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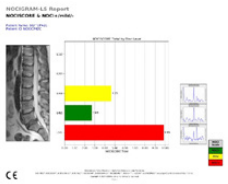
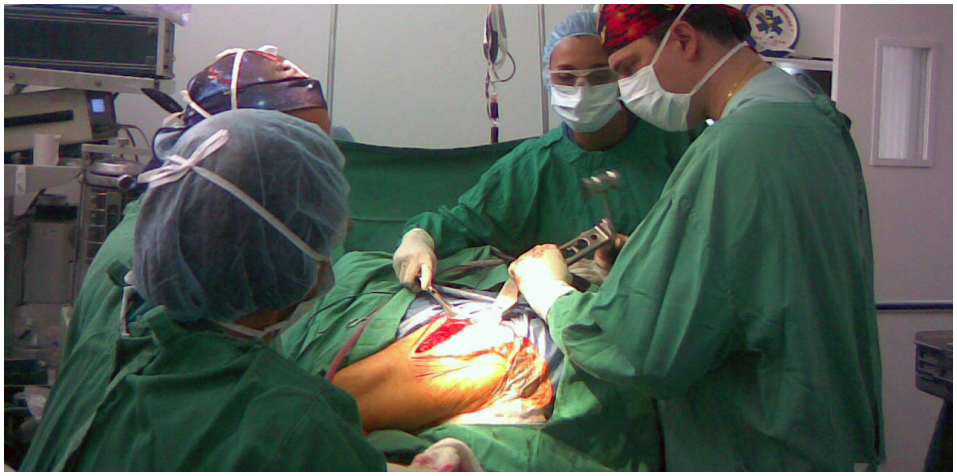
Orthopedics This Week

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: Ortho and spine stocks continue to face worries over rising costs and narrowing profit margins. Overall, the value of the 25 stocks in our universe fell 2.94% over the last 30 days. Excluding the big caps (MDT, JNJ, SYK, ZBH and GMED) market values fell 6.16% in 30 days. What does it take to stop the slide? Higher profit margins and increasing sales growth rates—in short, the building blocks of wealth. How did these companies close out 2024? We'll find out in the next 3 or 4 weeks. Notable: ATEC and GMED pre-announced better-than-expected results.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Pacira Biosciences	13.02%	1.52%	PCRX is a biopharma value stock—contradiction in terms, maybe—but in 5-years, returns should outpace average ortho. 2024 pre-announcement: $701mm sales, 3.85% growth. But huge pipeline.
2	3	Globus Medical	17.67	4.98	Preannounced 6.6% sales growth for Q4, 2024. That puts 2024 sales at $2.52 billion. The key, which was not announced, is operating margin. That will likely beat expectations.
3	6	Medtronic	19.17	(1.88)	Investors are giving MDT a better-than-average relative strength, which in this market is faint praise, but, in spine, with this team, MDT is beating expectations.
4	8	Xtant	(12.29)	30.25	Massive jump in Xtant's market value, of course, it's a stock with limited trading. Underlying everything is 36% Year-over-year sales growth. And, a broad and innovative product line.
5	5	ConMed	12.22	(5.87)	Most analysts expect CNMD to report just over 4% Q4 sales growth, which is low, but, interestingly, analysts are expecting 7% sales growth for Q1. Big jump.
6	NR	Alphatec	(20.35)	2.89	ATEC preannounced that Q4 sales were likely 27% !!! above last year's rates. No acquisitions. Straight up new orders. And positive cash flow. Gaining market share.
7	7	Zimmer Biomet	20.70	(2.00)	ZBH, Wall Street expects, will report just 3-4% sales growth for Q4, and all of 2025. So...ZBH remains the cheapest large diversified ortho stock trading today.
8	2	Integra LifeSciences	6.60	(9.69)	I think IART is way oversold...but chasing it now is like trying to catch a falling knive. When all the warning letter dust settles, investors can focus on IART's 12% sales growth.
9	10	Smith & Nephew	11.60	(7.05)	SNN is laying off about 150 employees from the former Richards Medical facility in Memphis. It's a response to rising costs. 5th cheapest ortho equity this week.
10	9	Axogen	(0.65)	21.47	Massive jump in Axogen, the supplier of nerve regeneration products (cool, right?). Pre-reported $187 million in sales, up 18% from last year.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Xtant Medical Hldgs	XTNT	$0.50	$69	30.23%
2	AxoGen	AXGN	$18.05	$794	21.47%
3	OrthoPediatrics Corp	KIDS	$24.44	$592	6.12%
4	SINTX Technologies	SINT	$3.39	$5	5.28%
5	Globus Medical	GMED	$87.07	$11,856	4.98%
6	Alphatec Holdings	ATEC	$9.97	$1,413	2.89%
7	Aurora Spine	ASG.V	$0.33	$25	2.73%
8	Dynatronics Corp	DYNT	$0.14	$1	1.82%
9	Pacira Biosciences	PCRX	$20.64	$953	1.52%
10	SI-BONE, Inc	SIBN	$13.72	$575	-0.80%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Nevro Corp	NVRO	$3.29	$123	-23.67%
2	MicroPort Scientific	0853	$0.68	$1,262	-23.33%
3	Bioventus	BVS	$9.28	$753	-19.86%
4	Anika Therapeutics	ANIK	$15.57	$228	-12.87%
5	Integra LifeSciences	IART	$21.81	$1,683	-9.69%
6	Orthofix	OFIX	$17.00	$650	-8.31%
7	Smith & Nephew	SNN	$23.95	$10,471	-7.03%
8	ConMed	CNMD	$68.82	$2,126	-5.87%
9	Aclarion	ACON	$0.12	$1	-3.69%
10	Johnson & Johnson	JNJ	$142.06	$342,027	-3.12%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Pacira Biosciences	PCRX	$20.64	$953	14.86
2	Johnson & Johnson	JNJ	$142.06	$342,027	18.54
3	Zimmer Biomet	ZBH	$104.54	$20,811	19.18
4	Medtronic	MDT	$80.66	$103,429	19.33
5	ConMed	CNMD	$68.82	$2,126	23.31

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Xtant Medical Hldgs	XTNT	$0.50	$69	105.06
2	Globus Medical	GMED	$87.07	$11,856	59.59
3	Medacta	MOVE	$121.77	$2,435	39.91
4	Smith & Nephew	SNN	$23.95	$10,471	39.81
5	Stryker	SYK	$365.66	$139,395	35.38

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Integra LifeSciences	IART	$21.81	$1,683	-6.90
2	ConMed	CNMD	$68.82	$2,126	1.21
3	Pacira Biosciences	PCRX	$20.64	$953	1.38
4	Medacta	MOVE	$121.77	$2,435	1.43
5	Zimmer Biomet	ZBH	$104.54	$20,811	2.80

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Johnson & Johnson	JNJ	$142.06	$342,027	6.18
2	Xtant Medical Hldgs	XTNT	$0.50	$69	5.25
3	Globus Medical	GMED	$87.07	$11,856	3.56
4	Smith & Nephew	SNN	$23.95	$10,471	3.52
5	Medtronic	MDT	$80.66	$103,429	3.51

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	$3.29	$123	0.29
3	Xtant Medical Hldgs	XTNT	$0.50	$69	0.76
4	Orthofix	OFIX	$17.00	$650	0.87
5	Integra LifeSciences	IART	$21.81	$1,683	1.09

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Aclarion	ACON	$0.12	$1	16.23
2	Globus Medical	GMED	$87.07	$11,856	7.56
3	Stryker	SYK	$365.66	$139,395	6.80
4	AxoGen	AXGN	$18.05	$794	5.00
5	Medacta	MOVE	$121.77	$2,435	4.77

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

Mid-Course Infection Risk Reduction Grade: A-?

BY TRACEY ROMERO

According to the American Academy of Orthopaedic Surgeons (AAOS), infection rates after total hip arthroplasty and total knee arthroplasty range between 0.5% and 2%.

