi-modal approach starting with pain medication and physical therapy or bracing with a belt and moving to interventional pain techniques like steroid injections, radiofrequency nerve ablation, and as a last result minimally invasive sacroiliac arthrodesis or fusion.

While the rule of thumb is to treat conservatively at first, sacroiliac joint fusion is increasingly being used to treat chronic SI joint pain. Because there are significant complications associated with open sacroiliac joint fusion, it is no longer routinely performed. Replacing it are MIS SI joint fusion systems designed by an ever-increasing number of companies, notably SI-BONE, SAIL Fusion, Nevro and SurGenTec.



MRI of the SI Joint / Source: Shutterstock

SI fusions initially occurred in the traditional hospital setting but have more recently expanded into ambulatory surgery centers (ASCs) and pain clinics as MIS systems and techniques have gained in popularity.

The most common SI joint fusion techniques are the lateral transiliac (LTI), posterolateral transiliac or posterior intra-articular approaches using cages, dowels, screws, and bone grafts.

Orthopedics This Week talked to Travis Greenhalgh, CEO of SurGenTec, Laura Francis, CEO of SI-Bone, Inc., and David Jansen, president and CEO of SAIL Fusion, about how their companies are trying to meet the needs of SIJ disease patients and doctors.

"Orthopedic surgeons and neurosurgeons have traditionally performed SI joint fusions, but recently there has been a surge of interventional pain management physicians performing these types of procedures in the past few years," Greenhalgh said.

SI-Bone, a pioneer in the field has designed several SIJ products includ-

ing iFuse Intra X Allograft Implant System for interventionalists and iFuse 3D and iFuse Torque for spine surgeons. SI-BONE's iFuse Implant System is designed to stabilize the joint through both bony adherence to implants and intraarticular joint fusion.

SurGenTec developed TiLink P for physicians, looking to stabilize and fuse the joint from a posterior approach with less risk profile. For those physicians that prefer the traditional lateral approach, they offer TiLink L, which can be used from a true lateral or posterior oblique approach.

Other companies like SAIL Fusion have stuck to just creating MIS systems for surgeons, like its BowTie SI Fusion System, which is exclusively offered to spine surgeons to be performed at hospitals or ambulatory surgery centers.

Controversy Lingers

The push to perform more fusions in pain clinics and ambulatory surgery centers has caused a lot of tension between spine and orthopedic surgeons and medical device companies.

One of the biggest concerns is that most of the current studies on MIS SI joint fusion are industry-funded and have the potential risk of bias. Another point of contention is the concern that interventionalists and pain management specialists may not have the level of surgical training required to perform some of these procedures—the lateral percutaneous, posterior oblique, or posterior intra-articular approaches, for example.

In a recent interview on the Hoag Medical Network blog "What's Next for SI Joint Fusion? 8 Spine Surgeon Insights," several surgeons spoke about their concerns.

Brian Gantwerker, M.D. of The Craniospinal Center of Los Angeles told Hoag: "The SI joint fusion groundswell has leveled off quite a bit in the past four to five years. While we cannot replace this joint, I think more interesting companies will come to the fore with simpler techniques and likely integrated with image guidance out of the box."

"This would be dually good and not so good for patients. While it would help make us better at the operation, it opens the door for unqualified people to do them on likely thin or nonexistent indications. The democratization of spine surgery should not mean everyone should do it, quite simply because they lack the training, insight, and abil-

ity to manage these patients in the long term."

Ali H. Mesiwala, M.D. of DISC Sports & Spine Center in Newport Beach, California, added, "There has been some controversy as to whether surgeons or specialists in pain management should treat these patients surgically, as procedures have been developed for both a lateral percutaneous approach and posterior percutaneous approach."

"Most lateral procedures involve screws and dowels and are generally reserved for surgical specialties. The reason for this is that complications, although rare, can occur and require substantial surgical revisions in order to salvage a patient's case."

Frank Phillips, M.D., Midwest Orthopaedics at Rush explained, "Validated sacroiliac joint fusion entails training and expertise in surgical techniques, fusion biomechanics and biologics as well as the ability to manage surgical complications. These all fall into the purvey of well-trained orthopedic or neurosurgeons."

"Initially SI fusion procedures were driven by excellent data collection and validation of the safety and effectiveness of these specific techniques in high-quality studies. Unfortunately, we have seen the expansion of modified procedures in this space billed as "fusion" procedures, performed by practitioners not trained in the field of fusion and more and more frequently performed in the office setting."

"Unfortunately to those of us trained in fusion surgery, it is painfully obvious that these so-called "fusion" procedures have little, or no biomechanical or clinical effectiveness data published and given that these are increasingly performed in office settings, we have no idea as to their safety profile. I would hope these fringe procedures are reined in to protect our patients' interests."

It is because of this tension, according to SAIL Fusion CEO Jansen, that his company doesn't promote its BowTie SI Fusion System to be used in the pain clinic setting.

"We recognize that our competitors are looking to expand their revenue through non-surgeon clinicians in pain management settings. Instead, SAIL Fusion's business philosophy aligns with the surgeon community that views SI fusions as a nuanced procedure most appropriately performed by surgeons in an ASC or

hospital. That is why we worked with a team of spine surgeons to help develop our BowTie SI Fusion System to ensure it meets the specific needs of the surgical community." said Jansen.

What Research Shows

One of the predominate reasons for caution is that most published data is from the lateral transfixing approach, and most of the MIS SI joint research is industry funded, which brings the potential of bias into question.

The INSITE study sponsored by SI-BONE found minimally invasive SIJ fusion with triangular titanium implants provided larger improvements in pain, disability and quality of life compared to nonsurgical management. Improvements after the joint fusion persisted to 24 months.

Nonsurgical treatments included pain medications, intraarticular SIJ steroid injections and radiofrequency ablation. The surgical arm of the study underwent a lateral transfixing approach, using the iFuse Implant System, an FDA-cleared triangular titanium implant with a porous titanium surface.

In another study published in the *International Journal of Spine Surgery*, different surgical techniques were compared including lateral transiliac (LTI), posterolateral transiliac (PLTI) and posterior interpositional (PI) procedures.

The only randomized trials available were for LTI. All studies with patient-reported outcomes showed improvement from baseline. Improvements in pain scores were highest for LTI and lowest for PI. Improvements in ODI scores were highest for LTI and lowest for PLTI procedures.

Implant malposition was 0.43% for LTI, 0% for PLTI and 0.2% for PI procedures. Wound infection was 0.15% of LTI, 0% of PLTI, and 0% of PI procedures. Bleeding requiring surgical intervention was reported in 0.04% of LTI procedures and not reported for PLTI or PI.

The researchers wrote, "Literature support for SI joint fusion is growing. The LTI procedure contains the largest body of available evidence and shows the largest improvements in pain and ODI [Oswestry Disability Index]. Only LTI procedures have independent radiographic evidence of fusion and implant placement. The adverse event rate for all procedures was low."

In another study published in *The Spine Journal*, 469 patients received minimally invasive SI fusion between 2007 and 2014. There was an overall complication rate of 13.2% at 90 days postoperatively and 16.4% at 6 months.

The researchers concluded that "minimally invasive SI joint fusion could possibly carry higher risks of complication than previously stated."

The Maude database gives a picture of complication rates for SIJ fusions as well. Patient injury was the most common type of event reported at 97.5% (1080/1107). Death was reported in 3 patients (0.3%). Malposition was the most common device problem at 49.5% (548/1107). The root cause of these events was primarily user error at 58.2% (644/1107). Revision surgery or reoperation occurred in 92.8% (1028/1107) of reports.

The Maude researchers reported, "The majority of complications reported to MAUDE for FDA 510(k) cleared SIJ fusion devices are user error due to improper placement of implants. These complications are likely underreported, and there is currently no formal tracking system of total SIJ fusions performed to calculate accurate complication and revision rates. Patient injury and health care costs can potentially be reduced with improved education, training, and oversight, which is currently lacking."

A Growing Market

As the SIJ fusion market grows, the focus has been on designing less invasive technologies with decreased risk profiles that can be performed in pain clinics, ambulatory surgery centers and hospitals.

"SurGenTec and other competitors are creating less invasive technologies with decreased risk profiles. The lateral approach requires multiple implants that may have risks of complications from vascular or nerve injuries. SurGenTec developed TiLink P for physicians, looking to stabilize and fuse the joint from a posterior approach with less risk profile," Greenhalgh explained.

