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Orthopedics This Week

WEEK IN REVIEW

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6 New, Powerful Insight Into Bone Aging and Repair From NYU >> A new study from NYU could have major implications for osteoporotic or osteopenic patient treatment. Turns out, blocking a signaling protein, nudges stem and progenitor cells into making bone. Only in mice, so far, but major step forward and likely pathway for future drug development.

8 MRI + Motion? Impossible You Say? HA!! >> The brilliant minds at UC Davis and Stanford have accomplished yet another mind-boggling proof of concept. This time they used magnetic resonance imaging to capture the motion of an articulating wrist joint. And the video that results is, well, remarkable.

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: Only one public orthopedic supplier increased in value over the past 30-days, Bioventus. All other ortho stocks fell, on average, 7.11%. Some, like ZimVie (#8 on the Power Rankings this week) are off more than 20% in a single month. The broader equity market (S&P 500) is down 10% from its July peak. This is a technical correction. In many ways, investors feel overwhelmed by all the changing risk/return variables—increasing expensive cash, continued supply chain issues, and a sense that the world is sliding inexorably into open global conflict.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	5	Bioventus	(5.33%)	8.94%	As the lone ortho stock in positive territory, BioVentus has the added feature of also being this industry's cheapest public stock in terms of future growth rates and expected P/E.
2	4	ConMed	7.42	(2.66)	CNMD delivered impressive sales and earnings for Q3. Sales rose 11.9%, beating estimates, and earnings per share came in at $0.90, well above the Street's $0.83 estimate.
3	1	Integra LifeSciences	17.32	(9.50)	IART is still having issues with the Boston facility, but every other part of the company is exceeding expectations with a 7.1% revenue growth rate. In more normal markets, investors would be buying.
4	2	Johnson & Johnson	24.97	(7.33)	Something of a leadership shake-up in JNJ MedTech, but no change in Aldo Denti's leadership of DePuy Synthes—which continues to outperform Wall Street's expectations.
5	7	Pacira Biosciences	23.50	(11.18)	PCRX reports Q3 results this week. Wall Street expects 3.3% sales growth. Odds are that PCRX will deliver an upside surprise, but in this market, investors will probably stay on the sidelines.
6	3	Globus Medical	22.59	(8.61)	With GMED stock so cheap, management announced a whopping $350 million stock buyback. In terms of comparative valuation, GMED is now 4th lowest PE, 2nd lowest PEG.
7	8	Anika Therapeutics	(20.94)	(3.34)	Anika is on the cusp of a remarkable year in terms of new product launches. It's been almost a decade in the making. For 2024, Wall Street thinks ANIK will grow 9%. Way conservative.
8	9	ZimVie	(5.96)	(23.70)	In just 30 days, ZIMV lost almost a quarter of its value. Only 6 positive trading days, all on tepid volume. Certainly, the market sucks right now. But ZIMV needs to define itself in investors' minds.
9	NR	Smith & Nephew	10.06	(11.06)	11% cheaper than it was one month ago, Smith & Nephew is the 6th lowest priced stock in ortho. That, combined with a comparatively modest sell off, lands SNN at #9 this week.
10	NR	Zimmer Biomet	19.31	(6.83)	New, younger management team and a clear focus on making digital technologies and processes the cornerstone of its future. Wall Street expects 7% sales growth and higher earnings for Q3.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bioventus	BVS	$3.29	$259	8.94%
2	Stryker	SYK	$261.91	$99,468	-1.74%
3	Aurora Spine	ASG.V	$0.28	$19	-2.51%
4	ConMed	CNMD	$94.96	$2,920	-2.66%
5	Anika Therapeutics	ANIK	$18.53	$271	-3.34%
6	Xtant Medical Hldgs	XTNT	$1.09	$140	-3.54%
7	MicroPort Scientific	0853	$1.45	$2,658	-5.51%
8	Zimmer Biomet	ZBH	$103.19	$21,563	-6.83%
9	Johnson & Johnson	JNJ	$145.60	$350,500	-7.33%
10	Globus Medical	GMED	$45.66	$6,382	-8.61%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	SINTX Technologies	SINT	$0.43	$2	-45.45%
2	OrthoPediatrics Corp	KIDS	$23.40	$546	-27.42%
3	Alphatec Holdings	ATEC	$9.55	$1,286	-26.43%
4	Dynatronics Corp	DYNT	$0.54	$2	-25.44%
5	AxoGen	AXGN	$3.73	$160	-25.40%
6	Nevro Corp	NVRO	$14.44	$522	-24.52%
7	ZimVie	ZIMV	$7.02	$186	-23.70%
8	SI-BONE, Inc	SIBN	$16.83	$677	-19.67%
9	Orthofix	OFIX	$10.74	$395	-14.83%
10	Medtronic	MDT	$69.43	$92,379	-11.24%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Integra LifeSciences	IART	$34.21	$2,674	14.81
2	Medtronic	MDT	$69.43	$92,379	16.39
3	Johnson & Johnson	JNJ	$145.60	$350,500	17.58
4	Globus Medical	GMED	$45.66	$6,382	21.56
5	Zimmer Biomet	ZBH	$103.19	$21,563	26.21

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Pacira Biosciences	PCRX	$27.57	$1,280	55.46
2	Medacta	MOVE	$112.06	$2,241	42.85
3	Smith & Nephew	SNN	$21.64	$9,450	42.38
4	ConMed	CNMD	$94.96	$2,920	35.25
5	Stryker	SYK	$261.91	$99,468	30.87

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Smith & Nephew	SNN	$21.64	$9,450	-5.30
2	Globus Medical	GMED	$45.66	$6,382	0.99
3	ConMed	CNMD	$94.96	$2,920	1.26
4	Medacta	MOVE	$112.06	$2,241	1.55
5	Stryker	SYK	$261.91	$99,468	3.06

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Medtronic	MDT	$69.43	$92,379	4.72
2	Integra LifeSciences	IART	$34.21	$2,674	4.00
3	Zimmer Biomet	ZBH	$103.19	$21,563	3.62
4	Johnson & Johnson	JNJ	$145.60	$350,500	3.59
5	Pacira Biosciences	PCRX	$27.57	$1,280	3.08