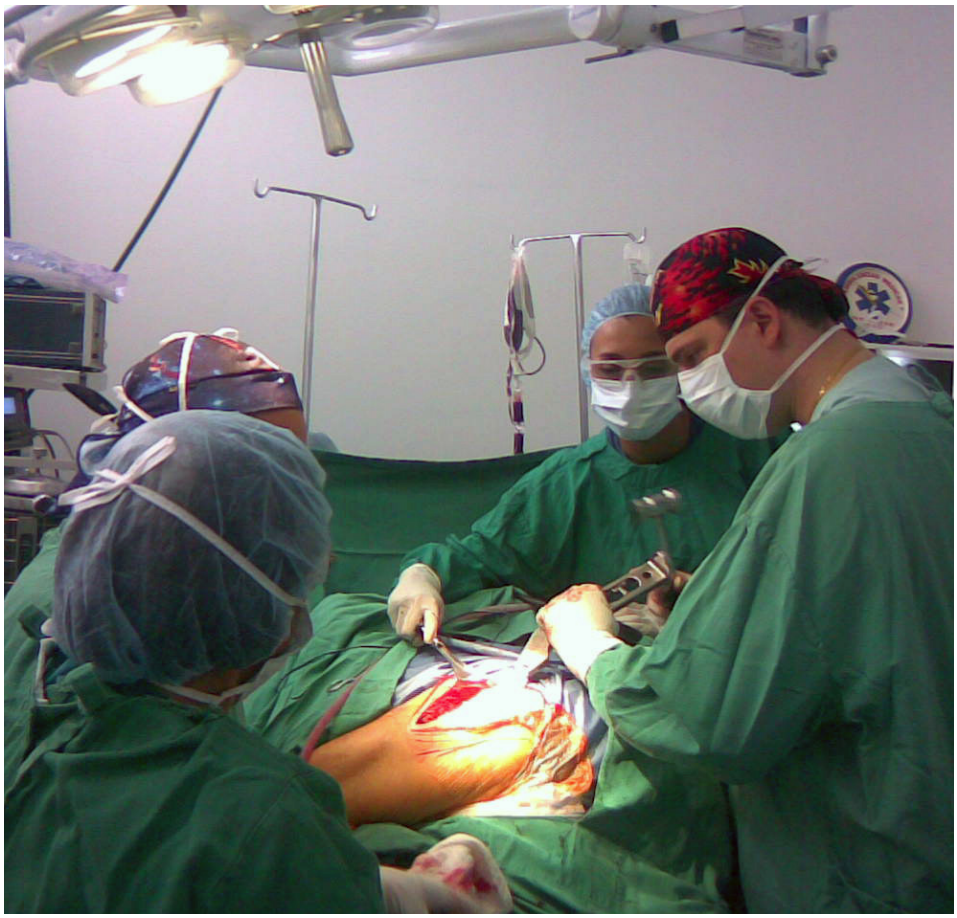
While this is a low percentage, because the number of total joint replacement surgeries performed continue to increase every year in the U.S., infection risk and the human and financial costs of treating surgical site infections is still a major concern.

Prosthetic joint infections, particularly, can lead to implant failure and the need for the removal and replacement of the implant, and in severe cases, amputation. Prosthetic joint infections, if they are not reduced, could cost insurers, hospitals and patients an estimated $1.8 billion by 2030.

The standard of care for preventing PJIs includes a combination of preoperative, intraoperative, and postoperative measures.

E. Bailey Terhune, M.D., assistant professor at Rush University Medical Center, and Joseph Bosco III, M.D., vice chair of clinical affairs at NYU Langone and professor at the NYU Grossman School of Medicine recently talked to Orthopedics This Week about the progress that has been made in infection risk with orthopedic surgeries and what work still needs to be done.

Terhune said that infection risk for primary arthroplasty has been hovering at about 1% for about five years, while Bosco said that infection risk for total joint and spine surgery has decreased by at least 50%.



Surgeons performing hip replacement surgery / Source: Wikimedia and Pasm

Patient Optimization

A big reason for the progress is patient preoperative optimization—where the physician and clinic staff take the time to identify and manage preoperative risk factors like obesity, anemia, malnutrition, glycemic control, and smoking.

According to the AAOS Clinical Practice Guideline for the Diagnosis and Prevention of Periprosthetic Joint Infections, patients with a BMI ≥ 35 have a two- to six-fold increased risk of PJI. (AAOS CPGs Offer Standards for Periprosthetic Joint Infection Prevention)

Malnutrition, another risk factor, is defined as either albumin < 3.5 g/dL, and or white blood cell counts of fewer than 4 cells x 103/ µL and/or hemoglobin < 12 g/dL, while anemia is defined as hemoglobin <12 g/dL in women and <13 g/dL in men.

Bosco emphasized that patients with these risk factors are given resources to help them get their comorbidities under control before surgery. Patients who need to lose weight are sent to a non-operative weight-loss program and patients who are smokers are forwarded to a cessation program.

"We educate our patients and motivate them to address their risk factors and provide them with the resources to do so," Bosco explained.

Staphylococcus aureus colonization in the nose at the time of surgery is another major risk factor for surgical site infection, tripling the risk in many cases.

One study, "Getting the drop on Staphylococcus aureus: Semiquantitative Staphylococcus aureus nasal colony reduction in orthopedic surgery reduces surgical site infection," found that the combination of intranasal povidone-iodine application and skin antisepsis signification decreases that risk in joint arthroplasty and spine surgery.

Bosco said that 25% to 30% of patients screen positive for Staphylococcus aureus nasal colonization and 2% for MRSA colonization. At NYU Langone, they decolonize with Betadine which is a very cost effective approach.

Both Terhune and Bosco told *OTW* by getting these conditions under control before surgery, the surgical team effectively reduces their patient's risk of infection and other complications.

Surgery Protocols

During surgery, there are also important protocols that can reduce the risk of infection including the administration of perioperative antibiotic prophylaxis, less time in the OR, proper irrigation, and closure of wounds.

According to Terhune, lessening the amount of time a patient spends on the operating table with open wounds and reducing the amount of traffic in and out of the OR during the procedure can decrease infection risk. Tranexamic acid has also been shown to decrease blood loss during surgery, which also reduces infection risk.

Cefazolin is an often-recommended antibiotic for patients undergoing total joint arthroplasty. In cases of a penicillin allergy, however, vancomycin should be used, research has shown.

Post Surgery Care

After surgery, routine follow-up care should include early detection and management of infections by educating patients of the signs of an infection which can include fever, erythema, swelling, and drainage from the surgical wound site.

Bosco said another important element of postsurgical care is antibiotic stewardship—which antibiotics, how much, and for how long. This requires a team approach that includes all those involved in a patient's care.

Thinking Outside the Box

In their pursuit to provide the best possible care to their patients, orthopedic surgeons continue to look for new ways to better address infectious disease and the risk of prosthetic joint infection.

One way they are doing that is to create surgery clinics that specialize in both infectious disease and orthopedic surgery.

One such clinic was established at Duke Health in 2020. It focuses on patients with severe infections or multiple prosthetic joint infection episodes, especially those patients who had been told that amputation was their only option.

Between July 2021 and March 2024, the clinic treated more than 300 patients and reported a low no-show rate of 5.0%. Treatments include debridement, antibiotics, and implant retention and explantation. Amputation was only required in 4% of the cases.

Striving for Excellence

The goal that both Terhune and Bosco shared is to reduce infection risk to as close to zero as possible and the key is sweating the details within the context of providing the best patient care possible.

In closing, Bosco reminded *OTW* that, while it is probably impossible to get infection risk down to absolute zero, "at NYU Langone, what drives us is excellent patient care. There will always be a risk of infection. We will never get to zero risk, but along the way we will increase quality and excellence."

Mid-course grade? A-. ♦

Massive 639,000 Patient Fracture Study Released

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

Source: Shutterstock

A research team from the Warren Alpert Medical School of Brown University research team collected data from 638,999 cervical and thoracic fractures reported in the U.S. between 2003 to 2021. Their work, "What Is the Epidemiology of Cervical and Thoracic Spine Fractures?" was published in the December 1, 2024 edition of *Clinical Orthopaedics and Related Research.*

Describing the impetus for this work, co-author Bassel G. Diebo, M.D., assistant professor of orthopedics at the Warren Alpert Medical School, Brown University, told *OTW,* "Insufficiently powered studies exist due to the high proportion of undiagnosed fractures, limited focus on younger populations, and challenges in collecting data in trauma settings, where the unpredictable timing and urgency of injuries make comprehensive data collection difficult."

Armed with the United States National Electronic Injury Surveillance System-All Injury Program database, the researchers analyzed:

- location of injury (the most common categories being "home," "recreation/sports facility," or "public property"),
- mechanism of injury ("fall," "sports," or "other," which included injuries of unknown mechanism along with motor vehicle accidents, auto-pedestrian, gunshot wounds), and
- disposition ("admitted" or "treated and released").

Study Results: Aging Population and Osteoporosis Driving Higher Fracture Rates

The team found that the incidence of cervical and thoracic fractures increased from 2.0 and 3.6 per 10,000 person-

years in 2003 to 14.5 and 19.9 in 2021, respectively.

Specifically, the authors wrote, "Incidence rates of cervical and thoracic fractures increased for all age groups from 2003 to 2021, with peak incidence and the highest rate of change in individuals 80 years or older."

"Most injuries occurred at home (median 69%), which were more likely to impact older individuals (median [range] age 75 [2 to 106] years) and females (median 61% of home injuries); injuries at recreation/sports facilities impacted younger individuals (median 32 [3 to 96] years) and male patients (median 76% of sports facility injuries). Falls were the most common injury mechanism across all years, with females more likely to be impacted than males. The proportion of admissions increased from 33% in 2003 to 50% in 2021, while the proportion of treated and released patients decreased from 53% to 35% in the same period."

"We believe this large increase is primarily due to the aging population, rising osteoporosis prevalence, and higher fall rates among older adults," stated Dr. Diebo.

"The findings from our study could potentially drive changes that affect clinical care. Early diagnosis and management of osteoporosis might reduce fracture incidences and associated healthcare costs. Some may argue that increased screening could initially strain healthcare systems, but it can potentially lower long-term demands by reducing hospital admissions and lower the need for surgical treatment of these fractures."