When *OTW* asked what are the challenges in creating SI joint products for these markets? Greenhalgh said, "SI joint fusion products are expensive and require rigorous FDA testing to enter the market. Even though the sacroiliac joint fusion market is growing there is more competition and difficulty with prior authorizations and reimbursement regardless of the technology."

"In-office procedures at pain clinics are being performed more frequently due to the lucrative payout for physicians. Surgery centers and hospitals are starting to see a decrease in procedures because of this. The limiting factor is not all payers cover in-office as a joint fusion procedure. Also, physicians looking to use SI joint implants with greater fixation and categorized under devices, cannot

use these in office. They are limited to bone allograft procedures," he said.

A positive that comes with the lower risk profile of these MIS fusions, Greenhalgh said, is that "SIJ patients treated at a pain clinic or ambulatory surgery center are generally treated in a more efficient environment with quicker release time. Hospitals are generally reserved for patients with greater risks of complications or require longer hospital stays."

He added, "Overall, regardless of the approach, the risk profile is low considering the amount of relief patients are getting from SI joint fusion when diagnosed properly. More studies are being conducted by numerous companies, including SurGenTec to show safety profile risk and effectiveness".

Francis agrees that MIS SIJ fusions are bringing much needed relief to SIJ patients offering them dramatic pain improvement and reduction in disabilities. Over a million people in treatment for SI joint dysfunction in the United States, and a lot of these patients are in chronic pain and are not getting the treatment they need.

"The average patient has been working with pain management specialists for five years. Look at treatment as continuum, it starts with primary doctor than a physical therapist and then pain management specialists and surgeons," she said.

When it comes to where a fusion procedure takes place—whether pain clinic, ambulatory surgery center or hospital—she said it is up to physicians, whether a surgeon or an interventionalists, to decide the best place to perform it based on each individual patient need.

"You really need to understand physician and site of service. When creating a product, we partner with physicians and back up with clinical evidence. We design products for different patients and different surgeons. Most fusions are still being done by spine surgeons though," Francis said.

SAIL Fusion's CEO Jansen added, "SI fusion manufacturers are adjusting to meet the procedural volume shift toward the ASC and hospital outpatient settings and their unique requirements. We feel traditional SI fusion systems are not an optimized solution for these markets and have left ample room for innovation by others like SAIL."

"SI fusions are a good candidate for the increasingly popular ambulatory surgery centers and hospital outpatient settings since they are relatively less invasive and can be performed faster than many other spinal surgeries," he explained.

"The challenge is ensuring that the surgeon's need for fast, repeatable procedures with low complication risk is met for these settings while maintaining or improving patient outcomes. These design criteria led to BowTie's shallow posterior-inferior surgical approach, which gives the surgeon straightforward access to the SI joint while avoiding significant neurovascular structures."

Jansen added, "We feel the capabilities and training of the person performing the surgery have a more significant impact on patient outcomes than where the surgery is performed. Therefore, selecting the right surgeon should be the patient's first goal. The surgeon can provide helpful guidance on the best surgical setting for the patient's unique situation." ◆

2025 Spine: Base to Summit: Program and Focus for 2025

BY TRACEY ROMERO

Grand Hyatt, Vail / Source: Grand Hyatt Vail Facebook Page

In just six weeks, the 35-year-old meeting *Spine: Base to Summit* convenes in beautiful Vail, Colorado. For orthopedic and neurological surgeons, this is one of the best collegial winter spine meetings covering pressing issues in adult deformity, cervical and lumbar degenerative, trauma, minimally invasive surgery, endoscopy, and emerging technologies.

This year's Program Directors, Gregory Mundis, Jr., M.D., Rick Sasso, M.D. and Vincent Traynelis, M.D., have developed an engaging program that features more than 30 case studies, along with lectures, panels, and debates. The focus is on insights and tips that surgeons can use in their clinic and OR when they return home.

The course is CME accredited and designed for all surgeons and fellows who include spine surgery in their practice.

Orthopedics This Week connected with Greg Mundis, Jr., M.D. about what makes this meeting so special.

"This is one of my favorite meetings. The sessions are highly interactive, honest, and open, and it results in a refreshingly engaging program. We're probably unique in that to maintain the meeting's character we won't allow it to grow above its current size."

Jeremy Longhurst, president of BroadWater, LLC, the company that runs the meeting, added, "It's a privilege to manage this outstanding meeting. Each year we hear superb feedback from attendees about the quality of the program and, of course, about Vail which is one of the best winter resorts in the world."

In addition, Longhurst said, "I'd encourage surgeons who want to attend to register very soon, as the meeting is filling very quickly."

When: January 17 - 20, 2025

Where: Grand Hyatt Vail, 1300 Westhaven Drive, Vail, Colorado 81657

Ground Transportation: Book transportation services from Epic Mountain Express to and from Denver International Airport and Eagle County Regional Airport.

Course Objectives

During different session formats, participants will discuss the indications, techniques, and outcomes for the surgical management of degenerative, deformity, trauma, and tumor spine cases as well as how to avoid complications. They will also discuss new surgical techniques and technologies and how to apply them in their practice.

The program directors have also built in plenty of free time for meeting participants to get out on the slopes with their families. 2024/2025 EPIC Passes are on sale now or you can purchase daily or a weekly pass online.

This year's highlights include multiple new faculty members, and a case-based, highly interactive program.

Faculty

- Hyun Bae, M.D., The Spine Institute Center for Spinal Restoration
- Sigurd Berven, M.D., University of California, San Francisco
- Ernest Braxton, M.D., Vail Summit Orthopaedics
- Brandon Carlson, M.D., University of Kansas
- Bob Eastlack, M.D. Scripps Health
- Jeff Goldstein, M.D., NYU Langone Health
- Regis Haid, M.D., Atlanta Brain and Spine Care
- Adam Kanter, M.D., Hoag
- Brian Kwon, M.D. New England Baptist Hospital
- Hani Malone, M.D., Scripps Health
- Michael McCarthy, M.D., Indiana Spine Group
- Kathryn McCarthy, M.D., Norton Neuroscience Institute
- Gregory Mundis, Jr., M.D., Scripps Health
- Pierce Nunley, M.D., Spine Institute of Louisiana

- Frank Phillips, M.D., Midwest Orthopaedics at Rush
- Sheeraz Qureshi, M.D., M.B.A., Hospital for Special Surgery
- Rick Sasso, M.D., Indiana Spine Group
- Christopher Shaffrey, M.D., Duke Health
- Vincent Traynelis, M.D., Rush University
- Luis Tumialan, M.D., Barrow Neurological Institute
- Alex Vaccaro, M.D., Ph.D., M.B.A., Rothman Orthopaedic Institute
- Michael Vitale, M.D., Columbia University Irving Medical Center
- Denise Walt, M.D.

Session Highlights

- **Friday**
  - Cervical Case Presentation #2: Complex C2 fracture after multiple fusion extension procedures
  - Lumbar Case Presentation #1: Degenerative spondylolistheses with leg pain only
  - Lumbar Case Presentation #2: 3rd time recurrent disc herniation…is it time to fuse?
  - Deformity Case Presentation #1: Multiple thoracic compression fractures with kyphosis
  - Career & Lifestyle: You think you're the only one? The current (attention grabbing) state of affairs in surgeon care
- **Saturday**
  - Highlighting the Issues: Degenerative deformity correction—Complications
  - Benefit vs risk. How much correction is necessary for a degenerative deformity?
  - Cervical Case Discussion #2: Old hangman's fracture
  - Learning from My Worst Complication in the Last Couple of Years
  - The Challenges of the Transition from Peds to Adult Patients
  - Trauma & Tumor Case Presentation #1: Management of dumbbell tumor
- **Sunday**
  - Trauma: Evaluation and Treatment
  - Case Presentation #2: Unilateral cervical facet dislocation
  - Case Presentation #3: Geriatric odontoid fracture
  - SPECT is the future of diagnostic imaging in TL degenerative pathology
  - The role of SPECT in cervical evaluations
  - Open, MIS, or Endo Case Presentation #1: L2 Burst fracture
  - Open, MIS, or Endo? Case Presentation #2: Lateral cervical disc herniation
  - Special Lecture: Creativity and innovation in your practice, career and life
- **Monday**
  - Highlighting the issues: SI joint fusion
    - Injections and ablations are adequate treatment
    - SI Symptoms are related to alignment not degeneration
    - Why are we so afraid of fusing to the pelvis? Hurdles, and how to overcome
    - What to do when you need pelvic fixation but the SIJ is full of metal

Case presentation #1: Retropharyngeal hematoma with airway compromise

Case presentation #2: CSF leak with ventral cervical surgery

Case presentation #3: Esophageal injury recognized intraoperatively during ACDF

Case presentation #4: Honeymooner's pedicle screw loosening after awake MIS TLIF

Exhibiting Companies

ATEC Spine, Augmedics, Axis Spine Technologies, Barricaid, Carlsmed, Cerapedics, Globus Medical, Highridge Medical, Kuros Biosciences, Medtronic, Orthofix-SeaSpine, OsteoCentric Technologies, SI-BONE, Spinal Stabilization Technologies, and Theragen ♦

The Best Technologies in Spine 2024: Bronze Award Winners

BY VESNA BRAJKOVIC

Every year, *Orthopedics This Week* highlights the cutting-edge advancements shaping the future of spine care through its Best New Spine Technology Awards.

