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Orthopedics This Week

WEEK IN REVIEW

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10 Bruce Heppenstall, M.D., Penn Medicine Institution, Dies at Age 82 >> Bruce Heppenstall, M.D., an orthopedic legend at the University of Pennsylvania School of Medicine in Philadelphia, Pennsylvania, passed away on January 4, 2024. Dr. Heppenstall was one of the first orthopedic surgeons to recognize the importance of soft tissue management in traumatic injuries.

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: Which industries are most vulnerable to artificial intelligence? At his annual meeting this past weekend, Warren Buffet said "any industry that is labor intensive." Which pretty much defines Life Sciences. But, as a data industry also, it has the capacity to exploit the Law of Large Numbers—as an AI and Data Driven industry—if it can capture a data ocean. Life Sciences is on the path to join other industries, Wall Street trading, insurance, retail and, yes, gambling that have deployed the Law of Large Numbers to manage risk and volatility. Life Science may be one of the last industries to go there, but it's heading in that direction.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Globus Medical	12.74%	(0.75%)	The integration of NUVA is proving to be costly, but with the current stock buyback and at these prices, #1 on the Power Rankings.
2	3	Pacira Biosciences	18.74	(6.20)	PCRX remains the cheapest equity in orthopedics but with exceptional cash flow and profits. #2 this week.
3	7	Anika	(14.97)	4.98	Blanchard and team are attracting investors because they are growing on the basis of innovative products. Top stock performer this past month and #3 on the Power Rankings.
4	6	Smith & Nephew	10.06	0.69	Also bucking the overall sell-off of orthopedic and spine stocks, is SNN. Core ortho business is the former Richards Medical in Memphis, Tennesee.
5	4	Medtronic	19.17	(3.89)	Relative to the other stocks in our universe, MDT's price is holding up better than most, now 8th cheapest equity, 3.47% forward dividend yield and the #1 market share in spine.
6	5	Conmed	12.24	(8.00)	Investors are expecting CNMD to report a respectable 9.2% sales growth for Q2, which is a great way to end the first half of 2024. Why the sell-off?
7	2	Zimmer Biomet	19.31	(6.42)	Investors were not impressed with ZBH's 4.4% revenue growth for Q1 (March quarter) nor with Torno's partnering with the top 3 pickleball organizations. Go figure.
8	10	Johnson & Johnson	19.22	(3.23)	JNJ's U.S. ortho business grew at just 2.3%, globally +3.2%. OUS grew at nearly 2x U.S. rates. Fewer selling days and a currency head wind (strong U.S. $) contributed.
9	8	Orthofix	(8.51)	(1.88)	OFIX is holding up pretty well. Most analysts expect that sales in Q1 will come in around $84 milion, up 9.30%. Between the numbers is a nice organizational rebound from 2023.
10	9	Integra LifeSciences	17.32	(14.78)	Investors keep punishing IART. Sales in Q1 FELL 2.5% and management reported a small loss. The Acclarent deal closed, but investors aren't buying. Quality company getting cheaper.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	SINTX Technologies	SINT	$0.05	$6	103.91%
2	OrthoPediatrics Corp	KIDS	$32.83	$781	19.86%
3	MicroPort Scientific	0853	$0.85	$1,562	11.82%
4	Anika Therapeutics	ANIK	$27.59	$410	4.98%
5	Dynatronics Corp	DYNT	$0.45	$2	4.79%
6	Alphatec Holdings	ATEC	$13.65	$1,883	1.11%
7	Smith & Nephew	SNN	$24.78	$10,833	0.69%
8	Globus Medical	GMED	$51.95	$7,033	-0.75%
9	Orthofix	OFIX	$13.60	$509	-1.88%
10	Johnson & Johnson	JNJ	$149.27	$359,245	-3.23%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	AxoGen	AXGN	$5.79	$253	-28.16%
2	Aurora Spine	ASG.V	$0.18	$13	-21.53%
3	Bioventus	BVS	$3.97	$316	-20.92%
4	Integra LifeSciences	IART	$28.89	$2,271	-14.78%
5	Xtant Medical Hldgs	XTNT	$0.85	$111	-13.53%
6	Nevro Corp	NVRO	$11.29	$411	-13.42%
7	SI-BONE, Inc	SIBN	$14.20	$585	-10.41%
8	ZimVie	ZIMV	$15.80	$430	-9.20%
9	ConMed	CNMD	$71.76	$2,210	-8.00%
10	Stryker	SYK	$328.45	$125,123	-6.42%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$81.69	$108,470	19.36
2	Johnson & Johnson	JNJ	$149.27	$359,245	19.38
3	Pacira Biosciences	PCRX	$27.21	$1,265	24.19
4	Zimmer Biomet	ZBH	$121.66	$25,029	26.21
5	ConMed	CNMD	$71.76	$2,210	27.15