OTW asked Dr. Diebo how osteoporosis screening might affect these results. He answered: "Strong epidemiological evidence is needed to justify lowering the age threshold or broadening the screening population, which would require consensus from major health organizations to balance public health benefits with resource constraints. Additionally, advocacy from our organizations like AAOS [American Academy of Orthopaedic Surgeons], AOA [American Orthopaedic Association] and public health experts would be crucial to overcome institutional inertia and drive policy change." ♦

When a Standard Spine MRI Won't Cut It

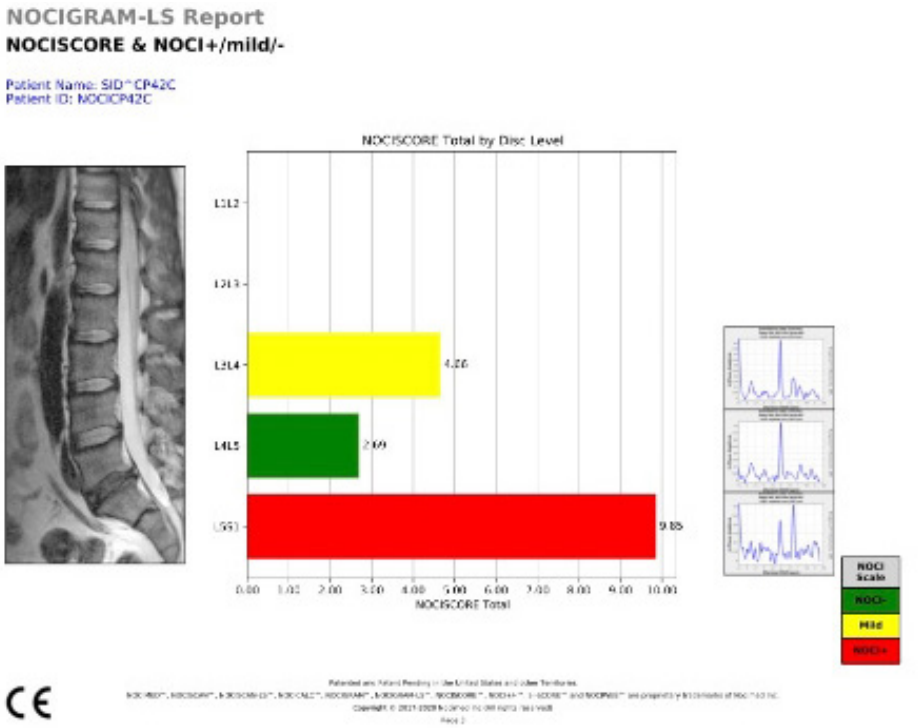
BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

Low back pain, already the leading cause of disability globally, is predicted to rise 36.4% by 2050.[1] Which means the number of times a surgeon asks—Where's the pain coming from?—will also rise 36.4%. Unfortunately, the ability to accurately answer that question has traditionally been something of a dark art—even with a standard MRI scan. An apparently healthy spine disc on an MRI could be, in fact, the pain generator.

In 2018, a team from the University of California, San Francisco (UCSF) tackled the issue of discogenic pain. David Bradford, M.D., now Chair Emeritus of the University of California, San Francisco Department of Orthopaedic Surgery, worked with John Claude, a respected biomedical engineer, Jim Peacock, a biomedical engineer and patent attorney, and Jeffrey Lotz, Ph.D., a renown spine researcher to, if possible, find a more precise method of pinpointing pain generating spine discs.

"The UCSF researchers took scoliosis disc material from young people who were not in pain and compared it to painful degenerating discs under a 7-Tesla magnetic scanner," explained Brent Ness, CEO of a company that is commercializing a new and more effective way of locating discogenic pain.

"They found that the content of the discs from scoliosis patients differed greatly from those with degenerative discs. Indeed, it was this recognition that the disc biomarkers differentiate between healthy and diseased discs. From there, the UCSF team went about correlating these painful-looking discs using provocative discography, an invasive procedure where pressure is injected into the disc to replicate the pain episode."



Aclarion's Nociscan / Courtesy of Aclarion, Inc.

Those UCSF studies were several years ago. We now know, says Ness, that "With disc degeneration the biomarkers aligned with structural integrity decline and nerves grow into the disc. When collagen and proteoglycan markers fall, and there is an acidic presence of alanine, lactic acid and propionate—that is the 'formula' for pain. And while acid hitting the nerves is painful, the traditional MRI image of that disc can look just fine."

Is this a signal versus noise problem?

In other words, would a higher resolution, more signal, less noise, image spot those pain generating changes in spine discs?

Ness, who is CEO of Aclarion, Inc., a company dedicated to improving spine surgeon's ability to precisely locate spine pain generators, went outside of traditional magnetic resonance experts to, in fact, the telecom sector to look at the signal/noise problem with "fresh eyes."

According to Ness, "Rather than using the traditional MR physicist's method of incoherent averaging—where you push more signal in—the telecom experts used coherent averaging, which reduced signal noise and allowed signals to come through loud and clear!"

That was the breakthrough Ness was looking for.

Ultimately, Aclarion's team invested more than $40 million to develop an

effective, noninvasive option for physicians who need to distinguish between painful and nonpainful lumbar discs. The product the Aclarion team developed is called Nociscan. Working with a cloud connection, Nociscan captures magnetic resonance spectroscopy data from an MRI machine for each lumbar disc being evaluated. Next, Nociscan uses proprietary signal processing techniques to extract and quantify chemical biomarkers shown to be associated with disc pain, information that feeds into proprietary algorithms to indicate if a disc may be a source of pain.

Brent Ness: "We now have evidence indicating that magnetic resonance spectroscopy accurately quantifies levels of degenerative pain biomarkers, differentiating painful versus non-painful discs in patients with chronic discogenic low back pain—and that, when used to inform treatment decisions, correlates with surgical success rates."

"One recently published study with 206 discs compared provocative discography to magnetic resonance spectroscopy, finding that in non-herniated discs, the latter technique had an accuracy of 93%, a sensitivity of 82% and a specificity of 93%. In addition, when all magnetic resonance spectroscopy-positive discs were treated, surgical success was 97% versus 57% when the treated level was magnetic resonance spectroscopy-negative, or 54% when the non-treated adjacent level was magnetic resonance spectroscopy-positive. We are thrilled to have such strong foundational science."

Alphatec Adds Nociscan to Its Informatics Platform

Alphatec, the fastest growing company in spine—having taken more market share than any other supplier in four of the last five years, added Aclarion's Nociscan to its informatics (brand named AlphaInformatiX) platform. The deal with Aclarion, which was signed earlier in 2024, gives surgeons a single, integrated platform that, among other features, says Ness, will reduce uncertainty for patients with chronic low back pain and improve outcomes.

Reimbursement

Over the near and intermediate future, Ness expects payer support to grow. "I foresee multiple local coverage decisions, additional enthusiastic surgeon users, and more data. We have already invested $40 million in this groundbreaking technology…and it is paying off for all involved. Not only does Nociscan help physicians ascertain painful versus nonpainful lumbar discs, but it furthers the conversation and shared decision making between surgeon and patient."

Quantifying the Chemistry of Low Back Pain – Precision Diagnostics

"Aclarion uses MR spectroscopy to analyze the physiological status of lumbar intervertebral discs. Being able to quantify the chemical biomarkers content of discs in chronic low back pain patients adds an entirely new dimension of clinically relevant information that anatomical imaging alone simply can't provide," said Simon Blease. M.D., Consultant Musculoskeletal and Spine Radiologist. "Having progressed through a careful integration of Nociscan into patient care pathways, we have found compelling results in over 20 patients so far. We are convinced this will be a game changer for how we will evaluate and plan treatment for this common and distressing clinical condition."

New U.S. Study Launched

Aclarion has launched the CLARITY Post-Market Trial for the evaluation of Nociscan in the diagnosis and treatment of chronic low back pain, an effort led by Nicholas Theodore, M.D., director of the Neurosurgical Spine Center at Johns Hopkins University. The research comprises an initial target of 10 sites and will enroll 300 patients with an interim analysis at 150 patients. Concurrently, the company will be collecting real world data through the CLUE Trial, which will offer near-term insights into the probability of success of CLARITY by quantifying how often Nociscan data results in a surgeon altering their original treatment decision.

"Diagnosing the source of chronic low back pain has been an industry conundrum for decades," said Dr. Theodore. "Moreover, as clinicians, we are challenged by important limitations with alternative diagnostic tools like MRI and discography. Aclarion's Nociscan tool has already illustrated a unique and compelling capability for objectively measuring pain-generating chemical biomarkers in the lumbar spine, and I am equally interested in how it may apply to measuring disc degeneration. I believe these innovations will become foundational to the diagnosis and treatment of chronic low back pain."

For more information, please visit www.aclarion.com. ♦

Reference:

1. https://www.healthdata.org/news-events/newsroom/news-releases/lancet-new-study-shows-low-back-pain-leading-cause-disability#:~:text=In%202020%2C%20619%20million%20people,peak%20age%20impacted%20is%2085.