This esteemed recognition celebrates the ingenuity of inventors, engineering teams, surgeons, and companies driving meaningful progress in the industry.

The 2024 program received an unprecedented number of entries, each evaluated by a panel of experts on key factors such as innovation, clinical impact, problem-solving potential, cost efficiency and contributions to patient care.

Categorized by Gold, Silver and Bronze, these awards showcase the standout achievements of the year.

Below, we present the recipients of the 2024 Best Spine Technology Bronze Awards, honoring solutions that exemplify excellence in innovation and practicality.

OTW's 2024 Best Spine Technology Bronze Award winners represent some of the most innovative, practical and significant products in spine care. / Source: RRY Publications LLC and Pixabay

ALLUMIN8

Winning Technology: A8 INTEGR8™ Porous Pedicle Screw System

Inventors: Alyssa Huffman, Matthew Shomper, Mike Milella, Mike Sherman, Charlie Barfield, Geoff Dillon / **Engineers:** Matthew Shomper

How it Improves Spine Surgery: The A8 INTEGR8 3D Printed pedicle screw is designed to both stabilize spinal fusions in weaker bone, but also incorporate an advanced diagnostic and therapeutic function. Specifically, during insertion, the screw system harvests and collects vertebral autograft which are captured by the screw's pores. That incremental increase in living autograft bone is meant to improve long-term bone fixation and construct stability. Once the screw is positioned, the proprietary CIRCUL8™ adapter allows the screw to draw in cell rich bone marrow. The novel system is intended to address such potential complications as spinal screw loosening and/or rod breakage. According to ALLUMIN8, the system can reduce revision rates, improve patient outcomes and increase surgical efficiency.

Company: ALLUMIN8

Website: allumin8.com/

Drue De Angelis, Alyssa Huffman, Robin Young, T.J. Halverson

Amber Implants

Winning Technology: BV VCFix Spinal System.

Inventors: Seyed Mohammad Ahmadi, Banafsheh Sajadi / **Engineers:** Sanne Aarts, Jonathan Caine

How it Improves Spinal Surgery: In a nutshell, reduced side effects from vertebral facture repair. The BV VCFix Spinal System was designed to address a variety of fractures, including compression and burst fractures, and to make treating them safer. Among the product's features are an expandable structure and a pedicle screw-shaped component which facilitates a minimally invasive transpedicular placement.

The implants can be expanded cranially upon insertion, realigning the vertebral endplates and correcting local kyphotic angles. It is modular and versatile. It can also be deployed with or without cement or be linked to a screw-rod construct, which, the inventors intend will reduce risks of complications and allow surgeons to treat, for example, traumatic burst fractures with a single-level fixation.

Company: Amber Implants

Website: amberimplants.com

Robin Young and Mohammad Ahmadi

Aspen Medical Products

#1 Winning Technology: Align PJK Orthosis

Inventors / Engineers: Aspen Medical Products

How it Improves Spinal Surgery: The Align PJK Orthosis brace helps patients maximize correct spinal mechanics, such as symmetrical spine loading and hinging from the hips rather than rounding the spine. The Align PJK Orthosis is a prefabricated TLSO that provides enhanced flexion control through a rigid anatomical axillary frame with a semi-rigid posterior frame that wraps circumferentially around mid-back. This provides a three-point pressure system for better sagittal flexion control.

The customizable design reduces pressure on surgical sites and has a dual density foam liner at the chest panel for increased comfort. The semi-rigid posterior strap self-aligns to the correct location as the anterior T-bar is adjusted to the patient height. Aspen Medical Products' Align PJK Orthosis brace brings "a new standard of care" to spinal deformity post-operative procedures.

Company: Aspen Medical Products

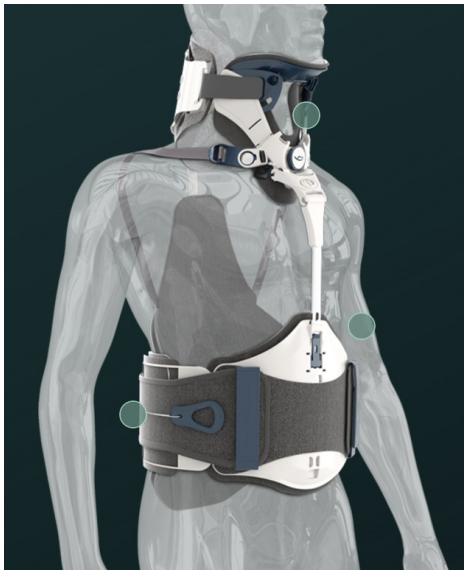
Website: www.aspenmp.com

#2 Winning Technology: VRTX System

Inventors / Engineers: Aspen Medical Products

How it Improves Spinal Surgery: Patients can ambulate faster and reduce the risk of complications because the VRTX system is the first off-the-shelf total spine solution with multiple connecting braces. The system delivers motion restriction from cervical to sacrum. Its prefabricated design comes with adjustable sizing for the vast majority of patient anatomies. Because it's essentially available from the manufacturer on demand, with fast delivery, it reduces the cost of customization, length of stay, inventory, staff time, costs, resources for hospitals and surgeons.

Finally, the VRTX System can be stepped up or stepped down to a collar, cervical thoracic orthosis, lumbar sacral orthosis, thoracic lumbar sacral orthosis or CTLSO. It is indicated for patients with traumatic, multi-level spinal injuries – which typically require a custom Cervical Thoracic Lumbar Sacral Orthosis (CTLSO) to stabilize their spine before or after surgery. The VRTX system changes all that.



Company: Aspen Medical Products

Website: www.aspenmp.com

Bioreplica S.L.

Winning Technology: Vertebral Prosthesis

Inventors: Rodrigo de Pablos Almazan **/ Engineers:** Rodrigo de Pablos

How it Improves Spinal Surgery: This vertebral prosthesis was designed to deliver a more precise and personalized implant for the patient while also helping the surgeon avoid sensitive structures while working around the spinal cord. It employs a 3D-printable

and biomechanically friendly two-part design to give surgeons the ability to personalize the implant to the patient making it a true vertebral prosthetic and, arguably, the most realistic vertebral prosthesis ever brought to market. Bioreplica S.L., is still finishing its investment round and noted to *OTW* that this technology shows promise as a treatment for osteoporotic fractures.

Company: Bioreplica S.L.

Website: www.biovertreplica.com

inFormed Consent

Winning Technology: inFormed Consent App

Inventors: Dr. Dan Kloster, Jason Penrod / **Engineers:** Joey Betzen, Propaganda3

How it Improves Spinal Surgery: Improve patient buy-in and understanding of their treatment plan while also reducing the potential for malpractice claims. This cloud-based app delivers an "easy-to-understand" information and procedure consent videos to patients, including animated explanations of hundreds of medical procedures and specialties including spine, orthopedics, pain management, bariatric, Interventional radiology, plastic surgery, anesthesia and regenerative medicine.

Important, the app uses a patient-video capture technology which ensures patients stick with and view the entire pre-appointment education and other information. Of course, it also employs a digital signature for both the patient and physician.

Studies have documented that using video in informed consent discussions increased the patient's buy-in and understanding of the treatment plan compared to traditional face-to-face consent discussions with paper or electronic forms. The app may also reduce the potential for malpractice claims.