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Xtant Medical Hldgs	XTNT	$0.85	$111	167.70
2	Medacta	MOVE	$124.99	$2,500	48.75
3	Smith & Nephew	SNN	$24.78	$10,833	41.19
4	Stryker	SYK	$328.45	$125,123	33.98
5	Integra LifeSciences	IART	$28.89	$2,271	33.52

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Smith & Nephew	SNN	$24.78	$10,833	-5.15
2	ConMed	CNMD	$71.76	$2,210	1.11
3	Medacta	MOVE	$124.99	$2,500	1.75
4	Globus Medical	GMED	$51.95	$7,033	1.77
5	Pacira Biosciences	PCRX	$27.21	$1,265	2.33

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Xtant Medical Hldgs	XTNT	$0.85	$111	8.39
2	Medtronic	MDT	$81.69	$108,470	5.56
3	Integra LifeSciences	IART	$28.89	$2,271	3.81
4	Zimmer Biomet	ZBH	$121.66	$25,029	3.72
5	Johnson & Johnson	JNJ	$149.27	$359,245	3.71

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Dynatronics Corp	DYNT	$0.45	$2	0.05
2	Bioventus	BVS	$3.97	$316	0.62
3	Aurora Spine	ASG.V	$0.18	$13	0.67
4	Orthofix	OFIX	$13.60	$509	0.68
5	ZimVie	ZIMV	$15.80	$430	0.94

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Stryker	SYK	$328.45	$125,123	6.10
2	OrthoPediatrics Corp	KIDS	$32.83	$781	5.25
3	Medacta	MOVE	$124.99	$2,500	4.89
4	Globus Medical	GMED	$51.95	$7,033	4.48
5	Johnson & Johnson	JNJ	$149.27	$359,245	4.22

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

AAOS's Vaughn Award Given to MOON Shoulder Group

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

Multicenter Orthopaedic Outcomes Network (MOON) Shoulder Group Wins Kappa Delta Ann Doner Vaughn Award / Courtesy of University of California San Francisco

A remarkable multicenter group of 40 surgeons at 16 centers, organized as the Multicenter Orthopaedic Outcomes Network (MOON) Shoulder Group, is the 2024 recipient of AAOS's Kappa Delta Ann Doner Vaughn Award for creating meaningful change in the way physicians treat patients with atraumatic, symptomatic rotator cuff tears.

This award recognizes research in musculoskeletal disease or injury with great potential to advance patient care.

The MOON group's award-winning research finding was that physical therapy is an effective treatment for over 70% of rotator cuff tear patients, improving pain and patient-reported outcome measures (PROMs) over an impressive 10-year follow-up period.

"When I finished my training in 1994, we were taught that surgery was the preferred way to treat a rotator cuff tear," said John E. Kuhn, M.D., M.S., chief of shoulder surgery and director of Vanderbilt Sports Medicine and director of the MOON Shoulder Group. "As the approach to treating rotator cuff tears remained unclear, we wanted a more thorough understanding of the disease to help define the indications for rotator cuff repair surgery and determine which patients would benefit from nonoperative treatment."

Prior to this study, we asked Dr. Kuhn, was physical therapy considered to be an effective treatment for a significant percentage, say 30% or 50% of rotator cuff tear patients?

According to Dr. Kuhn, not even 30%. "Before this work, very few surgeons would have thought physical therapy was effective in treating full thickness rotator cuff tears," said Dr. Kuhn.

"Most surgeons were taught these need to have surgical repair. When we set up the study, we thought physical therapy might be effective in elderly, low demand patients, and thought that maybe 15% of our patients would do well. We were surprised to see how effective therapy was."