COMPANY

Surgical Logistics Start-up Raises $4.8M

Left to right Dimitrios Stoimenou, Shahnawaz Ahmed, Yeshwanth Pulijala, Lee Lindley / Source: Scalpel AI

London-based Scalpel AI, a medical technology start-up focused on surgical logistics technology, has successfully raised $4.8 million in a funding round.

The funding round was led by Mercia Ventures, a venture capital investor focused on software, consumer, healthcare, and deep tech. Other investors included private investors and Tensor Ventures.

Scalpel AI is based in London and has an office in Houston. The company's technology is able to identify and track surgical instruments through a combination of computer vision and machine learning. According to the press release, the funding will allow Scalpel AI to "scale its global operations and roll out its technology with major players in the healthcare supply chain." Its clients include sterile services, hospitals, and third-party logistics services including U.S. based GlobalMed Logistix.

Scalpel AI can track surgical instruments throughout the supply chain process. It does this by generating a "digital twin" for each instrument throughout its journey from vendor warehouses to operating rooms and back. Scalpel AI is also able to confirm that the correct equipment is on the surgical trays when delivered to the operating room.

Mercia Ventures Investment Manager Lee Lindley commented, "Ensuring that surgical trays contain the right equip-

ment is essential for an effective healthcare system. Existing solutions use simple mechanisms such as barcodes, RFID tags, and manual validation. Scalpel AI's platform has the potential to transform how surgical trays are managed."

Lindley continued, "This investment will enable the company to scale internationally and pursue its goal of being recognized as the industry standard. We're excited to be supporting Yesh and Shah on this journey."

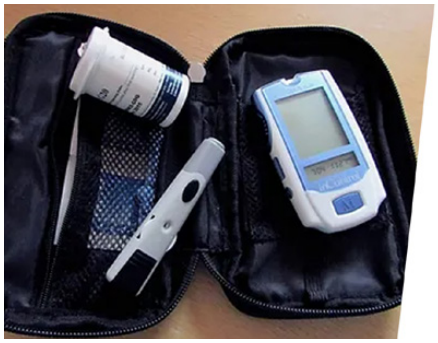
Yeshwanth Pulijala, Ph.D. and Shahnawaz Ahmed, Ph.D. founded Scalpel AI in 2017. Dr. Pulijala has a Ph.D. in medical visualization and Dr. Ahmed is a specialist in computer vision systems with a Ph.D. in object detection. Their education and experience formed the basis for Scalpel AI, bringing together medicine and technology. — *KD*

Biocomposites Buys Stake in PJI Testing Company

Biocomposites Ltd, an international medical device company, has invested in InfectoTest GmbH, a company that has pioneered an innovative way to quickly diagnose periprosthetic joint infection (PJI) in the OR, office or clinic.

Based in Keele, United Kingdom, Biocomposites products are used to reduce the risks of infection in bone and soft tissue. As part of that core objective, the company has purchased a minority share interest in InfectoTest, whose products, according to Biocomposites, will strengthen its infection reduction and management product line.

InfectoTest's novel bacterial point-of-care testing kit systems for periprosthetic joint infection (PJI), will complement Biocomposites' existing product portfolio, according to the company.



InfectoSynovia test kit / Source: Biocomposites Ltd and InfectoTest GmbH

The point-of-care PJI test is called InfectoSynovia and, according to the company, has the ability to diagnose PJI in under five minutes. The PJI test can "detect the infection in tiny quantities of synovial fluid using a unique method of electrochemical analysis." The test can use "a sample as small as 50 microliters (µl) of synovial fluid."

Biocomposites Chief Executive Officer Michael Harris explained, "Periprosthetic joint infection is a large and growing problem worldwide. Quickly and accurately pinpointing the bacteria that cause each infection is essential if patients are to receive the best care and maximize their chances of full recovery."

Harris continued, "Our investment in InfectoTest GmbH, reaffirms our commitment to providing and investing in a comprehensive range of products for the management of infection in bone and soft tissue."

The test can be used in the operating room as well as in an inpatient or outpatient setting. According to InfectoTest, the system includes a hand-held reader with digital display function and disposable sensor chips.

InfectoTest Managing Director Svetlana Karbysheva, M.D., Ph.D. said, "Our InfectoSynovia test has the potential to revolutionize the diagnosis of periprosthetic joint infection."

Dr. Karbysheva continued, "With the backing of Biocomposites, which has deep expertise in the management of infection in bone and soft tissue, and a significant global distribution network, InfectoTest will now be able to develop this essential test faster and bring it to clinicians and their patients sooner." — *KD*

LEGAL

FDA Clears Novel Intervertebral Body Fusion Devices

The U.S. Food and Drug Administration (FDA) has granted 510(k) clearance to two intervertebral body fusion devices.

According to the FDA 510(k) summary document, the devices are intended for "use at one level in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis." Further, "DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies."

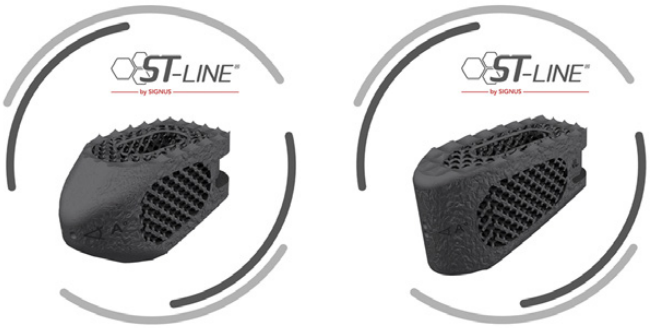
The lumbar devices are to be "used in patients who have had six months of non-operative treatment." Additionally, the devices are intended for "use with a supplemental internal fixation system and with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion."

SIGNUS Medizintechnik GmbH, based in Alzenau, Germany, is the manufacturer and its novel devices, brand named TETRIS® ST and TETRIS® R ST PLIF are cages made from structured titanium (ST).

The novel interbody implants incorporate the SIGNUS toothed cage design. This design, according to the company, lowers the risk of implant migration by providing "secure anchoring in the bone with high primary stability." According to Signus, the SIGNUS ST promotes bone-on and bone-in growth thanks to its "open, macroporous titanium design resembling natural cancellous bone architecture."

The unique design of the TETRIS ST allows it to be implanted without the "removal of the posterior vertebral body edges." The TETRIS R ST, said Signus, "offers an additional rotational technique with a tapered rotational edge, enabling a straightforward, low-impact rotation."

In order to qualify for the shorter and earlier 510(k) clearance the device must be substantially equivalent to a predicate device. Here, the primary predicate device is the SIGNUS TETRIS™ II. The additional predicate devices include the SIGNUS TASMIN® R and the SIGNUS MOBIS™ II ST. — *KD*



TETRIS® ST and TETRIS® R ST PLIF cages / Source: SIGNUS Medizintechnik GmbH

LARGE JOINTS

High BMI Increases Joint Arthroplasty Costs 2-8%

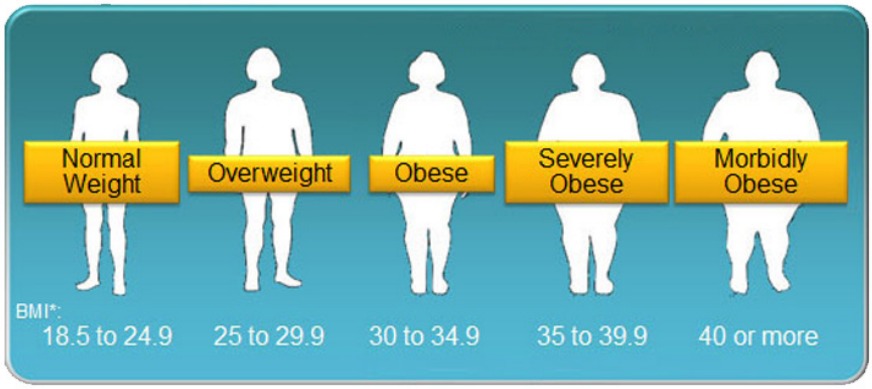
A new study from a Mass General/Harvard Medical School research team calculated the effects of body mass (measured using the BMI scale) on joint arthroplasty surgery facility costs and resource utilization. The full study, "Weighing the Impact: The Influence of Body Mass Index on Facility Costs in Total Joint Arthroplasty," appears in the December 2024 edition of the *Journal of Arthroplasty.*

"This study was driven by the need to better understand the economic impact of patient-specific factors, such as BMI [body mass index], on total joint arthroplasty (TJA) costs," co-author Christopher M. Melnic, M.D. of Massachusetts General Hospital/Harvard Medical School, explained to *OTW*.

"Using time-driven activity-based costing, a novel methodology for accurately calculating healthcare costs, our team sought to uncover how BMI influences facility costs and resource utilization in a real-world, high-volume dataset. The findings could inform discussions on healthcare equity, resource allocation, and physician reimbursement."