Company: inFormed Consent

Website: informedconsent.com

inFormed Consent App

Morpheus AG

Winning Technology: Rebellion Bone Removal System

Inventors: Timo Rack

How it Improves Spinal Surgery: How it Improves Spinal Surgery: Offered in six different configurations for versatility—the system was designed to reduce the risk of dural tears, minimize infections with single-use components and prevent thermal damage during bone removal. The system cuts surgery time up to 30 minutes for a typical two-hour procedure and keeps the surgical field clear.

Morpheus AG's Rebellion Bone Removal System is a disposable bone punch with integrated suction and an optional bone collector. Unlike traditional Kerrison punches, which require repetitive in-and-out motions, the Rebellion system connects to a surgical suction unit, allowing for continuous bone removal with each precise cut.

Company: Morpheus AG

Website: morpheus.com.ag

Ossium Health

Winning Technology: OssiGraft Prime

Inventors: Erik J. Woods, Wa'el Al Rawashdeh, Matthew Krach, and Kimberly Buchanan / **Engineers:** Erik J. Woods, Wa'el Al Rawashdeh, Matthew Krach, and Kimberly Buchanan

How it Improves Spinal Surgery: OssiGraft Prime™ is soft and cohesive, with the consistency of Play-Doh. Its properties allow it to be precisely molded into any desired shape. It also holds together during irrigation. These handling properties enable difficult approaches and tight packing to give surgeons more control and precision during spinal fusions, according to Ossium Health.

OssiGraft Prime, which is sourced from donors with a median age of 35, is Ossium Health's next-generation viable bone matrix allograft for use in spinal fusions and other orthopedic procedures. Because it is sourced from vertebral bone, which is naturally rich in cancellous bone, the composition provides a porous scaffold that promotes rapid bone revascularization.

Company: Ossium Health

Website: ossiumhealth.com

SC Medica

Winning Technology: FFX®

Inventors: Camille SROUR, Ph.D., Robin SROUR, M.D. / **Engineers:** Camille SROUR, Ph.D.

How it Improves Spinal Surgery: FFX® is a two-component system that includes a facet cage to act as a spacer to significantly increase the foraminal

Drue De Angelis and Camille SROUR, Ph.D.

height and facilitate indirect decompression to relieve pressure on spinal nerves and a facet screw designed with self-compressive progressive threads for a secure and stable fit to increase bony fusion rates. Its self-tapping profile allows insertion without pre-drilling, while the cannulated design enables guided insertion over a wire. The screw acts as an anti-migration locking system to prevent displacement and enhance the facet fusion process.

SC Medica's FFX is a minimally invasive fusion solution engineered for the "often underestimated" facet joints conditions. Studies reveal that facet joints can degenerate before discs. In different stages of facet degeneration, patients can experience facet syndrome, characterized by facet inflammation and back pain, or lumbar spinal stenosis, one of the most frequent spinal surgeries. Treatments for these spinal conditions give temporary relief or have several

challenges. FFX can provide a long-lasting pain relief for facet generated back pain.

Company: SC Medica

Website: sc-medica.com/en-us

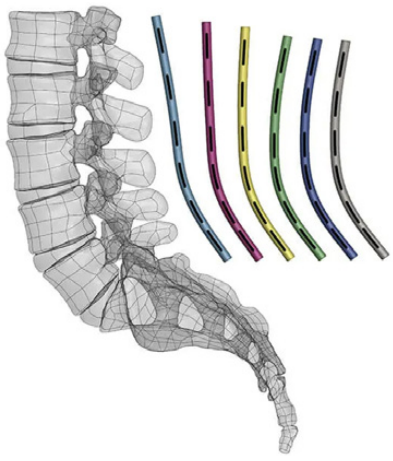
Spinal Alignment Solutions

Winning Technology: Pelvic Incidence (PI-Rod®) Implants

Inventors: Dr. Bassel Diebo, et al. / **Engineers:** Leighton LaPierre, Brandon Arthurs, Renaud Lafage

How it Improves Spinal Surgery: The PI-Rod® Implants provide pre-bent rods matched to a range of patient pelvic incidence measurements for precise segmental sagittal lumbar alignment. The PI-Rod's design integrates extensive postoperative clinical data to ensure each rod profile is tailored to match the normative alignment data from both asymptomatic individuals and successful spinal fusion patients. The rod designs for degenerative lumbar spinal fusion have six predefined lordotic rod curvatures.

Surgeons benefit from robust, data-informed systems that simplify decision-making and enhance surgical predictability. That's why Spinal Alignment Solutions created the PI-Rod Implant technology for degenerative spinal surgery. Available in 5.5mm titanium alloy for alpha launch, the PI-Rods provide robust and flexible off-the-shelf options for various lumbar surgical needs including degenerative, trauma, tumor and infection.



Company: Spinal Alignment Solutions

Website: www.pi-rod.com/about-us

Spinal Simplicity

Winning Technology: Liberty SI

Inventors: Todd Moseley, Colton McQuinn, Melissa Frock, Jeffrey Lee, Nick Furman, Adam Frock / **Engineers:** Colton McQuinn, Melissa Frock, Jeffrey Lee, Nick Furman, Adam Frock

Adam Frock, Parker Snedden, Drue De Angelis, Melissa Frock, Hope Sandifer, Robin Young, and Jonathan Hess

How it Improves Spinal Surgery: Unlike traditional, lateral sacroiliac (SI) joint fusion systems where screws with variable pitch threads are used to achieve fusion by compressing the joint, Spinal Simplicity's Liberty SI Lateral Implant System employs a unique anchor wing mechanism against the strongest part of the SI joint, the sacral cortical wall, to achieve joint compression and stability.

The system relies on a dual mechanism—a threaded main body and two deployable wings—to create the compressive force across the SI joint. As the compressive body is tightened along the proximal end of the device, it reduces the overall length of the implant, thereby generating compression across the joint – for a truly compressive and minimally invasive approach.

*Data on file.

Company: Spinal Simplicity

Website: spinalsimplicity.com

SurGenTec

Winning Technology: OsteoFlo HydroFiber

Inventors: Travis Greenhalgh, Gui Pires

How it Improves Spinal Surgery: HydroFiber improves each surgeon's ability to place osteopromotive bone graft in difficult, hard-to-reach spaces. HydroFiber' s excellent handling gives surgeons a flowable graft that also prevents migration, making it perfect for post-filling cages.

OsteoFlo HydroFiber is a fully synthetic bone graft which employs a blend of biomaterials that are hydrophilic and can be reconstituted with BMA,

Robin Young, Drue De Angelis, Travis Greenhalgh, and Matt Marta

blood, saline and more. Once hydrated, HydroFiber turns into a putty-like consistency with fibers to keep the graft together. Because most synthetic bone grafts are hydrophobic due to their carriers, the volume once implanted as the carrier dissipates. OsteoFlo HydroFiber not only maintains volume but can expand slightly.

Company: SurGenTec

Website: www.surgentec.com

Ventris Medical

Winning Technology: Backpack®

Inventors: Russell Cook, John Brunelle, Sahil Jalota / **Engineers:** John Brunelle, Molly Kimbley

How it Improves Spinal Surgery: Improves efficiency, efficacy and safety of bone graft in spinal fusion procedures while eliminating the potential for migration and heterotopic ossification. Ventris Medical's Backpack® system uses a proprietary biologic bovine collagen mesh bag which is prefilled with either osteoinductive demineralized cortical bone fibers (AF) or Ventris's patented osteoinductive biphasic ceramic granules (AMP).

Milly Maganda, Robin Young, Russell Cook, and John Brunelle, PhD

The versatile system is available in three configurations: Backpack AF, Backpack AMP and Backpack M/T. The first two, Backpack AF and Backpack AMP, employ the collagen mesh bag prefilled with either AF or AMP bone void fill. The third configuration, Backpack M/T, uses an empty collage mesh bag which the surgeon can fill with their preferred graft. The Backpack family uses a proprietary biologic bovine collagen sheet designed to resorb in 30 days.

Company: Ventris Medical

Website: www.ventrismedical.com

Waypoint Orthopedics

Winning Technology: Waypoint GPS

Inventors: Dr. Stephen Banco, MD., Jeffrey F. O'Donnell, Jr., Richard Briganti, Lawerence Husick, JD.

How it Improves Spinal Surgery: Waypoint GPS is a more cost efficient 'smart' pedicle screw placement system that was designed to prevent pedicle breach—which can have catastrophic complications in spine surgery—and reduce the amount of harmful ionizing radiation in the operating room. To date, Waypoint has cannulated 45 pedicles with 100% accuracy. These numbers were confirmed with post-screw placement X-ray and neuromonitoring.