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Dynatronics Corp	DYNT	$0.54	$2	0.06
2	ZimVie	ZIMV	$7.02	$186	0.20
3	Bioventus	BVS	$3.29	$259	0.50
4	Orthofix	OFIX	$10.74	$395	0.86
5	Aurora Spine	ASG.V	$0.28	$19	0.99

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	SI-BONE, Inc	SIBN	$16.83	$677	6.36
2	Globus Medical	GMED	$45.66	$6,382	6.24
3	Stryker	SYK	$261.91	$99,468	5.39
4	Medacta	MOVE	$112.06	$2,241	5.13
5	OrthoPediatrics Corp	KIDS	$23.40	$546	4.47

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

Spine's Dream Team Now Leading ATEC

BY ROBIN YOUNG

Clockwise from left: Pat Miles, Chairman and CEO of Alphatec Spine, Keith Valentine and David Demski

The top news at the 2023 annual meeting of the North American Spine Society was Alphatec Spine, Inc.'s announcement that two of the most accomplished spine company executives—Keith Valentine, who was one-third of the triad that built NuVasive, Inc. into a billion dollar sales company and David Demski, who was president, CEO and a key leader of the team that built Globus Medical, Inc. into a billion dollar sales company—have joined the other third of NuVasive's triad, Pat Miles, to lead Alphatec—the top market share gainer for three of the last four years.

It is Spine's Dream Team.

Of course, there is a back story.

Newton's third law states that for every action in nature there is an equal and opposite reaction. If object A exerts a force on object B, object B also exerts an equal and opposite force on object A.

Mr. Demski was chief executive officer of Globus Medical, until August 2022, when he tendered his resignation. Demski had played such a critical role in Globus's remarkable sales growth and steady stream of innovations—notably the Excelsius system for robotic assisted spine surgery—that the industry's initial reaction to his resignation was disbelief.

Whatever Demski's reason for leaving, it was clear he was leaving his corporate home of 19 years, not the industry. Indeed, Mr. Demski, it seems, has been itching to tie his skates back on and get back to body checking competitors against the boards.

Then, just six weeks ago, September 12, 2023, Orthofix fired, for cause, three highly regarded spine industry executives, first among them: Keith Valentine.

The exact reason for Orthofix Board's unanimous decision has never been revealed—which, to this writer, seemed analogous to performing an amputation but without disclosing the diagnosis. Still, contours of that decision clearly pointed to a failure in judgement and leadership on the part of the now former execs.

People who've known all three fired executives, speaking on and off the record, uniformly voiced support and disbelieve at the implied causes for such a public dismissal.

Again, no details for these dismissals have ever been publicly disclosed.

At 2023 NASS, a reaction was delivered.

Pat Miles Steps Up

Pat Miles, chief executive officer of Alphatec, the top market share gainer in spine for three of the past four years, announced that Alphatec was appointing Dave Demski to its board of directors and that Keith Valentine had been appointed Special Advisor to the Board.

In Alphatec's press announcement, CEO Miles said: "A defining element of the ATEC turnaround has been our willingness to act boldly when a door of opportunity opens."

"While conglomerateurs and capitulants continue to form awkward alliances, ATEC has emerged as the most clinically focused spine-only company."

The word "conglomerateur" (as in entrepreneur—and perhaps distinct from "entrepreneur" as used in Mr. Miles's context) means someone who heads or forms a conglomerate. It was a not-too-subtle reference to Globus Medical's acquisition of NuVasive.

The word "capitulant," a noun, refers to a person who capitulates or surrenders.

Mr. Miles went on to say, in the press release, "I want to address one matter, clearly and directly."

"We are aware of the recent negative commentary directed at Keith by his former employer. Years ago, I too was the target of a very public assault. During that time, I was blessed to be supported by friends who knew me best, and who rejected the accusations of strangers."

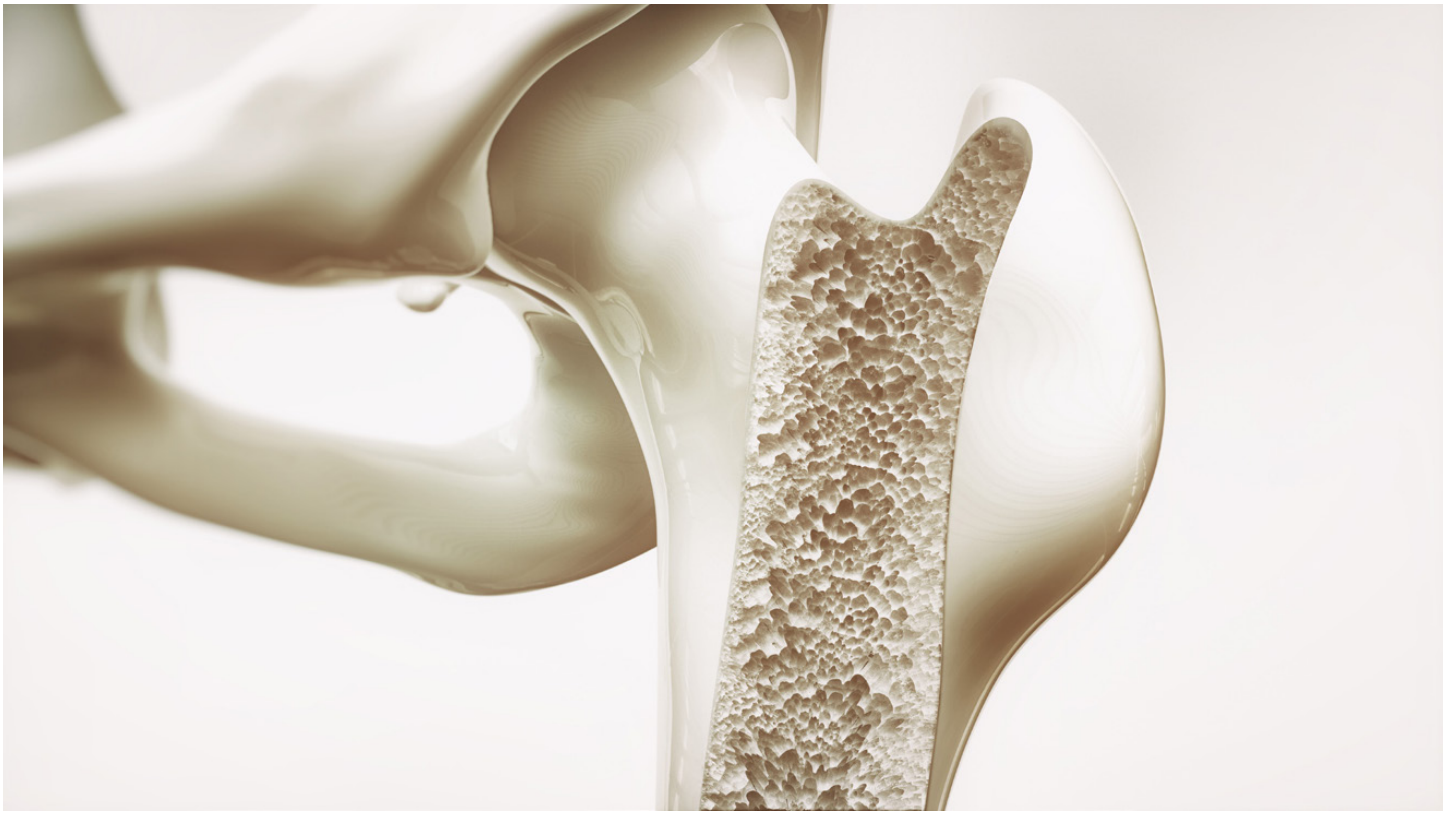
It is worth noting that Mr. Miles sued NuVasive, and the two parties spent years in litigation. Pat Miles won his case.