The team collected data from 7,340 total knee arthroplasties (TKAs) and 6,466 total hip arthroplasties (THAs) performed between 2019 and 2023, then stratified the patient data into four BMI categories:

- Index group: Less than 30% body fat (Body Mass Index: BMI)



Higher BMI=more resource utilization / Source: Wikimedia Commons

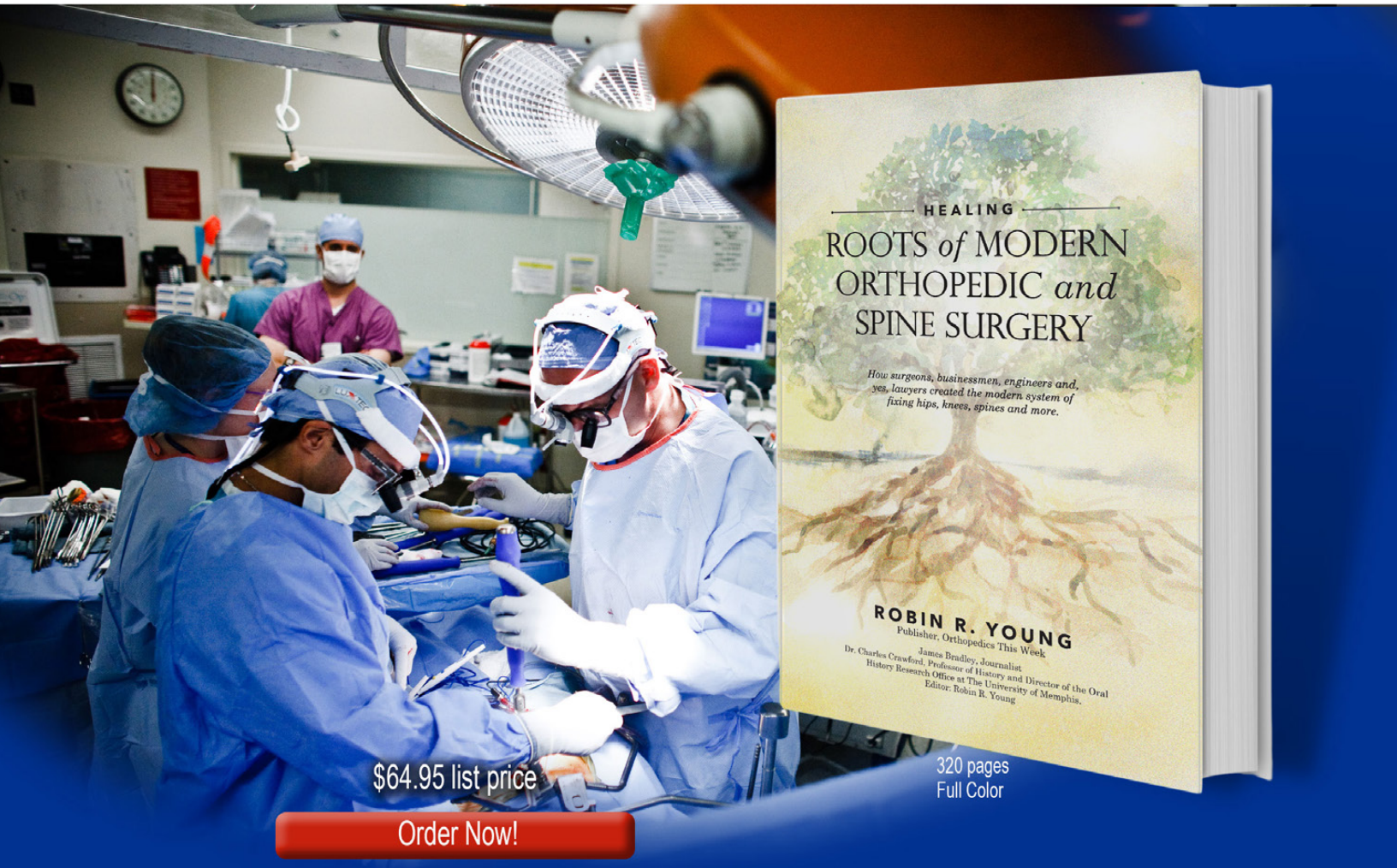
- Study groups:
  - o Between 30% and less than 35%
  - o Between 35% to less than 40%
  - o Greater than or equal to 40% BMI.

The team found that costs rose in proportion to BMI rates, specifically:

- Patients whose BMI were between 30% and under 35%
  - o TKA:
    - 3% higher personnel costs than patients whose BMI was under 30%.
    - 1% higher supply costs
    - 2% higher facility costs
  - o THA:
    - no change in personnel costs
    - 1% higher supply costs
    - 1% higher facility costs
- Patients whose BMI were: between 35% and less than 40%:
  - o TKA
    - 7% higher personnel costs
    - 4% higher supply costs
    - 5% higher facility costs
  - o THA
    - 8% higher personnel costs
    - 4% higher supply costs
    - 5% higher facility costs
- Patients whose BMI is greater than or equal to 40% BMI
  - o TKA:
    - 13% higher personnel costs
    - 4% higher supply costs
    - 8% higher facility costs
  - o THA:
    - 8% higher personnel costs
    - 3% higher supply costs
    - 5% higher facility costs

When factoring in demographics and comorbidities, the research team found that BMI values of 35%, 40%, and 45% were associated with 2%, 3% and 5%,

First of a Series on the History of Modern Orthopedics and Spine Surgery



FROM OUR READERS

"Robin Young has so meticulously and thoroughly crafted the incredible and true story of the spine and orthopedic industry - I felt as though I was reliving every moment. Fascinating recollection. A real page turner. Kudos!" **– Alex Lukianov, Founder and past chairman & CEO of NuVasive**

"Spectacular book. Loved it!" **– Alexander R. Vaccaro, M.D., Ph.D., M.B.A., President Rothman Orthopedic Institute, Philadelphia, PA.**

"Robin Young has taken us on a splendid journey from the origins of orthopedic surgery as a specialty through it's early development to the important and essential collaboration between orthopedic surgeons, engineers and industry that has produced a compendium of treatments that have enriched the lives of millions of patients. For those of us who love orthopedic surgery, the best part is that this is only volume 1 with more to come!!" **– Joseph D. Zuckerman, M.D., Walter A.L. Thompson Professor of Orthopedic Surgery and Chair, Department of Orthopedic Surgery, NYU School of Medicine, New York, NY**

"Robin Young describes the early development of orthopedic medical devices and the intersection of surgeons, corporate, and engineering leaders. The manuscript is an easy read. Dr. Charnley who is most responsible for bringing innovation to orthopedic surgery, like Thomas Edison, failed at many techniques and materials before finding success. Ron Pickard built Danek into the industry leader Sofamor-Danek but more importantly withstood the attacks by plaintiff attorneys in their pedicle screw ligation. In both cases and as demonstrated in many other examples in the book, holding to what is best for patients and to basic core principles will result in the best outcomes. Robin shows convincingly how anyone who has the idea, commitment, can assemble a team and overcome the many hurdles and failures can produce dramatic results that can help patients and revolutionize an industry." **– Paul A. Anderson MD, Former Professor of Orthopedic Surgery, Neurologic Surgery and Biomedical Engineering, University of Wisconsin, Madison.**

"Anyone not knowing the history might think the currently available orthopedic devices either always existed or formed on their own, but each product needed the right people at the right place at the right time working with a company to develop, produce, and introduce to surgeons the new advance. This book chronicles the roots of today's orthopedic/spine industry and tells the untold story of often unknown people who by their actions ended up helping millions of orthopedic surgery patients around the world. "The book Robin Young wrote is is Orthopedics This Last Century. I recommend all the OTW readers order a copy." **– Richard Treharne, Ph.D., Vice President Orthopedic Research, Active Implants, Inc., Memphis, TN**

respectively, increases in total facility costs for total knee arthroplasty procedures. For total hip arthroplasty, those same BMI values of 35%, 40% and 45% were associated with 3%, 5%, and 7%, respectively, increases in facility total costs.

"The most compelling result was the clear correlation between BMI and increased facility costs for both TKAs and THAs," said Dr. Melnic.

"Patients with higher BMI categories had proportionally greater personnel and supply costs, leading to a 2–8% increase in total facility costs compared to those with lower BMI. These findings highlight the cumulative impact of obesity on healthcare resource consumption and emphasize the value of granular, patient-level cost analysis."

When *OTW* asked how physician compensation models in this population should be addressed, Dr. Melnic said, "Physician compensation models should be revisited to account for the increased complexity and resource demands of treating patients with higher BMI."

"Risk-adjusted procedural codes and value-based payment models tailored to BMI and other patient-specific factors could create a more equitable framework for compensating providers. This adjustment could potentially help to align incentives with the additional effort and resources required for complex cases. Hopefully, this will allow for sustainability for both public and private payors in the long run."

"This study underscores the importance of moving towards patient-centered, cost-informed care models. Time-driven activity-based costing provides actionable insights that could guide hospital administrators, policymakers, and payors in developing targeted interventions to optimize resource utilization. Further research should focus on validating these findings across diverse healthcare systems and integrating risk-adjusted payment structures to promote equity in physician reimbursement."