Waypoint can also be used adjunctively with navigation and robotics, which studies have shown may have up to a 10% failure rate. The Waypoint GPS is "ultra-low cost" and fits seamlessly into a surgeon's standard workflow. While the device looks, feels and performs like a standard bone awl, the Waypoint GPS is a "smart" pedicle probe that uses light and color to allow physicians to see the bone type as they create pilot holes.

Company: Waypoint Orthopedics

Website: waypointorthopedics.com ♦

Drue De Angelis, Jeffrey F. O'Donnell, Jr. and Robin Young

LEGAL

Cause of Litigation No Longer Infection: Guess What it IS!

Approximately 15% of orthopedic surgeons are named in medical malpractice lawsuits at some point in their career[1]. A team from Massachusetts General Hospital and Harvard Medical School set out to to more fully understand the trends behind these expensive and damaging forms of litigation, particulary in cases of total joint arthroplasty (TJA).

The results of their study, "Medical Malpractice Litigation Trends Following Primary Total Hip and Knee Joint Arthroplasty: An Updated Nationwide Analysis," was published in the September 16, 2024 edition of *The Journal of Arthroplasty.*

Co-author Young-Min Kwon, M.D., Ph.D., professor and vice chair of the Department of Orthopaedic Surgery at Massachusetts General Hospital and Harvard Medical School told *OTW*, "We undertook this work because of the surge in demand and utilization of hip and knee TJA combined with arthroplasty having the highest representation of orthopaedic surgery malpractice suits. It is important for arthroplasty surgeons to understand what may contribute to suboptimal outcomes and patient satisfaction rates and try to mitigate these outcomes."

"Given the increasing high demand for TJA, the rare postoperative complications may be more ubiquitous than those from other less commonly performed surgeries, resulting in patient dissatisfaction or poor outcomes and potentially a medical malpractice claim."

Source: Shutterstock

The authors used a legal database to find cases between 2018 and 2022 involving primary hip and knee TJA in the U.S. The cases were listed as original rulings or appeals and reviewed for the alleged negligence, damages incurred, demographics, and verdicts. Appeals were further assessed for appellant details, preliminary judgment, and outcomes.

OTW asked Dr. Kwon about the challenges he and team confronted setting up or executing the study. He said, "The biggest challenge probably is that while we used a national legal database, which does not include cases that never made trial or did not reach the verdict in time for this study."

"It is also challenging to identify, collect, and compare different variables for each case. In contrast to traditional orthopaedic retrospective reviews that use EHRs [electronic health records], legal databases only provide limited and necessary information for the purpose of a trial."

Working with 59 cases: 33 (56%) total knee arthroplasty (TKA) and 26 (44%) total hip arthroplasty (THA), the authors found:

- TKA cases had a relatively high percentage of pain complaints (24%),
- THA cases tended to cite nerve injuries (31%).

The research team determined that negligence largely stemmed from:

- procedural error (47%),
- postsurgical error (27%), and/or
- failure to inform (14%).

Case outcomes were decided in favor of the defense in 66% of cases.

Overall, 90% of primary verdicts led to appeals and, of those, 71% were initiated by the plaintiff. Interestingly, upon appeal, the initial court rultings were upheld 53% of the time for defendants but a much higher 87% rate for plaintiffs.

Dr. Kwon: "The focus of malpractice has been shifting in a short amount of time and should be reviewed to address emerging litigation trends in TJA, as they will help identify risk points and improve the overall quality of TJA. While majority of trialed malpractice claims have ended in the favor of the defendant (surgeon or institution), these findings will aid arthroplasty surgeon care teams in further improving patient care and outcomes."

OTW asked Dr. Kwon if the shift from infection to ongoing/worsening pain in TKA means that we have a better handle on infections. Dr. Kwon said, "With increased efforts to identify infections clinically with a low threshold and to hold preoperative discussions about the risks of infection in advance with the patient, the prevalence of malpractice claims relating to infection may have been mitigated."

"Ongoing/worsening pain may be attributed to patient expectations, as TKA is cited as one of the most successful procedures in orthopaedic surgery. Also, as the mean age of patients undergoing arthroplasty decreases, there is an increasing number of younger patients who are left unsatisfied with their TKA performance in returning to more robust strenuous activities."

"Awareness of these gaps and areas of improvement is the first step. Arthroplasty surgeons may benefit by reviewing these findings of recent litigation trends as they can be talking points that need to be emphasized to the care team as well as the patient prior to surgery to avoid such situations in their future practice."

"While this information can only be extracted through a litigation database such as Westlaw, there are inherent limitations. Future work ideally would have a greater sample size to extract and review data from. A future research review may also focus on if there were any litigation trends with the shift from inpatient to outpatient TJA as there is a growing prevalence of outpatient and ambulatory surgical center TJA." — *EH*

Reference

1. https://www.nejm.org/doi/full/10.1056/NEJMsa1012370

Ongoing Patent Battle: Extremity Medical vs Fusion Orthopedics

Extremity Medical LLC is claiming victory in the latest decision in its ongoing patent battle with Fusion Orthopedics, LLC.

In a recent press release, Extremity Medical claims that its alleged victory over Fusion Orthopedics comes from

Source: Extremity Medical LLC, Fusion Orthopedics, LLC, Pixabay, and Mohamed Hassan

the United States Patent and Trademark Office's (USPTO) Patent Trial and Appeal Board's (PTAB) most recent ruling in the patent dispute.

The patent at issue is U.S. Patent No. 11,298,166 ('166 patent) for intraosseous intramedullary fixation assembly and method of use. There is parallel litigation involving the patent and the two parties in United States District Court for the District of Arizona. For *OTW*'s original coverage of the litigation, see "Patent Fight: Extremity Medical vs Fusion Orthopedics."

Earlier this year, *OTW* reported that the PTAB had ruled against Extremity Medical and had instituted an inter partes review of the patent at issue. This latest decision is the result of that review. For *OTW*'s initial coverage, see "Patent Fight Continues: Extremity Medical vs Fusion Orthopedics."

Earlier this month, the PTAB issued its Final Written Decision. The PTAB ordered that Fusion Orthopedics "has not shown by a preponderance of the evidence that claim 11 of the '166 patent is unpatentable." This failure means that Claim 11 of the '166 Patent is patentable over all of the prior art Fusion Orthopedics cited in its petition and therefore is not invalid.

The PTAB did determine that some challenged claims were unpatentable. Notably, the PTAB ordered that Fusion Orthopedics "has shown by a preponderance of the evidence that claims 1–10 and 12–15 of the '166 patent are unpatentable."

According to the USPTO website, inter partes review is a "new trial proceeding conducted at the Board to review the patentability of one or more claims in a patent only on a ground that could be raised under §§ 102 or 103, and only on the basis of prior art consisting of patents or printed publications." Here, the inter partes review was regarding the patentability of claims 1–15 of the '166 patent.

According to the Extremity Medical press release, "Now that the patent has survived the IPR, the next step in the case is likely to be that the matter will be referred back to the District Court of Arizona for a determination of infringement by Fusion."

Extremity Medical Chairman and CEO Matthew Lyons commented, "Extremity Medical invests significantly in intellectual property and intends to vigorously enforce its rights as needed." — *KD*

LARGE JOINTS

407 Patient NEJM Study Tests Semaglutide for OA Patients

Authors of a new 407-patient study, sponsored by Novo Nordisk, wrote that obese patients with knee osteoarthritis (OA) and moderate-to-severe pain benefit from weekly semaglutide injections.

To be clear, the twin subjects of semaglutide and weight loss are THE hot topic today. A quick search on Google Scholar using the terms "semaglutide" and "obesity" bring up about 20,000 studies. Combining those search terms with "knee OA" and the tally drops to 800, with the #1 study being the subject of this article.

The study, a 68-week, double-blind, randomized, placebo-controlled trial at 61 sites in 11 countries, resulted in a *New England Journal of Medicine* (NEJM) paper titled, "Once-Weekly Semaglutide in Persons with Obesity and Knee Osteoarthritis," which was published in the October 30, 2024 edition.

According to the study authors, patients treated with semaglutide reported, using the Short Form-36 physical function scale, greater improvement than patients in

Source: Wikimedia Commons and Petr Kratochvil

the placebo group. How significant of a difference? The average change in the treated group was 12.0 points while the average change in the control group was about half that or 6.5 points.