"I have known Keith for 30 years—I know his imperfections, but I also know his heart. He is beloved by many in our industry and his impact on spine care over the years is undeniable. Keith has made it clear he is ready to devote his considerable energy to making ATEC better, and I am thrilled to have him join our effort."

Finally, explaining why he supported both Dave Demski's and Keith Valentine's appointment to Alphatec's board, Mr. Miles said: "Our success is due to our relentless pursuit to improve spine care, and certainty that people and know-how will always differentiate ATEC. Dave and Keith bring with them a combined 50 years' experience leading some of spine's most successful organizations. I admired Dave's accomplishments from a distance as he ran Globus over the years. As I have come to know him better, I have no question that the addition of his influence will make us a better company." ♦

New, Powerful Insight Into Bone Aging and Repair From NYU

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



Source: Shutterstock

In a sign of hope for those of us with deteriorating bones (all of us?), new research has found that by blocking the Notch signaling pathway in aging skeletal stem cells (mouse model), there was a "massive increase" in bone mass and bone-healing ability.

The work, "Loss of Notch signaling in skeletal stem cells enhances bone formation with aging," conducted by a team from NYU Langone in Manhattan, appears in the September 27, 2023, edition of *Bone Research*, a *Nature* journal.

Past studies, wrote the NYU researchers, show that skeletally mature or elderly stem and progenitor cells tend to become cells that make fat more often than bone. So, they wondered, would a genetically engineered mouse, which lacks the protein that is part of the Notch signaling chain, Nicastrin, nudge these stem and progenitor cells away from an adipose tissue tendency and toward bone building?

The Notch signaling chain, incidentally, refers to cell-cell communication or signaling where transmembrane ligands on one cell activate transmembrane receptors on a juxtaposed (adjacent?) cell.

Using mice that lacked the essential protein for Notch signaling, the NYU team organized their study and…found that, indeed, as hypothesized, the stem and progenitor cells, when not affected by the protein Nicastrin and therefore Notch signaling, do tend to choose the bone-making cell pathway, and increased bone formation "even beyond that seen in young mice."

"Our findings reveal that Notch in skeletal stem cells becomes abnormal with age, and that blocking it prevents age-related skeletal degeneration," says corresponding study author Philip Leucht, M.D., Ph.D. the Raj-Sobti-Menon Asso-

ciate Professor in the Department of Orthopedic Surgery and Cell Biology at NYU Langone Health.

"The reprogramming of adult stem cells as a source of bone-making cells in healing-compromised people has profound therapeutic potential, and we hope to confirm the value in future studies of Ebf3 as a drug target in preventing osteoporosis."

When *OTW* asked why the molecular mechanisms that underlie this detrimental transformation are largely unknown, Dr. Leucht noted, "Loss of stem cell function with aging is a multifactorial process, and therefore we all assume that finding a single miracle cure is unlikely to happen."

"When we come across data like the one presented in this manuscript, where manipulation of one single pathway reverses an entire phenotype, this catches us by surprise."

"Most likely, if we succeed to translate this into humans, the gain of bone formation seen in mice will not be shown in humans. Rather, we will see a more subtle but still substantial gain in bone mass."

"Only if other aspects of aging are addressed at the same time, will we be able to reverse the skeletal aging phenotype."

Unexpected Side Effects (in the Mouse Model)?

Dr. Leucht noted one logical side effect, but which, in fact, had a favorable outcome in the mouse model. "The amount of bone formation is incredible, yet not detrimental to the mouse. Our first thought was that hematopoiesis, which happens in the bone marrow cavity would be affected by the increase in bone in the marrow space."

"But our data show that this is not the case. In humans, we would not like to reproduce a massive increase like the one seen in mice. Rather a subtle increase in trabecular bone volume in the metaphases of long bones and in the spine would have the greatest benefit for patients with osteoporosis, as those are the locations most prone to osteoporotic fragility fractures."

"We are currently in the process of identifying druggable targets that would allow us to translate this to humans. So more on that in the next few years. It is hard to predict if we can devise a safe strategy for translation, but we are hopeful." ♦

MRI + Motion? Impossible You Say? HA!!

BY ROBIN YOUNG

Patient having his wrist scanned with a video producing low power MRI / Source: UC Davis

A UC Davis and Stanford team, that has been working on the problem of combining motion and MRI for ten years, has created a video of articulating wrist joint using an MRI machine. Yes, the patient moves while inside an MRI core.