"Additionally," Dr. Melnic told *OTW*, "our message for clinicians is that they should be aware of the heightened resource demands associated with higher BMI in TJA patients. Preoperative optimization programs aimed at weight reduction could reduce costs and improve outcomes. Simultaneously, beginning to understand these cost drivers supports advocacy for risk-adjusted payment models that reflect the true complexity of caring for this population." — *EH*

SPINE

Head Fake? Vancomycin Doesn't Reduce SSIs?

Source: Shutterstock

A new meta-analysis from Brown University has found evidence that vancomycin may not prevent surgical site infections (SSIs) after spine surgery as effectively as some surgeons expect. The Brown University meta-analysis appears in the December 1, 2024 edition of *Clinical Orthopaedics and Related Research*: under the title: "Does the Application of Topical Vancomycin Reduce Surgical Site Infections in Spine Surgery? A Meta-analysis of Randomized Controlled Trials."

This study collected data from and analyzed six randomized controlled trials with 2,140 patients (1,053 in the vancomycin group and 1087 in the control group).

According to study co-author, Alan H. Daniels M.D., chief of the Division of Spine Surgery at Warren Alpert Medical School of Brown University, "The meta-analysis found no significant difference in the risk of overall SSIs (3.0% vs. 3.9%), deep SSIs (1.8% vs. 2.7%), or superficial SSIs (1.0% vs. 1.4%) between the vancomycin and control groups."

"Sub-analyses by instrumented and non-instrumented procedures also showed no differences. These findings do not prove that vancomycin is effective. Rather, our current data from randomized controlled trials has yet to definitively prove its effectiveness."

Is This a Head Fake?

OTW asked Dr. Daniels to describe the genesis of this study and explain why the randomized controlled trials he examined seem to challenge the efficacy of topical vancomycin in preventing SSIs after spine surgery. He said, "Disagreements likely stem from variations in study design, such as differences in dosing (0.5 mg to 2 mg), placement location (wound bed vs. disc space), and surgical procedures (instrumented vs. non-instrumented, deformity vs microdiscectomy, anterior vs posterior, etc.)."

"Furthermore, heterogeneity in patient populations, definitions of SSIs, and follow-up durations contributes to the conflicting results. The lack of standardization and variability in trial quality also play a role, with some randomized controlled trials lacking robust blinding and allocation concealment methods."

Dr. Daniels and his research colleagues utilize topical vancomycin in their current spine surgery practice and believe that a comprehensive infection prevention program including topical antibiotics in the wound bed decreased infection rates after spine surgery.

"This study should not convince surgeons not to use topical antibiotics," said Dr. Daniels and his co-authors, "rather it should encourage a holistic approach to preoperative optimization, optimal sterility and efficiency in surgery, and careful postoperative protocols to reduce infection rates. Future studies are needed to prove the effectiveness of topical vancomycin in preventing postoperative spine infections. These studies should have standardized dosing and methods, yet showing efficacy is difficult because as a specialty we have greatly lowered postoperative infection rates via comprehensive infection prevention programs."

Regarding any challenges/milestones in setting up the study, Dr. Daniels said, "The meta-analysis faced limitations in identifying smaller differences due to a lack of power for minor effect sizes (below 1.5%). The heterogeneity of included studies (e.g., differences in patient populations, vancomycin dosages, and follow-up times) and the inability to assess publication bias due

to the small number of included trials were key obstacles."

"Although we were excited to successfully limit the analysis to randomized controlled trials, thus reducing bias associated with retrospective and observational studies, this methodology failed to show effect of topical vancomycin in spine surgery which is not a believable result to most spine surgeons. The use of the Cochrane Risk of Bias tool to assess trial quality and the calculation of fragility indices strengthened the analysis." — *EH*

NEW Study: Longer Spine Surgery, Faster Complications?

According to a National Institutes of Health (NIH) study, adult spinal deformity develops in as many as 68% of healthy adults over the age of 651. With that in mind, a multicenter team set out to establish standardized values for the rates of complications by type of surgery performed. Their work, "Benchmark Values for Construct Survival and Complications by Type of ASD Surgery," was published in the September 2024 edition of *Spine*.

"Adult spinal deformity encompasses a broad spectrum of presentations, each requiring varying surgical strategies," co-author Virginie Lafage, Ph.D., told *OTW*.

Dr. Lafage, associate VP of Clinical Research at Lenox Hill Hospital | Northwell Health in New York City, explained the genesis of this study to *OTW*, "Our interest stemmed from a desire to understand the proportion of patients treated with the approaches commonly associated with adult spinal deformity, the complication rates linked to each major surgical strategy, and the timing of these complications. Surprisingly, it is challenging to find clear and detailed benchmark values for adult spinal deformity treatment. We aimed to contribute to the field by providing this essential information."

To tease out these values, the research team collected patient data from a 20-center North American Adult Spinal Deformity database and organized that data into the following patient diagnostic categories:

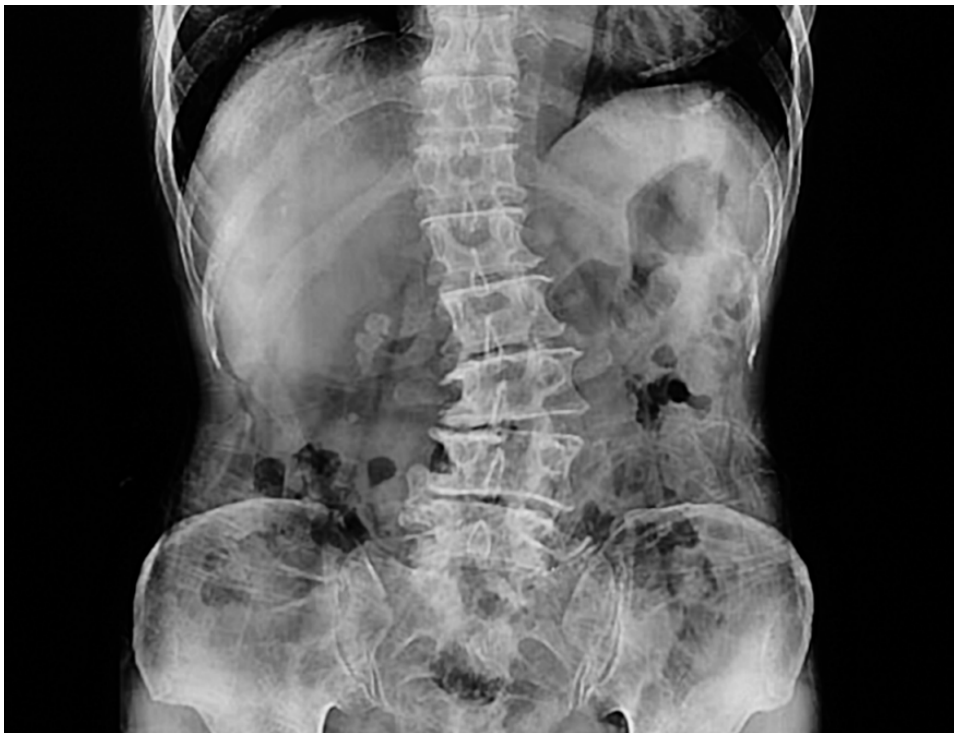
1. scoliosis ≥20°,
2. sagittal vertical axis (SVA) ≥ 5 cm,
3. pelvic tilt (PT) ≥ 25°, or
4. thoracic kyphosis ≥ 60°."

The team then categorized the surgical treatment type according to:

1. upon the number of levels treated,
2. positions of the upper and lower instrumented vertebrae,
3. use of three-column osteotomy, and
4. presence of previous spinal fusion.

Using these categorization criteria generated eight distinct surgical scenarios:

1. short lumbar,
2. thoracic to lumbar,
3. upper thoracic to pelvis (with three-column osteotomy, primary, and revision subtypes), and
4. lower thoracic to pelvis (with



Source: Shutterstock

three-column osteotomy, primary, and revision subtypes).

As for what is it about the relationship between type of surgery and construct survival that is challenging to capture, Dr. Lafage told *OTW*, "Analyzing the relationship between construct type and survival is challenging because the construct is only one of many factors influencing outcomes. Patient characteristics play a significant role. For instance, comorbidities such as osteoporosis—common in this population—can greatly impact results. Past medical history (e.g., prior infections) and the specifics of the surgical correction (e.g., overcorrection or under correction, implant malposition) also contribute to both early and long-term outcomes."

"Construct type is, arguably, the easiest variable to standardize and study. However, it was not feasible to account for every factor affecting outcomes. First, many such factors exist, and some may remain unidentified. Second, controlling for all variables would require a much larger sample size. Instead, our goal was to provide a benchmark analysis, adjusting for select patient characteristics, to help providers estimate the 'normal' course of Adult Spinal Deformity treatment outcomes from a statistical perspective."

Study Results

The team was able to collect data from 1,073 patients. After analyzing the data, the team determined that survival curves for major complications (with or without reoperation), while controlling for demographics, differed significantly among surgical types.