The authors also report that adverse events that led to permanent discontinuation of the trial regimen occurred in 6.7% of the semaglutide treatment group and 3.0% in the placebo group. Gastrointestinal disorders were the primary reason for discontinuation.

Key attributes of the study patients were:

- Mean Body Mass Index of 40.3, and
- Mean Western Ontario and McMaster Universities Arthritis Index pain score of 70.9
- 81.6% of the participants were women
- Semaglutide patients recorded a mean body weight change from baseline to week 68 of –13.7%
- Placebo patients recorded a mean body weight change from baseline to week 68 of –3.2%,
- Semaglutide patients reported a Western Ontario and McMaster Universities Arthritis Index pain score change from week 1 to week 68 of –41.7 points
- Placebo patients reported a Western Ontario and McMaster Universities Arthritis Index pain score change from week 1 to week 68 of –27.5 points

"Obesity-related knee osteoarthritis is a progressive condition that can lead to pain and stiffness of the knee and impair critical daily functions such as walking or moving around," said lead study author Henning Bliddal, M.D., M.Sci. of Copenhagen University Hospital in Denmark, to *OTW*. "*The risk of developing the condition is more than four times higher in people with obesity.* Weight reduction along with physical activity is often a recommended approach to managing painful symptoms, but adherence can be challenging. There is a significant need for non-surgical and sustainable treatment options for those living with obesity-related osteoarthritis. The STEP 9 trial aimed to provide rigorous evidence as to how semaglutide may help these people." — *EH*

Perceived vs Actual TKA Outcomes: Closing the Gap

A new retrospective cohort study of 88 patients undergoing total knee arthroplasty (TKA) for advanced osteoarthritis has found a possible discrepancy between perceived recovery and actual functional improvement.

Their work, "Evaluating Knee Recovery Beyond Patient Reports: A Comparative Study of Smart Implantable Device-Derived Gait Metrics Versus Patient-Reported Outcome Measures in Total Knee Arthroplasty," appears in the December 2024 *Journal of Arthroplasty.*

Co-author Charles DeCook, M.D., with Arthritis and Total Joint Specialists, Northside Hospital Forsyth, in Cumming, Georgia, told *OTW,* "One of the motivations behind this work was our dissatisfaction with the existing PROMs (Patient-Reported Outcome Measures), which, while mandated, often fell short in reliably gauging patient satisfaction or providing actionable insights."

"We view smart implantable devices as a pathway to gaining more reliable, objective, and predictable data, helping us align outcomes with patient expectations more effectively."

For this study, a smart, implantable device collected daily gait metrics, including step count, distance traveled, walking speed, stride length, cadence, and functional knee range of motion.

Source: Wikimedia Commons and GIANLU

The PROMs, including Knee Injury and Osteoarthritis Outcome Score-Joint Replacement, Veterans Rand 12 Physical Component Summary, and Veterans Rand 12 Mental Component Summary, were compared to smart implantable device gait metrics.

Study Results

The research team found that all gait metrics, except stride length, significantly increased at the 12-week post-op point. The PROMs also significantly improved postoperatively.

The initial low positive correlations between 12-week PROMs and smart implantable device (SID) metrics decreased after adjusting for demographic variables, leaving only weak correlations between the Veterans Rand 12 Physical Component Summary and Knee Injury and Osteoarthritis Outcome Score-Joint Replacement with functional knee range of motion and Veterans Rand 12 Mental Component Summary with step count and distance traveled.

The authors concluded that "both PROMs and smart implantable device gait metrics show significant improvements post-TKA, though they correlate weakly with each other, suggesting a possible discrepancy between perceived recovery and actual functional improvement."

"The smart implantable device gait metrics might provide a valuable addition to traditional PROMs by offering an objective representation of physical capabilities unaffected by patient compliance or subjective perceptions of recovery."

Positive Clinic Economic Effect

"Using smart implantable devices in our patients, we have successfully reduced the number of required patient visits while creating a more personalized and efficient recovery path," stated Dr. DeCook to *OTW*. "This not only improves the patient experience but also streamlines care delivery."

"We believe smart implantable devices represent a transformative advancement in the arthroplasty world, offering unprecedented opportunities to enhance both patient outcomes and clinical workflows."

Co-author Thomas Bradbury, M.D., also with Arthritis and Total Joint Specialists, Northside Hospital Forsyth, added, "Using objective smart implantable device data to generate a 'recovery curve' that predicts a great final outcome is extremely valuable. With this data, surgeons are finally able to objectively answer one of the most common questions we hear from patients after knee replacement surgery: 'Am I doing ok?!?' Such knowledge benefits the surgeon and patient alike." — *EH*

SPINE

Short or Long Spine Constructs for Parkinson's Patients?

A new muliticenter study which included researchers from the Mayo Clinic and St. Louis University looked at the very interesting question of whether Parkinson's patients experienced better (or worse) outcomes depending on the length of their spine implant contruct.

The research term compared Parkinson's patients who'd received short (1-3 level) constructs to long (>3 levels) constructs for thoracolumbar fusions. Their work is pending publication.

"A combination of two factors led to this work," co-author Matthew Lindsey, M.D., told *OTW*. "First, there is a small amount of literature on patients with Parkinson's who have spinal fusion, and most of it involves small case series. As a result the data is mixed about how best to treat them."

"Second, we found that the database at the Mayo Clinic had enough patients that we could shed some light on the subject. We went in without preconceived notions, and it was enlightening."

As for why there hasn't been much work on the best way to treat these patients, Dr. Lindsey, an orthopedic surgeon at St. Louis University and in the U.S. Air Force, said to *OTW*, "It is a smaller, complex patient population who have a disease that is rare. All of this makes it so that substantive amounts of patients at one location are harder to come by."

The researchers looked at all adult Parkinson's patients who had posterior

Source: Shutterstock

thoracolumbar fusion for deformity, degenerative, and traumatic indications at Mayo Clinic between 2017-2022 (n=92). Of these, 63 (68%) underwent short fusion and 29 (32%) had long fusion constructs.

The team found that short fusion constructs were more strongly associated with radiculopathy (51% vs 21%) while extended fusions had a higher indication of spinal deformity (41% vs 10%) or fracture (34% vs 8%) and were more likely to have decreased mobility prior to surgery (79.7% vs 53.9%).

Short constructs had a higher rate of listhesis (20% vs 0%) or stenosis (34.5% vs 4%) at the upper instrumented vertebra (UIV) or UIV +1, proximal screw loosening (13% vs 0%), proximal junctional complications (53% vs 12%) and proximal junctional failures (37% vs 8%). In-hospital complications, 90-day and 1-year mortality, reoperation rate, infection rate, progressive neurologic decline, and fusion rates were statistically similar between the two groups.

Regarding clinical outcomes, the team determined that the overall mortality rate was 2.2% at 90 days and 6.5% at 1 year. The rate of fusion among all cases was 72.9% at one year; major complications occurred in 20.6% of all cases.

Turning to radiographic outcomes, overall screw failure or loosening occurred in 19.1% of all cases [this occurred at a higher percentage in the lower instrumented levels than the upper instrumented levels (15% of cases vs 8.9% of cases)]. Overall reoperations occurred in 15 of the 92 patients (16.3%).

Dr. Lindsey, noting that their study appears to be the largest cohort study to date evaluating outcomes following thoracolumbar spinal fusion in Parkinson's patients, told *OTW*, "What was not surprising was that we confirmed that this is a patient population with high risks of complications and morbidity.

"What was unusual was that paradoxically, patients with larger surgeries fared better in the long run while not having a higher rate of complications. By fared better, I mean that they had less rate of hardware failure, proximal and distal junctional failure, and peri implant stenosis."

"This work sheds further light on how we should approach patients who need arthrodesis and also have Parkinson's disease. It can help guide providers to choose levels with the long term outcomes and need for future surgeries in mind."

"As with any retrospective work, a prospective work would allow for a more causative relationship. However, we hope to be able to compare cervical cases and identify Parkinson's-specific metrics that might be predictive of fusion failure or success. Furthermore, a comparison of fusion vs decompression only would be another line of questioning that could be fruitful." — *EH*

Wireless, 3D NAV Pedicle Screw Placement Review

Hoping to shake things up in the pedicle screw placement arena, a team from Weill Cornell Medicine—Department of Neurosurgery, NewYork-Presbyterian Och Spine Hospital has revisited previous work regarding a wireless, Single-Step Pedicle Screw placement system.