Kudos to Abhijit Chaudhari, professor in the UC Davis Department of Radiology and interim director of the UC Davis Imaging Research Center; Krishna Nayak, who directs the Dynamic Imaging Science Center at the University of Southern California; Robert Szabo, distinguished professor of orthopaedics and chief emeritus of hand and upper extremity surgery at UC Davis; and Robert Boutin, professor of radiology at Stanford University and musculoskeletal radiologist.

Their proof-of-concept study, "Real-time MRI of the moving wrist at 0.55 tesla," was just published in *The British Journal of Radiology.*

How did they do it?

First, they used a low-field, 0.55 tesla, MRI (magnetic resonance imaging) system. Standard MRI's use 1.5 – 3.0 tesla power. In this instance the word "tesla" is the scientific unit of measure for magnetic strength. A refrigerator magnet, for example, uses roughly 0.001 tesla power output. A standard MRI, therefore, would be using the equivalent of 1.5-3.0 million refrigerator magnets to generate soft tissue images.

Also, of course, this unit of measure honors one of the greatest inventors and electrical engineers in history—Nikola Tesla, who died in 1943.

But we digress. How did Chaudhari and Boutin combine motion with MRI imaging? From their study, the two authors described how a novel low power MRI was able to capture wrist motion:

> "High-performance 0.55T systems offer a high acquisition duty cycle, typically achieved using efficient k-space trajectories, not possible or practical at higher field strengths and resulting in the mitigation of image artifacts. These systems can further utilize pulse sequences, such as balanced steady-state press precession (bSSFP), that provide superior signal-to-noise ratio and efficiency enabling a vast increase in imaging speed compared to higher field system."

So, in effect, using a high-performance, but much lower power MRI produced cleaner images, at a higher acquisition duty cycle. More and better images faster—fast enough, in

fact, to create a video of wrist joint motion.

Anyone who's had an MRI remembers the high-power MRI machines clunk along, slowly taking one picture, then another—while being told to lies motionless for several minutes.

We asked Drs. Sabo and Chaudhari about the incongruence of using MRI to capture motion videos of articulating joints and they said: "Indeed, typically patients are asked to lie motionless on the scanner. However, several pathological conditions underlying wrist dysfunction occur only during motion or when performing specific tasks using our hands."

"These conditions often result in pain, limited range-of-motion and loss of strength. Therefore, there was a strong motivation to 'look inside' the wrist and understand these conditions when the wrist is moving."

"Higher field strengths (1.5T or 3.0T) provide outstanding image quality and allow us to observe minute changes in tissues of the stationary wrist. However, when motion is conducted, that disturbs the high magnetic field, and the resulting images show severe artifacts."

"At low field (0.55T), there is much less perturbation of the magnetic field, given that the field itself is low. Therefore, images during motion demonstrate much lower artifacts. This helps in visualizing the wrist tissues during motion and assess the trajectories of the various tissues."

"An obvious question is that while images during motion are better quality using 0.55T, what about images of the static wrist? Are they reasonable quality so that we can use images of the stationary and the moving wrist together for assessing wrist dysfunction? Our paper demonstrates that this indeed is the case, and therefore a comprehensive assessment of wrist dysfunction should be possible with the 0.55T system."

What's next?

As has been established by many other studies, imaging articulating joints under loads and/or in motion, can change the game when it comes to diagnosing soft tissue injuries.

So, of course, we asked the study authors what they thought were next steps for them. They told *OTW*:

"Our next steps include several studies:

1. To use this technique to examine patients with wrist pain and nor-

mal X-rays and normal MRIs and see if there is any pathology that can be identified.

2. To study different normal wrists which have different motion patterns established with static images and see how these structures move in real time to understand how factors such as laxity relates to instability.

3. To study abnormal wrists with known ligament tears in either the carpal or distal radio-ulnar joints and demonstrate how that affects motion.

4. To compare preoperative and postoperative studies early and long-term to evaluate the success of different wrist reconstructions for carpal instability problems.

And that is just the beginning!!"

The wrist has eight carpal bones and many ligaments. It is not uncommon for patients with chronic wrist pain to be told, after their doctor takes several static MRI or CT images, that their pain is indeterminant.

The imaging didn't find the problem.

"Moving images give us a new tool to diagnose wrist dysfunction, either during motion or when there is load on the joint," said Abhijit Chaudhari. "The wrist is highly complex, so the ability to visualize motion will have enormous impact."

Ten Year Project, So Far

For Chaudhari, Szabo and Boutin this work started ten years ago, in 2013. Initially, they could only produce two to three MRI frames per second—using, notably, a powerful three tesla (3T) MRI machine. The 3T machine produced visual artifacts, such as bands without signal, which obscured wrist anatomy.

"We were doing all our work on 3T systems, and we realized we could not do much better because these systems have limitations," said Chaudhari. "Whenever the patient moved within the high-field strength magnet, they disturbed the magnetic field a lot, and that created artifacts in images that disrupted our ability to assess the joints."

Developing the 0.55T System

Krishna Nayak, who directs the Dynamic Imaging Science Center at the University of Southern California and is a co-author on the new paper, had received a National Science Foundation

grant to develop a 0.55T MRI system specifically for dynamic imaging.

Chaudhari, Szabo and Boutin then teamed up with Nayak to see if his 0.55T machine could produce diagnostic-quality images, either as stills or as a short, 78 frame-per-second movie.

Nayak's 0.55T machine was incredibly fast. It produced high-quality videos in 5 seconds or less.

The researchers discovered that Nayak's rapid capture MRI delivered videos without adding significant cost.

"This approach allows us to study the trajectory of structures in an actively moving wrist," said Szabo. "The dynamic pictures, along with standard, still MRI scans, show us specific wrist anatomy that had never been evaluated to this degree before. This has tremendous relevance to evaluate injuries and conduct further research into how the wrist functions."