Specifically, fusion procedures short of the pelvis had the best survival rate, while upper thoracic-pelvis with three-column osteotomy had the worst survival rate. Longer fusions and more invasive operations were associated with lower two-year complication-free survival, however, there were no significant associations between type of surgery and renal, cardiac, infection, wound, gastrointestinal, pulmonary, implant malposition, or neurological complications.

"The results were largely as expected: longer and more invasive surgeries are associated with higher complication rates. We had hoped to identify a particular surgical approach that performed significantly better, but the findings align with existing literature and our understanding of this complex treatment."

"What stood out was the behavior beyond the first 100 days post-surgery. It appears that trajectories of outcomes remain relatively parallel for the first two years. It will be fascinating to revisit this analysis with longer-term data (e.g., at 5- or 10-year follow-ups) to explore how these trajectories evolve."

"Complications and, ultimately, revision surgeries are an inherent part of adult spinal deformity treatment. We want surgeons to have realistic expectations for construct survival across different surgical strategies, enabling them to counsel patients more effectively about the risks associated with these procedures. From a health economics perspective, understanding expected survival is also critical for designing appropriate bundled payment models. We hope our findings provide a foundation for both clinical decision-making and economic planning in adult spinal deformity care." — *EH*

Reference:

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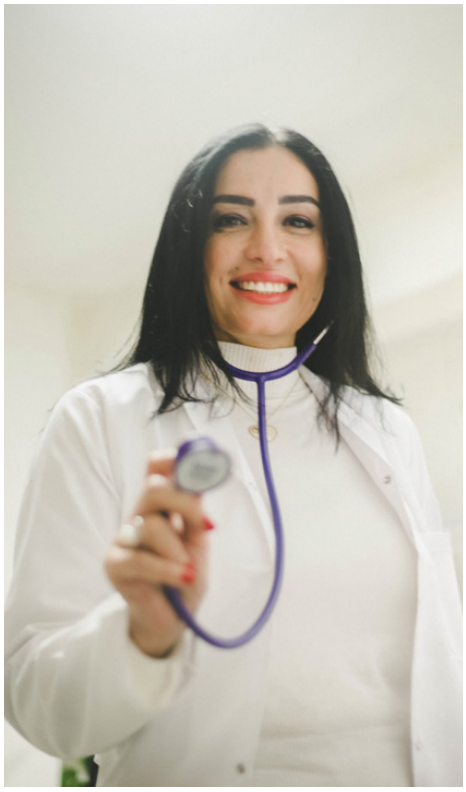
Happier Doctors Are Better Doctors: New Study

Half of all orthopedic surgeons may not enjoy their work—and that depressing statistic prompted a team from The University of Texas at Austin to develop and test a new "happiness" measure which, the team hopes, will capture the "positive attributes to which a team aspires." Their work, "Development of a Brief, Positively Framed Care Team Experience Measure," was published in the December 3, 2024 edition of *Clinical Orthopaedics and Related Research*.

Co-author David Ring, M.D., Ph.D., professor and associate chair for Faculty Academic Affairs at Dell Medical School at The University of Texas at Austin, told *OTW*, "We have a long-



Happy doctor/ Source: Wikimedia Commons

standing interest in the importance of enjoying one's work and feeling appreciated and useful. The process started with University of Texas Health Austin at Dell Medical School seeking a brief, positively framed, team-oriented measure of clinician and care team experience to monitor our culture and the results of interventions to improve it."

Existing methods of measuring a clinician's sense of personal fulfillment and/or work engagement, according to the research team, are long and overly burdensome. Additionally, existing measurement tools were usually negatively framed or addressed personal well-being at the expense of measuring care team status.

OTW asked Dr. Ring to expand on his assertion that current measures are "negatively framed," and he explained, "Many current measures ask about personal factors from a negative frame. For instance, asking respondents to consider phrases like 'A sense of dread when I think about work I have to do' or 'I feel emotionally drained by my work.' Items like this could be influenced by personal circumstances, workplace climate, or job demands among other things. Those are all important. When the goal is enhancement of care team experience, it helps to use aspirational, positively framed items (this is where we're headed), and ask about the team rather than one's personal experience."

A New Measure of Job Satisfaction: 'Care Team Experience Measure'

The University of Texas team then set out to craft a new and, they hoped, a better measure—the "Care Team Experience Measure"—and put it to the test in a large, 274 physician practice. Forty-four percent of those physicians (n=120) participated in the test. The study control was the Team Climate Inventory questionnaire, which measures team climate in healthcare organizations.[1]

The survey of 120 clinicians in the multispecialty test group practice asked about three factors that affect the care team experience:

1. "collaboration" (nine items),
2. "enjoyment of work" (six items), and
3. "effectiveness" (six items).

The researchers then obtained data from 493 patient-facing employees of a statewide musculoskeletal specialty practice, who rated 12 items and completed the Team Climate Inventory.

For their test, the research team also stratified the results according to clinical and administrative roles:

- physical, occupational, or hand therapy;
- imaging;
- nurse practitioner or physician assistant;
- medical assistant;
- physician; and
- "other" clinical roles such as cast technician.
- Administrative roles such as:
    - management,
    - marketing,
    - patient services,
    - coding and billing, and
    - "other" administrative role.

Clearly, this was a comprehensive look at "Care Team", broadly defined, experience.

Using factor analysis, the team identified two groups of items representing "effectiveness" (nine items, including "I am proud of the work we do") and "collaboration" (three items, including "Our team encourages everyone's input before making changes"). The best-performing items of "effectiveness" (two items) and "collaboration" (one item) were selected to form the three-item Care Team Experience Measure.

Study Results

The data the team pulled from their survey provided evidence of a strong correlation between the Care Team Experience Measure and the Team Climate Inventory, which is a measure of four factors:

1. clear and realistic objectives,
2. participative safety,
3. support for innovation, and
4. commitment to high standards of performance.[2]

The authors opined that these items can be characterized as addressing humility, curiosity, collaboration, and a collective growth mindset.

"Patients will get better care from teams that feel appreciated and effective," explained Dr. Ring to *OTW*. "This measure can be used periodically with limited burden to monitor and enhance care team experience in your organization or unit."

OTW asked if he might alter the study in any way, he added, "The most difficult part is to get enough engaged people willing to complete surveys. Much gratitude to Lonestar Orthopedics for their collaboration. Additional validation in other settings and with other groups is warranted."

"If organizations put effort into the well-being of their teams," said Dr. Ring to *OTW*, "both those teams and the patients they serve will benefit. Given the evidence that a safety culture and joy in work go hand in hand, such efforts, including routine measurement using the Care Team Experience Measure, have the potential to increase the quality, safety, and effectiveness of care."

"This simple, aspirational, team-oriented clinician experience measure might be useful for routine measurement of clinician experience with the aim of improving enjoyment in patient care," wrote the authors. "It would be straightforward to send these three items and a verbatim text inquiry regarding care team experience via email, internal communication software, or text every 3 months or so and track trends and themes for improvement. This would also measure improvement or decline in experience with quality improvement initiative or other changes in the organization, facilitating more specific and effective attention to care team experience." — *EH*

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3- and 6-Month RCT Data for Novel Nerve Stim Treatment

A multicenter team has recently published 3- and 6-month data from the largest randomized controlled trial to date on the use of a micro-implantable pulse generator to treat chronic peripheral pain.

The resulting paper, "Clinical study of a micro-implantable pulse generator for the treatment of peripheral neuropathic pain: 3-month and 6-month results from the COMFORT- randomised controlled trial," appears in the May 2024 edition of *Regional Anesthesia & Pain Medicine*.

The study, nicknamed COMFORT—Clinical Study Of A Micro-Implantable Pulse Generator FOR the Treatment of Peripheral Neuropathic Pain—used a novel neurostimulation system, which, unlike other peripheral nerve stimulation (PNS) systems, allows for a temporary trial lead placement. The system also gave physicians a broad menu of therapeutic stimulation parameters and waveforms.

The study's primary end point was effectiveness and safety of peripheral nerve stimulation and conventional medical management versus conventional medical management alone.

Co-author Mehul J. Desai, M.D., M.P.H., chief of the Division of Pain Medicine at Virginia Hospital Center and CMO at Virdio Health, told *OTW*, "There was an enormous need or gap with regard to the evidence in support of the use of peripheral nerve stimulation in the treatment of chronic pain."

"While other good studies have been published, a randomized, controlled trial of this size and design was missing.

Peripheral nerve stimulator / Courtesy of Nalu Medical

Additionally, there is tremendous pressure from payers to continue to publish high quality studies in this area. We face a number of challenges from payers with regard to coverage in this space."

OTW asked Dr. Desai to elaborate on "Conventional Medical Management." "Defining conventional medical management has been a challenge in the pain medicine literature for decades", said Dr. Desai, "Candidly, there is very little that is standardized. For the purposes of this study, it was defined as 'the best standard of care for each individual subject, as determined by the investigator.'"

The study enrolled 89 subjects, 58 of whom were randomized to the active arm and 31 to the control arm. The researchers found that peripheral nerve stimulation therapy delivered by a micro-implantable pulse generator device significantly reduced pain and improved functional outcomes in over 80% of subjects treated.