The team set out to predict nonoperative treatment failure rates of rotator cuff tears. After creating a standard, evidence-based PT protocol that included a "gold standard" PT protocol, the researchers enrolled patients aged 18 to 100 years with shoulder symptoms and MRI-documented, symptomatic, atraumatic, full-thickness rotator cuff tears.

Partial findings include:

- Most patients who decided to have surgery within six months were driven primarily by their expectations of the effectiveness of physical therapy. In other words, if they thought PT would work, it worked. If they didn't believe it would work, it didn't.

- When comparing those who had surgery before six months and those who had surgery between six months and ten years, worker's compensation status and activity level were more important in predicting the need for surgery after six months.

"As far as what we know about surgeons actually making the shift to treating patients with atraumatic, symptomatic rotator cuff tears using physical therapy, Dr. Kuhn told *OTW*, "surgery numbers are increasing over time, but that could reflect the population aging. A recent study demonstrated that only 19.8% of Medicare patients with atraumatic rotator cuff tears were treated initially with surgery, 38.8% with watchful waiting, and 41.3% with physical therapy, with surgery rates trending downward and physical therapy rates trending upward with time (Chapman et al 2018)."

"Additionally, many insurance companies now require an attempt at physical therapy in their clinical pathways before approving surgery."

"Today, we know that physical therapy is very effective in treating atraumatic rotator cuff tears. We also know that surgery is effective. We do not know which treatment is best and for whom. Our MOON Group is involved in a randomized controlled trial led by Dr. Nitin Jain and funded by the Patient-Centered Outcomes Research Institute to help answer that question. The ARC Trial has just completed enrollment, and we should have some answers in the next few years!"

The MOON Shoulder Group also includes the following researchers: Warren R. Dunn, M.D., M.P.H., , Rosemary Sanders, B.A., Keith M. Baumgarten, M.D., , Julie Y. Bishop, M.D., Robert H. Brophy, M.D., James L. Carey, M.D., M.P.H., , Brian G. Holloway, M.D., Grant L. Jones, M.D., C. Benjamin Ma, M.D., Robert G. Marx, M.D., M.S., Eric C. McCarty, M.D., Sourav K. Poddar, M.D., Matthew V. Smith, M.D., Edwin E. Spencer, M.D., Armando F. Vidal, M.D., Brian R. Wolf, M.D., M.S., and Rick W. Wright, M.D. ♦

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Steps2Walk: Enriching Generations Via Surgery and Education

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



Photo 1 Dr. Mark Myerson with young patient in Pakistan; Photo 2: Patient in Pakistan with a severe foot deformity; Photo 3: Dr. Myerson teaches local surgeons during Bolivia program / Courtesy of Steps2Walk

"Voted off the island" and "voted out of the tribe" are familiar sayings in the reality TV arena. But in the real world, whether someone is intentionally excluded or cannot participate in community activities, the resulting isolation, inability to earn a living or go to school—not to mention the accompanying psychological damage—take their toll.

Who is excluded? Millions of people around the world. Why? Because they cannot walk—or they walk despite severe foot and ankle deformities.

To begin to turn the tide for those with disabling foot and ankle injuries, Steps2Walk, a global humanitarian nonprofit, is making concrete, sustainable strides in bringing relief, hope, and orthopedic education to underserved areas of the world.

Founder Mark Myerson, M.D., a visiting professor of foot and ankle surgery at The University of Colorado Anschutz Medical Campus, told *OTW*, "When we started in 2000, it soon became clear that although humanitarian trips are helpful for a certain number of people, Steps2Walk could have a much bigger impact if we were to train hundreds of surgeons so they could go forth and ultimately help thousands of patients."

Twenty-four years later, Steps2Walk has trained more than 600 surgeons annually and performed over 1,700 operations in 24 countries.

Reanimating Entire Communities

Anish Kadakia, M.D., a veteran of Steps2Walk's life-changing programs, is a foot and ankle surgeon at Northwestern University Feinberg School of Medicine in Chicago. "Eighteen years ago, I was Mark Myerson's fellow," says Dr. Kadakia. "Upon hearing him lecture on Steps2Walk's cases and impact—including their not-so-common dedication to orthopedic education—I was fascinated."

Now, having participated in three trips, Dr. Kadakia lauds the organization's multiple benefits. "First of all, when we perform surgery in America, for the most part we are making people somewhat better. When operating in impoverished areas around the globe, however, you make a vast difference. These surgeries can ultimately reanimate whole communities as they give people the opportunity to participate in society. As it is now, these children can't walk to school and adults cannot walk to work, creating massive downstream economic and psychological problems."