A Wealth of Applications

In addition to advancing real-time MRI, the new 0.55T system could provide much-needed clinical versatility. The magnetic field does not extend far beyond the machine, eliminating the risk of disturbing metallic devices in the room. The instrument could also help patients with surgical implants, who currently cannot use high-field MRIs. Also, the machine has a smaller footprint, allowing it to be placed in smaller rooms.

"This could be quite beneficial for intraoperative applications, in which you take the patient out of the scanner and immediately perform the intervention," said Chaudhari. "The applications of these low-field scanners continue to expand."

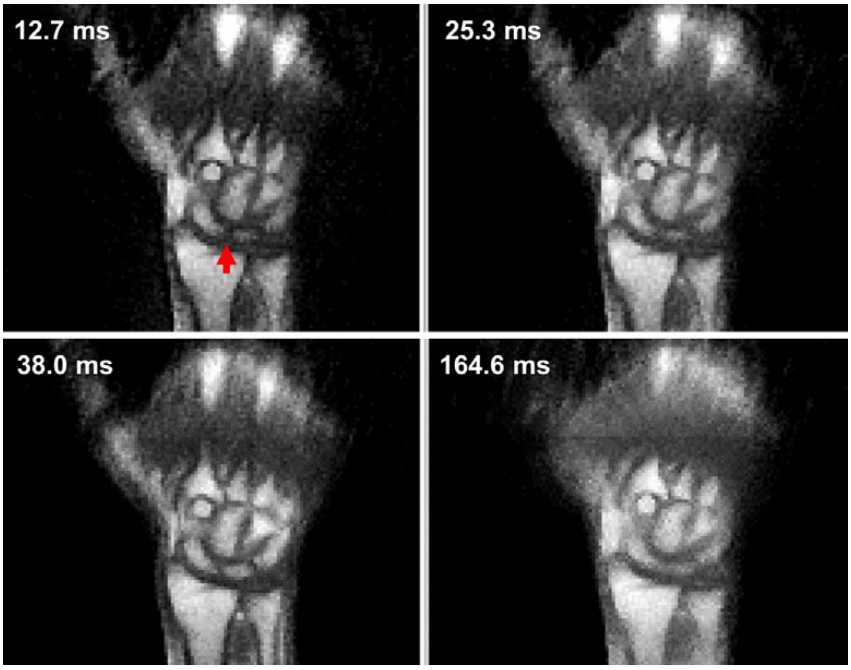
"Using this technique before and after wrist reconstructive surgery would allow us to see if our techniques restore normal anatomy in our patients," said Szabo. "Imagine the difference between taking a movie of someone's wrist while they are throwing a baseball compared to taking a still picture. Now imagine taking a moving MRI showing the inside of the wrist compared to an X-ray or static MRI. The added information will really improve care."

Additional co-authors on the paper include Christopher Bayne of UC Davis, Yongwan Lim of the University of Southern California, and Sophia X. Cui of Siemens Medical Solutions.

The study sponsors were the National Science Foundation Grant MRI-1828736 and Siemens Healthineers. ♦

More Images From the Study

Here are some static images of the wrist in the coronal plane ; (a) proton-density weighted 2D fat-suppressed, TSE image showing the visualization of the SL ligament (orange arrow) and the TFCC (green arrow); (b) T_1w 2D TSE image demonstrating the anatomical structures of the wrist; and (c) 3D T_1w gradient recalled echo pulse sequence with Dixon-based water reconstruction, illustrating the anatomical template to segment the bones. / Source: UC Davis



Here are images of the wrist under motion, performing the RUD maneuver with varying temporal resolution, with a spiral bSSFP sequence. Snapshots of the wrist in the neutral position with full sampling (164.6 ms per image), and with acceleration by factors of 92%, 85 and 77%. Temporal blurring is induced by lower temporal resolution and obscures the visualization of the wrist joints (red arrow shows the SL interval). Slice thickness is 6 mm. / Source: UC Davis

LEGAL

Bienville Orthopaedic Specialists Sued Over Data Breach

Courtesy of Bienville Orthopaedic Specialists and RRY Publications

Mississippi Gulf Coast-based Bienville Orthopaedic Specialists, LLC (BOS) is facing a potential class action lawsuit after a cyberattack on its computer systems earlier this year.

Seven class action lawsuits were filed last month against BOS in the United States District Court for the Southern District of Mississippi. The lawsuits were initiated by current and former patients of BOS and could involve approximately 242,986 class members if granted class-action status.

In a September 2023 notice regarding the data privacy event, BOS stated the following: "On March 5, 2023, BOS became aware of a cyberattack on our computer systems. We promptly took steps to secure our systems and began an investigation into the nature and scope of the incident. The investigation determined that in connection with the incident there was unauthorized access to certain systems in our environment between February 3, 2023, and March 5, 2023, and as a result, certain data stored on our systems was subject to

unauthorized acquisition on March 4, 2023. We then undertook a comprehensive review of the affected data to identify what information was within the files at issue. On July 31, 2023, we determined that information in the files at issue contained protected health information and that some of that information related to current and former patients."

According to Bienville Orthopaedic Specialists, compromised data from the files included: names, Social Security numbers, medical information, health insurance information, usernames and passwords, financial account information, and driver's license numbers.

A number of the plaintiffs are alleging that the data breach was a "direct result of Defendant's [BOS] failure to implement adequate and reasonable cybersecurity procedures and protocols necessary to protect its clients' patients' Private Information from a foreseeable and preventable cyber-attack." Complaints include allegations of negligence, breach of implied contract, breach of fiduciary duty, invasion of privacy, and unjust enrichment.

BOS provides orthopedic care at five locations on the Mississippi Gulf Coast. In a recent pleading, BOS asserts that it "was a victim of a cyber-attack."

Past data breaches and cyberattacks have cost hospitals, clinics, and health insurance companies. For *OTW*'s previous coverage of cyberattacks, see "The Price of a Data Breach," "Banner Health Agrees to Pay $6 Million for Data Breach," "Victims Can Sue Ortho Clinics if Data Hacked," and "Anthem Pays a Record $16 Million to Settle Data Breach." — *KD*

LA County Ortho Surgeon Faces Sexual Misconduct Allegations

Los Angeles County and Louis Kwong, M.D., former head of the orthopedics department at Harbor-UCLA Medical Center in Los Angeles County, are facing a number of employment violation allegations related to the medical center and Dr. Kwong's alleged behavior.