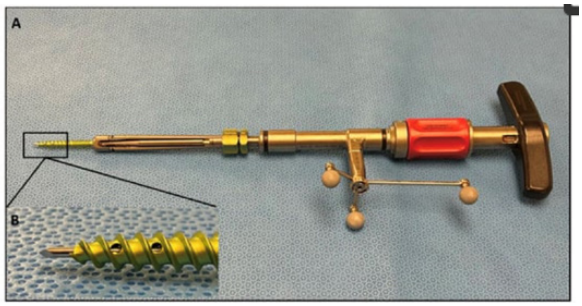
Their study, "High Accuracy of Three-Dimensional Navigated Kirschner-Wire-Less Single-Step Pedicle Screw System (SSPSS) in Lumbar Fusions: Comparison of Intraoperatively Planned versus Final Screw Position," appears in the August 29, 2024 edition of *Brain Sciences*.

In their prior work, the researchers reported that 90% of pedicle screws were inserted without a breach. Digging deeper, the team, while acknowledging that their study only assessed anatomical accuracy postoperatively with CT scans, decided to compare planned intraoperative screw trajectories with final screw position using the Gertzbein and Robbins classification system.

Comparing intended pedicle screw placement to final screw position offers surgeons a better evaluation of how closely their surgical execution matches their planning, explained the authors.

"If there are any major deviations between intended and final screw position, surgeons can study these errors and devise plans to avoid them in the future. Given our previously reported 90% grade 0 breach, we anticipated a high percentage of screws placed exactly as intraoperatively planned," they wrote.

"The idea was to simplify the tools that we use in the workflow for navigation and percutaneous placement of



Three-Dimensional Navigated Kirschner-Wire-Less Single-Step Pedicle Screw System / Source: Roger Härtl, M.D.

screws," said Roger Härtl, M.D., the Hansen-MacDonald Professor of Neurological Surgery and Director of Neurosurgery Spine at Weill Cornell Medicine, to *OTW.*

"In the past, the insertion of the screws required monitoring multiple separate tools and instruments for the insertion of screws. This new system now combines everything in one tool. This was really developed by the technical engineers at DePuy Synthes. It greatly facilitates and improves the workflow for his placement of screws either with Ap fluoro or 3-D navigation."

For the study, the research team enrolled patients who'd received instrumented fusion for lumbar degenerative disc disease. The study patients, all adults, underwent a transforaminal lumbar interbody fusion, anterior lumbar interbody fusion, or lateral lumbar interbody fusion procedure using a navigable Single-Step Pedicle Screw System workflow.

According to the study authors, the workflow was as follows:

- A skin incision is marked using navigation guidance.
- Navigation is manually verified using the Brainlab pointer to identify and palate a transverse process at a distance from the reference array.
- The navigated screw with the screw driver is calibrated.
- After inserting the screw, the screws are test stimulated with an extended electrode probe. A threshold of 8 mA is used to consider screw repositioning.
- A final intraoperative CT is completed with the navigation reference in place in case of further instrument adjustment or decompression.
- The patient's wound is generously irrigated and washed after meticulous hemostasis is performed. Osteo-stimulative bone graft is packed under the rod. Local anesthesia is used to infiltrate the muscle and the wound is closed.

A total of 47 patients were included in the analysis. Out of 206 screws, 196 (95%) were accurately placed—no complications. The team found that the Single-Step Pedicle Screw System workflow, even without K-wires and other traditional instruments, facilitates accurate and reliable pedicle screw placement.

Dr. Härtl commented to *OTW,* "Some surgeons believe that for the safe placement of percutaneous screws it is necessary to use separate K-wires. The study clearly shows that that's not the case. This again further facilitates the workflow." — *EH*

PEOPLE

Docs: Don't Tank Your Practice With Social Media

Social media is ubiquitous BUT healthcare professionals usage guidelines are sparse, so the American Society of Pain and Neuroscience set out to rectify this situation and the results to that effort are titled, "Social Media Behavior Guidelines for Healthcare Professionals: An American Society of Pain and Neuroscience NEURON Project," and appears in the November 5, 2024 edition of the *Journal of Pain Research.*

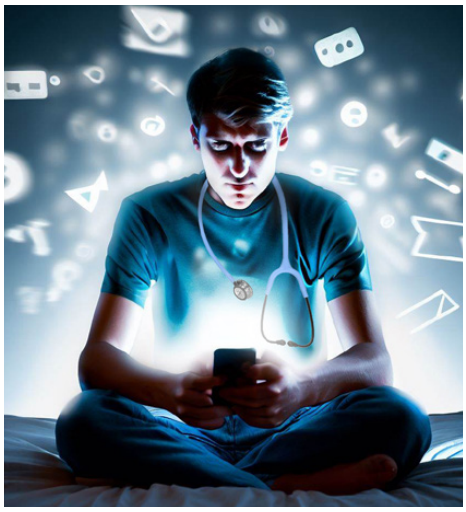
According to the National Institutes of Health reported that in 2024, 71.2% of physicians are utilizing social media1.

Co-author Timothy R. Deer, M.D., president and CEO of The Spine and Nerve Center of The Virginias, told *OTW*, "The number of healthcare professionals on social media makes this an important issue currently and going forward."

Deer and his team selected a panel of experts based on their expertise, publications, diversity, and own social media presence. Along with expert guidance, the committee conducted an extensive analysis of peer-reviewed literature in communication and medical journals to determine best social media practices for healthcare practitioners.

As Dr. Deer, chairman and founder of the American Society of Pain and Neuroscience, told *OTW*, the most important issues surrounding healthcare providers and social media are:

1. Confidentiality
2. Branding versus improper self-promotion



Source: Wikimedia Commons and Doctorxgc

3. Improper behavior creating animosity and division on LinkedIn and creating public argument

4. Improper "anonymous" comments to create distrust in the posting person

The committee determined that social media messages significantly affect patients' and colleagues' perceptions and actions regarding medical issues. Thus, healthcare professionals must be aware of legal and ethical considerations while maintaining a consistent, educational, and digestible persona online.

Noting that published research has demonstrated that the perception of medical professionals' social media content may differ from that of the wider public,2 the authors encourage healthcare professionals to assess their social media presence and even seek a review of their publicized communications from a non-medical reviewer.

OTW asked Dr. Deer about the "lowest hanging fruit" as far as addressing concerns and he said, "Creating a professional and proper venue for both agreement and pleasant disagreement that is constructive not destructive."

As for where most doctors go astray when it comes to social media, he added, "Most doctors do not go astray. The most common areas of failure are 'intentional creation of improper disruption' and improper posting of patient data—when a photo or X ray is published and although there is no patient name it is easily identifiable."

The committee recommended that "practitioners have separate personal and professional social media accounts and establish accounts solely dedicated to engaging in discourse related to the healthcare industry, as well as with colleagues, industry, and patients for marketing and educational purposes."

"As such, a well-defined distinction between personal and professional relationships with patients should be emphasized by physicians. In addition, healthcare practitioners are counseled to treat all disseminated content on social media platforms as inherently public, regardless of privacy settings, and prudence is advised when expressing potentially contentious viewpoints."

Dr. Deer offered several guidelines for those who wish to communicate an area of disagreement. "Use your real name and profile and be pleasant even in areas of disagreement. Lastly, if you are angry about a post wait a period of time before responding." — *EH*

References:

1. https://www.tandfonline.com/doi/full/10.1080/10872981.2024.2316489
2. https://pubmed.ncbi.nlm.nih.gov/34507932/

Meditations on Violent Acts

The tragic and brazen murder of UnitedHealthcare's CEO, Brian Thompson, on a New York City street sent shock waves throughout the musculoskeletal community. To us, members of that community, the most tragic aspect of this attack was that we've seen it before—as similarly violent acts against orthopedic and spine caregivers.

On July 11, 2023, Benjamin Mauck, M.D., 43, a well-loved hand surgeon at Campbell Clinic in Collierville, Memphis, Tennessee, was shot and killed by a patient in his exam room.

Preston Phillips, M.D., one of the musculoskeletal community's best, brightest, and most generous surgeons, was shot and killed in his own clinic on June 1, 2022, by a patient he'd recently treated.

Stephanie Husen, M.D., Amanda Glenn, and William Love were also shot in that same attack that killed Dr. Phillips and also Dr. Husen.