"As opposed to a fly-in fly-out model, Steps2Walk does not leave a wasteland of complications behind. We work with local surgeons, return to the same place annually, and the local surgeons have continual access to the medical team via WhatsApp throughout the year."

Medicine at its Purest and Best

"Our goal for each program is that they do their best to follow up with patients and communicate that progress with us, though it can sometimes be impossible due to how far some patients have to travel for care. We strive to go back to each country regardless of circumstances as we believe with each program, the coordination and communication with local hosts will become more efficient. Flexibility, on our part and that of the local hospitals, is key. The ultimate goal of a mission is to train local surgeons to the point where Steps2Walk is no longer needed in their community."

"Second, Steps2Walk missions take medical professionals away from the rigamarole and administrative burden we deal with every day. There is a genuine joy that we all feel when helping these patients…**this is pure medicine.**"

The third reason Dr. Kadakia is a proponent of Steps2Walk is intellectual. "When I first encountered an extremely complex case on a trip, I literally had no idea how to help the person, a young man of 22 who was born with one of his feet facing backwards. This type of congenital deformity doesn't occur in the U.S., and this was an opportunity for me to learn from surgeons who had participated in prior mission trips."

Sustainability Is the Mantra

Dr. Myerson, who participates in 1-2 mission trips per month, explained the details of this kind of medical practice, "We see a good deal of patients with congenital conditions, while others have injuries resulting from trau-

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ma or previous injuries that were not adequately treated at the time. We may encounter patients with spina bifida, arthritis, high arches, club foot deformities, and other foot and ankle conditions that affect their quality of life and ability to walk."

"Our foundational mantra is 'sustainability,'" adds Dr. Myerson. "Continuity of care is about ongoing education, which is where the Steps2Walk Global Institute plays a vital role. I've just returned from Pakistan where we had 48 surgeons who had come from all around the country. We also included residents because we want people trained as early as possible. This is critical because Pakistan, a country of 223 million people, doesn't have a single fellowship-trained foot and ankle surgeon."

With a network of more than 250 surgeon volunteers from around the globe, including 125 who regularly participate, Steps2Walk is growing in popularity. "Next week we will be in Tanzania, another country without any foot and ankle surgeons. We will be welcoming now only Tanzanian surgeons but also several from Uganda and Kenya. While we are so appreciative of our member surgeons, we would love to welcome new members."

The Biggest Challenges

OTW asked Dr. Myerson to describe the biggest challenges that new surgeons experience as they come onboard. "Surgeons are often intimidated by the type of work we do as 50% of the surgeries involve deformities no longer seen in the Western world," Myerson explained. "*But as Anish Kadakia and many others have done, they can push past that and have unforgettable experiences on our team.* In recruiting new surgeon volunteers, we determine if they have special language or surgical skills. It's not all about the surgery…if I take a brilliant surgeon on a trip, but that person can't teach and can't communicate then I have failed."

In order to deliver the most impact, says Dr. Myerson, it is important to focus on teaching the local surgeons how to contend with things such as ankle fractures, flatfeet, and arthritis. "It is imperative that we teach what is useful and only bring equipment that meets their needs, i.e., is *not* fancy and *is* sustainable."

"Surgeons who participate in our trips come home enriched, gratified, and feeling blessed by the opportunity they were given. They have helped beyond measure, had an unusually fulfilling orthopedic

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experience—as surgeons and educators—and have garnered lifelong friendships with the international faculty as well as the local orthopedic population."

Money and Donations

Regarding donations, things have advanced since the organization's early days, when, says Dr. Myerson, they would pack surgical equipment in their suitcases and hope for the best. "We don't have too much of a struggle acquiring equipment donations… the bigger issue is that some countries won't allow us to bring any instruments or other supplies. This involves a lot of negotiation."

Indeed, to start up in a *new* country it takes roughly two years to plan. "We need surgeons on the ground who will function as hosts, and we need a local hospital with the appropriate infrastructure. We may want three ORs, but if it's a remote hospital with only four ORs then it's not easy for them to make that commitment. Then of course the local surgeons have to make a plan to find patients, and 'market' to surgeons in their region."