Source: Shutterstock

At least two lawsuits have been filed against Dr. Kwong and Los Angeles County in Los Angeles Superior Court. Los Angeles County operates the Harbor-UCLA Medical Center. The allegations include retaliation, hostile work environment, harassment, gender discrimination, and pregnancy discrimination. Dr. Kwong was placed on administrative leave last year.

One lawsuit was filed by orthopedic surgeons Haleh Badkoobehi, M.D., MPH and Jennifer Hsu, M.D. Another lawsuit was filed by Madonna Fernandez-Frackelton, M.D., Harbor-UCLA Medical Center's former director of emergency medicine.

There are a number of claims being made against Dr. Kwong. Some of these claims allege that Dr. Kwong committed sexual misconduct on unconscious patients at Harbor-UCLA Medical Center. This includes an allegation that Dr. Kwong was observed inserting fingers into a surgical hip wound and making sexual noises.

Another claim against Dr. Kwong is that he purportedly delayed performing acute procedures to perform elective procedures. Additionally, it is alleged that Dr. Kwong had his staff switch an operating room monitor to a baseball game during a surgical procedure.

The physicians who filed lawsuits assert that Harbor-UCLA ignored their complaints. They also contend that when they complained about Dr. Kwong's behavior they were demoted or retaliated against.

In a comment to the press, Harbor-UCLA Medical Center stated, "Harbor-UCLA Medical Center is committed to the health and safety of our patients and staff. These misconduct allegations are being thoroughly investigated and, if substantiated, will result in appropriate corrective actions. We deeply value the trust the public places in our dedicated medical and patient care teams. Safeguarding patient care is our highest priority." — *KD*

FDA Clears Novel, 3D Printed Integrated Cervical Plate

The FDA has just cleared for commercial sale a novel, 3D printed integrated cervical plate. Just looking at the design, it is clear that this implant is unique.

The implant, brand named Cervical Spine Truss System (CSTS) Integrated Plating Solution, is indicated for degenerative disc disease (DDD) of the cervical spine at one or two contiguous levels. This is an anterior implant at C2 to T1 levels of the cervical spine and, as you can see from the design image, each integrated plate is secured to the anterior portion of the cervical spine using two screws.

The manufacturer, 4WEB of Frisco, Texas, told *OTW* that this design is part of its proprietary Truss Implant Technology™ and is the latest addition to 4WEB's implant portfolio.

Jonathan Hires, 4WEB's Director of Research and Development explained some of the key features of the Cervical Spine Truss System (CSTS) Integrated Plating Solution to *OTW.*

- **Plate heights which are sized to the CSTS interbodies** – Interbody specific Integrated Plates allows for the plate to be sized and paired with the height of each the CSTS interbodies, no guesswork required by the surgeon.
- **Recessed and flush plating options** – Depending on surgeon preference, the built in recessed feature of the Integrated Plates allows the interbody to be placed 2mm deeper than the flush plate option.
- **Streamlined surgery** – The implant can be attached on the OR back table, implanted as a single construct and locks down in a single-step.

Cervical Spine Truss System / Source: 4WEB Medical

- **Offset design** – The offset design allows for adjacent level implantation without having to worry about screws interfering with each other.

Furthermore, said Hires, "With two product launches in Q3 and regulatory clearance for the integrated plate, we have built significant momentum towards completing the company's comprehensive cervical portfolio by the end of the year."

The CSTS Integrated Plating Solution clearance follows several recent milestones including the launch of a non-integrated cervical plating solution and a second-generation cervical interbody fusion device which came to market in Q3. Additionally, the company has previously announced plans to launch an integrated anchor fixation system in early Q4. The expanded suite of products will provide a variety of cervical fusion constructs for varying anatomical needs. With this portfolio expansion and continued product development, 4WEB has established itself as a leader in the cervical interbody fusion market.

"The launch of the CSTS Integrated Plating Solution builds on an already robust product portfolio. We are excited to launch several new cervical products before the end of the year and look forward to capitalizing on this success with significant growth in 2024," said Geoff Bigos, Vice President of 4WEB Medical's Spine Division.

About 4WEB Medical

4WEB Medical, founded in 2008 in Frisco, Texas, is an orthopedic implant company. Thirty years of research in topological dimension theory led to the discovery of a novel geometry, the 4WEB, that can be used as a building block to create high-strength, lightweight web structures. The company leveraged this breakthrough to develop 4WEB Medical's proprietary Truss Implant Technology™. 4WEB was the first company to receive 510(k) clearance for an implant manufactured with 3D printing technology. The 4WEB Medical product portfolio includes the Cervical Spine Truss System™, the Stand Alone Cervical Spine Truss System™, the Stand Alone Anterior Spine Truss System, the Anterior Spine Truss System™, the Posterior Spine Truss System™, the Lateral Spine Truss System™, the Osteotomy Truss System™. — *RRY*

FDA Clears SI BONE's Latest SI Fusion Innovation

The FDA has cleared six additional posterior spinal fixation rods for use as pelvic implant devices.

The agency's 510(k) clearances covered six variations on the iFuse Bedrock Granite® Implant System. The system is intended for sacroiliac joint fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

Silicon Valley-based SI-BONE, Inc. submitted the device for 510(k) clearance. With clearance, the device now has expanded compatibility. SI-BONE recently announced that "certain CD Horizon® Solera® 5.5mm and 6.0mm posterior spinal fixa-

iFuse Bedrock Granite® Implant System
Courtesy of SI-BONE, Inc.

tion rods manufactured by Medtronic Sofamor Danek USA Inc., a division of Medtronic plc, meet SI-BONE's criteria for compatibility."