Also, clinical associate professor in the Department of Anesthesiology & Critical Care at the George Washington University School of Medicine," Dr. Desai added. "The results of this study set a new standard in outcomes for patients treated with peripheral nerve stimulation. An 88% responder rate at six months, with over 70% reduction in pain scores at six months."

"This study is a large foundational work in the support of the use of peripheral nerve stimulation. It is likely that more patients will be offered peripheral nerve stimulation and specifically this device due to its device-related capabilities."

Providing background on the research was Patrick Martin, VP of clinical affairs at Nalu Medical Inc., who told *OTW* that the sponsor of the study was Nalu Medical, the supplier of the tested product. "Nalu is sponsoring two randomized controlled clinical trials (COMFORT and COMFORT 2) in order to generate Level 1 evidence to protect and ensure patient access to appropriate and medically indicated peripheral nerve stimulation therapy."

"Please note that the study's pragmatic randomized controlled trial design was intended to mimic the actual clinical care patients receive in the U.S. for chronic pain so that the results would be broadly applicable outside of the study. As such, the conventional medical management that patients received varied based on multiple factors faced in the 'real world,' such as patient preference, physician prescribing practices, availability of treatments, and importantly what is covered by a subject's health insurance company.

"In the U.S., peripheral nerve stimulation is a 'treatment of last resort.' In other words, before insurance (private or public) will pay for peripheral nerve stimulation therapy, patients need to exhaust all other treatment options covered by their insurance before they are eligible for peripheral nerve stimulation. This is why subjects were required to have been receiving conventional medical management before their enrollment in the study."

"From Nalu's perspective we were struck by:

1. The magnitude of improvement seen in COMFORT is magnitudes greater than previous PNS randomized controlled trials for permanently implanted PNS devices.
2. That these results—88% responder rate (% of patients who achieved ≥50% pain relief) with an average pain reduction of 70%—are almost identical to published outcomes from Nalu's nPower U.S. and nPower AUS studies, as well as RWD [real world data].

Related supporting longer-term data on COMFORT and COMFORT 2 has been accepted for the upcoming New York and New Jersey Pain Congress." — *EH*

PEOPLE

$317,000 to Start Smart Shoulder Implant Project

A team of researchers from Scripps Health has received a grant of $317,000 from the National Institutes

Darryl D'Lima, M.D., Ph.D., director of orthopedic research at Scripps Health / Source: Scripps Health

of Health (NIH) to create what the development hopes is the world's first smart shoulder replacement implant—one that can continuously and remotely monitor and transmit detailed data from patients' new shoulders.

According to NIH, more than 800,000 U.S. patients had had total shoulder replacements (2017 data) and those numbers are expected to grow by over 200% by 2025, outpacing both hip and knee arthroplasty.[1]

The NIH's $317,000 will be used to pay for the initial phase of research, which is expected to last two years at the Shiley Center for Orthopaedic Research and Education at Scripps Clinic on Torrey Pines Mesa. During this development phase, the team will work on design and produce and test the functionality of a smart implant prototype. They also aim to demonstrate proof of concept by testing the device in the shoulder of a human cadaver to validate the implant's operability and consistency.

"Shoulder replacement surgery represents an important area of study," said Darryl D'Lima, M.D., Ph.D., director of orthopedic research at Scripps Health and the initiative's co-lead investigator, along with Heinz Hoenecke, M.D., an orthopedic surgeon and researcher at Scripps Clinic.

"Studies show that the number of these procedures has grown significantly in recent years in the United States and the trend is expected to continue. We need to gather and review data to better understand ways we can improve shoulder prosthetics and rehab approaches for patients, and this grant funding is an important first step toward that goal."

Making a Smart Implant

The Shiley's team intends to improve an existing shoulder implant by equipping it with customized wireless technology, such as advanced sensors and capabilities for data storage, external communication and rechargeable power.

In addition to being a functional shoulder joint replacement, it is also a research tool that can continually record and transmit data, such as mechanical forces, temperature, range of motion, and other metrics. The team cautions that actual surgical implantation of the smart shoulder device in a living patient is likely still a few years away.

Once the device is implanted, researchers and surgeons can collect and analyze data which could reveal new ways to enhance physical therapy protocols for shoulder replacement patients, as well as to improve the design of future implant devices.

Asked what challenges they anticipate with regard to design, production and functionality verification, Dr. D'Lima told *OTW,* "We need to modify a traditional implant to house the sensors and electronics. These have to be miniaturized to fit within the very small space. We also need to develop wireless rechargeable medical grade batteries and implement remote communications. All of these have to be tested to survive within a patient's arm for 20 years or more."

When *OTW* asked researchers how they will know if they're on the right track after a year, Dr. D'Lima said, "We hope to meet all the design specifications, such as, sensor performance and accuracy, power requirements, data storage and retrieval, and telemetry communications. The proof of concept will be demonstrating full functionality after implantation in a human shoulder cadaver specimen."

Also working with the Shiley Center team are Scott Delp, Ph.D., the James H. Clark professor at the schools of engineering and medicine at Stanford University, Scott Banks, Ph.D., professor and director of the orthopedic biomechanics laboratory at the University of Florida, and B.J. Fregly, Ph.D., professor at the department of mechanical engineering at Rice University and a scholar in cancer research with the Cancer Prevention and Research Institute of Texas. This team has experience collaborating with Scripps on collecting, processing and analyzing data on Scripps' smart knee implant. — *EH*

Reference:

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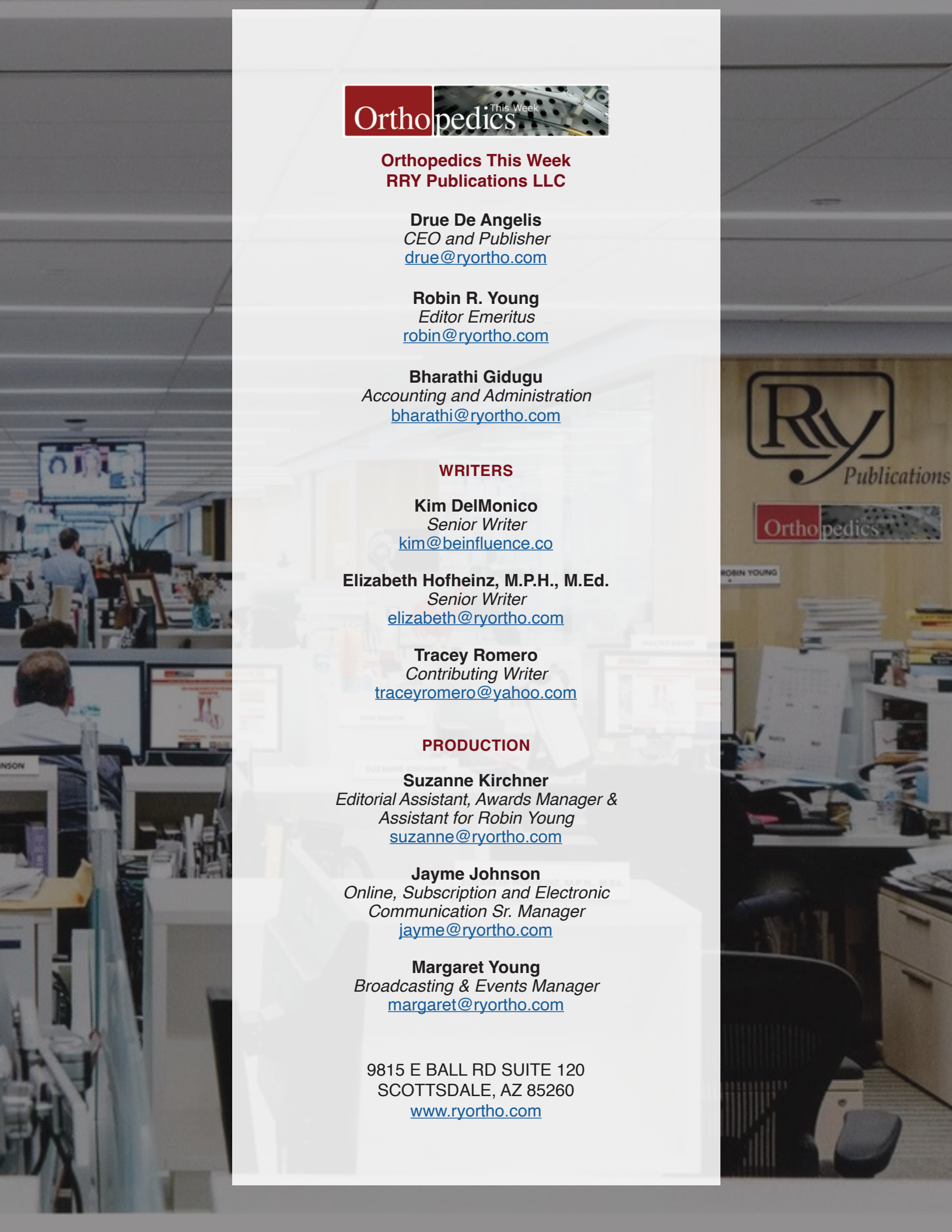

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