On September 16, 2010, a 50-year-old family member of a patient grew "overwhelmed" when a Johns Hopkin's spine surgeon told him about his mother's care and pulled a small semi-automatic handgun from his waistband and shot Dr. David Cohen in the chest. Dr. Cohen survived the attack.

Blunt Truths

Surgeons, their staffs and other caregivers are on the front lines—often caught between the private and public reimbursement system—and their patients—who are desperate for relief, can struggle to understand their pain, pathology, and a complicated care program.

Source: Shutterstock

It would not surprise me at all if a common reaction to the awful news about Brian Thompson was: "That could have been me or someone I know." Put aside the daily fights over prior authorizations and insurance mismanagement. The sadness for Brian Thompson's family and colleagues runs deep and is visceral.

Think simply about healing and pain and, of course, one of the integral parts of the healing professions, bad news—a suspicious image on an MRI, a poor prognosis, or an insurance turn down. Then imagine handing that information to an anxious patient. Put that on your shoulders. Carry it home. Marinate on it overnight and then go back for another day of clinic.

There's no villain here. The gestalt of that patient's pain and anxiety seeps upward through the healthcare chain and last week, it reached its apex ending the life of a good man, an accomplished man, a family man—not unlike the caregivers who've also faced an armed and desperate patient.

The system needs healing. The caregiver isn't the problem, the caregiver is the solution. We're in this together.

Please post your reactions, meditations even, to these acts of violence against the healing community and the reimbursement system that funds it. — *RY*

Rob Burnett, M.D. Joins Midwest Orthopaedics at Rush

Robert A. Burnett, M.D., a fellowship-trained orthopedic surgeon specializing in primary and revision hip and knee replacement, has joined Midwest Orthopaedics at Rush in Chicago.

Dr. Burnett is a graduate of the Rush orthopedic residency program and specializes in routine and complex primary and revision hip and knee reconstructions and partial knee replacement. He has also been trained in minimally invasive techniques and direct anterior total hip arthroplasty.

Dr. Burnett, who earned his undergraduate program at St. Louis's Washington University, was a member of the varsity basketball team for four years. He received his medical degree from the University of Iowa Carver College of Medicine and was selected to the Alpha Omega Alpha Honor Medical Society and the Gold Humanism Honor Society.

While in residency at Rush, Dr. Burnett was named "Best Chief Resident." He completed an additional year of fellowship training at the University of Utah, specializing in hip and knee replacement surgery.

Now an assistant professor at Rush University Medical Center, Dr. Burnett enjoys training residents and fellows in adult reconstruction. On the research front, his interests include the biomechanics of hip and knee replacements, revision joint replacement techniques, patient outcomes, perioperative care optimization, and health policy. He is completing a health policy fellowship with the American Association of Hip and Knee Surgeons.

OTW asked Dr. Burnett about his philosophy of training/education. "I think that training and educating residents and fellows within orthopedics and joint replacement improves my own skills and ability to care for patients."

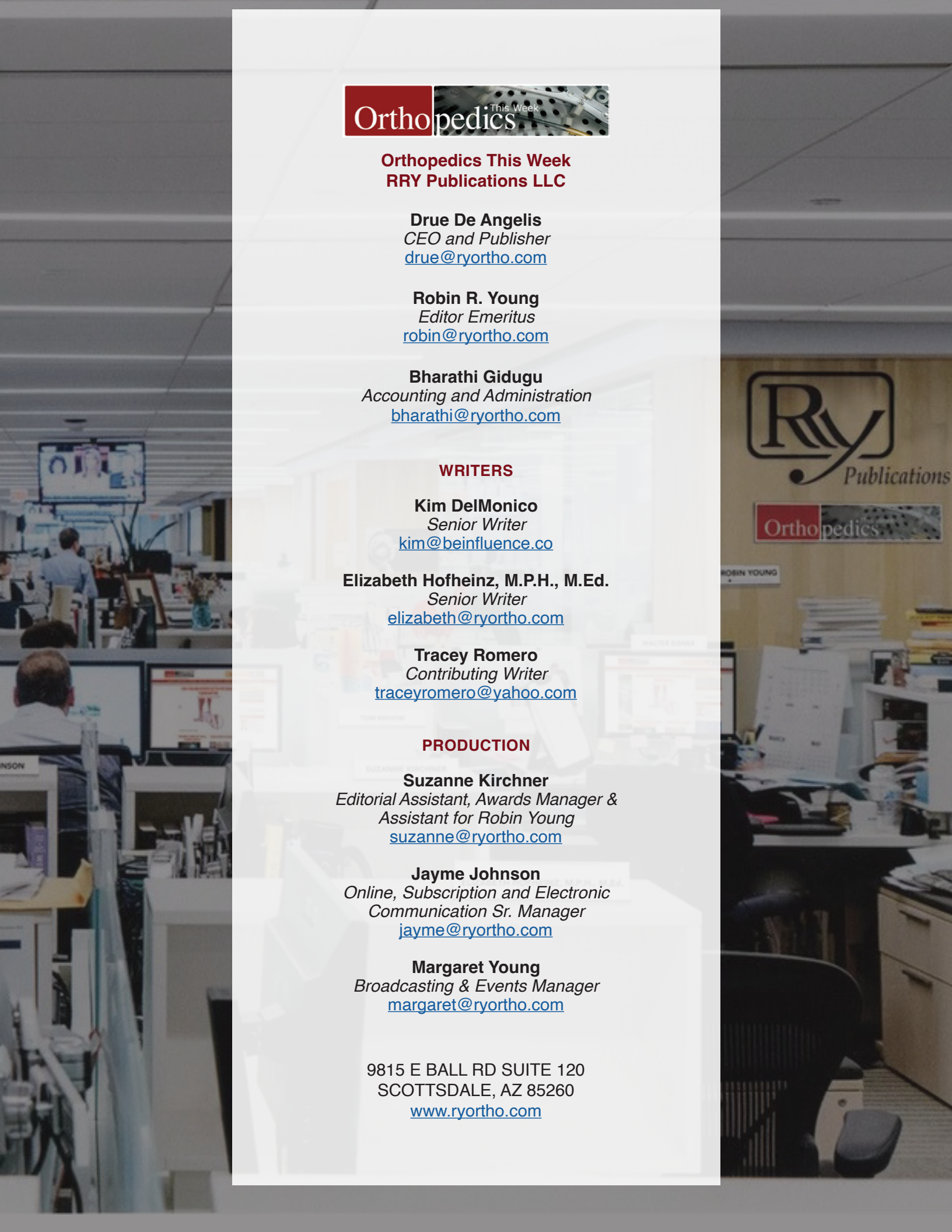
"An important aspect of education is staying up to date on the most modern techniques and trends to strive to deliver a better outcome for patients."

OTW also asked Dr. Burnett about his health policy fellowship. "The Health Policy Fellowship is completed outside of regular work hours. I attend regular meetings with an advocacy group whose mission is to understand the problems that patients and surgeons face from a health policy standpoint," he said.

"Some of these issues include improving access to surgeons for patients around the country as well as working with legislators to make sure policies don't get approved that would compromise health care delivery."

Dr. Burnett pushes the field of hip and knee arthroplasty forward by performing cutting edge research that is frequently presented at national meetings. His most recent research has focused on allergic reactions to a specific dressing type that patients may receive after surgery and how surgeons can avoid this complication in the future. — *EH*

Robert A. Burnett, M.D. / Courtesy of Rob Burnett, M.D.



Orthopedics This Week
RRY Publications LLC

Drue De Angelis
CEO and Publisher
drue@ryortho.com

Robin R. Young
Editor Emeritus
robin@ryortho.com

Bharathi Gidugu
Accounting and Administration
bharathi@ryortho.com

WRITERS

Kim DelMonico
Senior Writer
kim@beinfluence.co

Elizabeth Hofheinz, M.P.H., M.Ed.
Senior Writer
elizabeth@ryortho.com

Tracey Romero
Contributing Writer
traceyromero@yahoo.com

PRODUCTION

Suzanne Kirchner
Editorial Assistant, Awards Manager & Assistant for Robin Young
suzanne@ryortho.com

Jayme Johnson
Online, Subscription and Electronic Communication Sr. Manager
jayme@ryortho.com

Margaret Young
Broadcasting & Events Manager
margaret@ryortho.com

9815 E BALL RD SUITE 120
SCOTTSDALE, AZ 85260
www.ryortho.com