According to SI-BONE, the following Medtronic CD Horizon Solera rods meet iFuse Bedrock Granite implant compatibility criteria:

- CD HORIZON SOLERA Ø5.5mm Lined Titanium Alloy Straight Rod, length = 500mm
- CD HORIZON SOLERA Ø6.0mm Lined Titanium Alloy Straight Rod, length = 500mm
- CD HORIZON SOLERA Ø5.5mm Lined CHROMALOY Straight Rod, length = 500mm
- CD HORIZON SOLERA Ø5.5mm Lined CHROMALOY Plus Straight Rod, length = 600mm
- CD HORIZON SOLERA Ø6.0mm Lined CHROMALOY Straight Rod, length = 500mm
- CD HORIZON SOLERA Ø6.0mm Lined CHROMALOY Plus Straight Rod, length = 500mm

SI-BONE CEO Laura Francis said, "Given the strong initial reception for Granite, we are thrilled to confirm that a number of Medtronic's Solera® rods, used by many spine surgeons, meet Granite's compatibility criteria."

Francis continued, "Our existing general rod compatibility clearance, along with confirmation that these Medtronic Solera rods meet the criteria for compatibility with the Granite implant will give spine surgeons additional confidence in using our leading pelvic fixation implant with the Medtronic Solera system." — *KD*

LARGE JOINTS

HSS Study: Ketamine + Aspirin for Pain Management

Can the combination of oral ketamine and aspirin manage post-op pain effectively after total knee arthroplasty? And, if it can, how does it compare with opioid treatment?

Ketamine is a dissociative anesthetic used medically for induction and maintenance of anesthesia. It is also used by physicians as a treatment for depression and as a pain management tool.

Authors of a May 26, 2023, National Institutes of Health (NIH) article wrote: "Ketamine (ketamine hydrochloride) has been approved for general anesthesia either alone or in combination with other medications. It is a superb drug for use in short-term medical procedures that do not require skeletal muscle relaxation, and it has approval for the induction of general anesthesia as a pre-anesthetic to other general anesthetic agents."

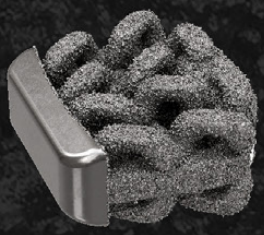
The Hospital for Special Surgery (HSS) research team, led by Michael P. Ast, M.D., a hip and knee surgeon and chief innovation officer at HSS, designed a pilot study to gather data on the use of oral ketamine + aspirin as a post-operative pain management tool for total knee arthroplasty patients.

Dr. Ast spoke to *OTW* about this interesting study and notably, his personal experience with the overuse of opioids to manage post-operative pain. "My childhood was spent in an area that has been hard hit by the opioid epidemic and I personally know people who have died from opioid overdoses. The orthopedic community has made great strides in finding alternatives to opioids, but my colleagues and I knew there was room for improvement."

Dr. Ast and his team enrolled 22 men and women between the ages of 47 and 81 who were scheduled to have a total knee replacement procedure. The participants had no history of opioid use. Each person received an oral dose of

Source: Shutterstock

CERVICAL



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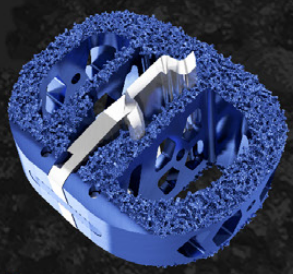

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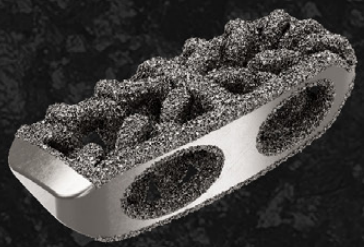

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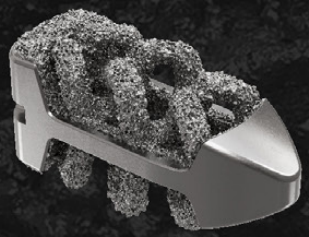

Camber Spine

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aspirin and ketamine four times a day until discharge (up to 72 hours).

OTW asked Dr. Ast about the specially formulated ketamine used in the study, Dr. Ast said, "This formulation of ketamine allows for oral use and is also manufactured in a way that it cannot be abused by melting or crushing. It allows the patient to let the pill's coating dissolve for about 20 seconds and then swallow, which primes the system to absorb the drug. That mechanism of action seems to change the bioavailability of ketamine, which was always a huge challenge."

"The combination of oral ketamine and aspirin had previously been studied in a Brooklyn, New York emergency room where that particular research team compared opioids to an oral ketamine/aspirin combination for pain relief. They reported excellent results so that made me think that this might work for TKR [total knee replacement] as well."

"Prior basic science studies have found that nonsteroidal anti-inflammatories like aspirin can mitigate the effects of other drugs by adjusting the pH/altering the environment. You can use fairly low doses of ketamine, which can prevent the dissociative feelings and perhaps reduce the potential for abuse."

Laser focused on patient safety, Dr. Ast told *OTW* that his team strategized to undertake a small pilot study to lay the groundwork for a larger research initiative. "We kept a close eye on patients to ensure overall safety and that there were no dissociative side effects."

"Because of this formulation's unique bioavailability and the low dose, we found the use during this study to be extremely safe. Anecdotally, patients obtained excellent pain relief. The majority of patients—18 of the 22—reported no side effects from the treatment. Two patients reported feelings of dizziness. Two others withdrew from the study early because they felt they needed more pain relief."

Eventually, rather than sending patients home with 20 or more opioid pills, Dr. Ast wants to be able to release patients with only a few—safe and effective—pills.

"Our manuscript is being prepared for presentation and publication and we look forward to the next study, which will be a randomized controlled trial in TKR. It's been exciting so far and has been great to see the interest of the orthopaedic community and beyond. We look forward to continuing this journey." — *EH*

PEOPLE

Michael R. Klein, M.D. Receives 2023 NASS Spine Advocacy Award

Michael R. Klein, M.D. / Courtesy of North American Spine Society

Michael R. Klein, M.D., a clinical professor in the Department of Orthopedic Surgery at the University of California, Davis Medical Center, has been given the Spine Advocacy Award by the North American Spine Society (NASS). This award recognizes members of NASS who have made exceptional contributions to the federal advocacy efforts on behalf of patients and members of the society.

"I am overwhelmed being honored by my colleagues with this prestigious award," said Dr. Klein to *OTW*. "I didn't think I was doing as much as the other members of the Advocacy Council & SpinePAC Advisory Committee and our dedicated staff. I continue to learn the intricacies of advocacy and the wonderful feeling of having done something that enhances spine care in our country."

The founder of MRK Medical Consultants, Dr. Klein was the first medical

director of Northern California Orthopedic Centers, now called Summit Orthopedics. He participated in the development of the orthopedic section of the Level II Trauma Center at Mercy San Juan Medical Center in Carmichael, California.

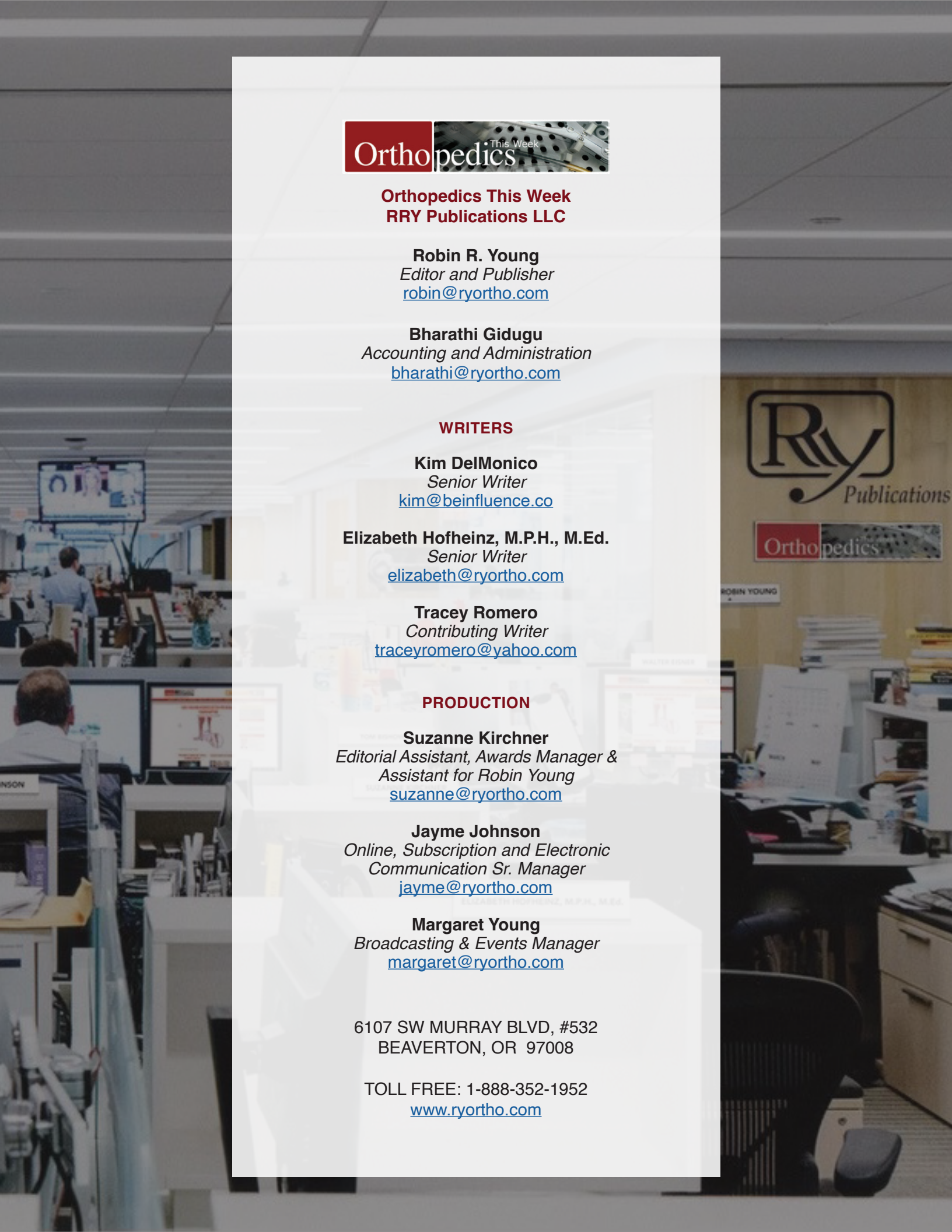
A NASS member for 14 years, Dr. Klein was awarded the David Selby Award in 2020 for his contributions to multiple committees as the facilitator of SpineConnect and co-chair of the SpinePAC Advisory Committee. As co-chair of the SpinePAC Advisory Committee, he has opened his home, hosting many successful SpinePAC fundraising dinners. He has hosted numerous such events across the country as well and is making plans for additional fundraisers.

"Dr. Klein has been extremely generous with his time and efforts to NASS over the years," said Eric Muehlbauer, NASS Executive Director. "From hosting SpinePAC events to helping create an online platform, we appreciate his wide-ranging expertise."

Dr. Klein retired from the USAF Medical Corps in 1998 after being on active duty during the Vietnam War; in 1991 he was activated for Operation Desert Storm. A private pilot who enjoys international travel, Dr. Klein most enjoys spending time with his four grandchildren. Dr. Klein received his Master of Science in anatomy from Drexel University and his medical degree from the University of Miami School of Medicine.

When asked by *OTW* how surgeons can participate in fundraising and advocacy, Dr. Klein said, "Encouraging U.S. NASS members to donate to SpinePAC is a constant challenge. All our efforts focus on connecting with members of Congress who are on committees writing, discussing, and eventually passing legislation beneficial to maintaining and improving spinal care to Americans. We rely on their contributions to meet our goals we are not permitted to accept financial assistance from industry."

"SpinePAC is your ONLY voice on the hill. Unless we continue our dialogue with members of Congress to rescind pending bills to decrease reimbursement and markedly limit pre-authorization, U.S. spine care providers are facing severe changes in their income and ongoing aggravation of spending increased time fighting for authorization of diagnostic studies and procedures." — *EH*



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