Sustainability of such sweeping undertakings calls for continuous funding. "We have recently launched our 'Stepping Together' campaign in conjunction with our orthopedic industry partners. If a company donates $50,000 and then matches employee donations, then that becomes a powerful multiplier. It not only sends a message that the company is philanthropically inclined, but it spreads the word about the Steps2Walk mission."

"The enormous and concrete advances that these patients make are astounding," states Dr. Kadakia. "After surgery, they can go to school, walk, get a job, and participate in society. Seeing how much people can tolerate has been eye opening. *I have seen children running and smiling with an* ***equinus*** *deformity of 70 degrees!* Working with Steps2Walk has made me a better surgeon and a better human being. I can't wait for my next trip."

In 2023, Steps2Walk conducted 11 missions to underserved regions around the world, including to countries where foot and ankle orthopedic surgeons are scarce or non-existent. Their team of volunteer surgeons treated 165 patients and provided essential training to 260 local surgeons in 2023.

In 2024, Steps2Walk is planning on visiting 17 countries, including Sri Lanka, Pakistan, Mexico, Philippines, Namibia, Tanzania, Kenya, Chile, Argentina, Brazil, Peru, Bolivia, China, Honduras, India, and Uruguay.

For additional information on the Steps2Walk programs, please visit:

https://steps2walk.org/

https://www.facebook.com/Steps2Walk/

https://twitter.com/steps2walk

https://www.youtube.com/channel/UC2BnFt4FjluP32NlFYoPqSQ

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Bruce Heppenstall, M.D., Penn Medicine Institution, Dies at Age 82

BY TRACEY ROMERO

Bruce Heppenstall, M.D., an orthopedic legend at the University of Pennsylvania School of Medicine in Philadelphia, Pennsylvania, passed away on January 4, 2024.

His tenure with Penn started when he completed a residency in orthopedic surgery at the University of Pennsylvania School of Medicine in 1969.

Dr. Heppenstall spent a year in San Francisco, California, for a fellowship at the University of California-San Franciso before returning to Penn.

At the Hospital of the University of Pennsylvania, he focused his research on wound healing and the treatment of fractures under the mentorship of Drs. Edgar Ralson and Carl Brighton. Dr. Heppenstall authored three authoritative textbooks and multiple peer-reviewed and widely cited journal articles on the practice and art of fracture treatment. His first book was published in 1980 and is still used by medical students today.

Dr. Heppenstall was one of the first orthopedic surgeons to recognize the importance of soft tissue management in traumatic injuries. He collaborated with the renowned biophysicist Dr. Britton Chance on the metabolic effect of tissue ischemia. Heppenstall served both as a researcher, orthopedic surgeon and served as Chief of Fracture Service at the Hospital of the University of Pennsylvania.

Dr. Heppenstall served as the Chief of Orthopedic Surgery at the Philadelphia Veterans Affairs Medical Center. For his pioneering work in fracture biology, Heppenstall was awarded the Kappa Delta Award at the American Academy of Orthopaedic Surgeons in 1986.

Bruce Heppenstall, M.D. / Legacy.com

He was also a member of the prestigious 20th Century Orthopedic Association and was loved and respected by his colleagues and patients.

When Dr. Heppenstall retired in 2016, after 45 years serving the global community of orthopedic physicians and patients, he was the Associate Chair and Professor Emeritus at the University of Pennsylvania School of Medicine.

The Annual Bruce Heppenstall Trauma Lectureship was created to honor his impact on the field of orthopedic surgery.

Heppenstall was born on October 26, 1941, to Alfred and Edna Heppenstall in Winnipeg, Manitoba, Canada. Before moving to the United States, he earned both an engineering and medical degree from the University of Manitoba in 1962 and 1966, respectively.

He also conducted post-doctoral work at the Health Sciences Centre in Winnipeg and completed a general surgery internship and residency at the Winnipeg General Hospital.

When he wasn't engrossed with research or serving his patients, Heppenstall loved to travel and go sailing along Long Beach Island with family and friends. When he was diagnosed with Alzheimer's Disease later in his retirement, he moved to California to be closer to his children. He is survived by his son Mark David and his daughter Darcy, his former wives Carol Heppenstall and Betty Jane Bruck, and his stepchildren Christopher Bruck and Matthew Bruck. ♦

COMPANY

Bernie Haffey Joins Accelus Board of Directors

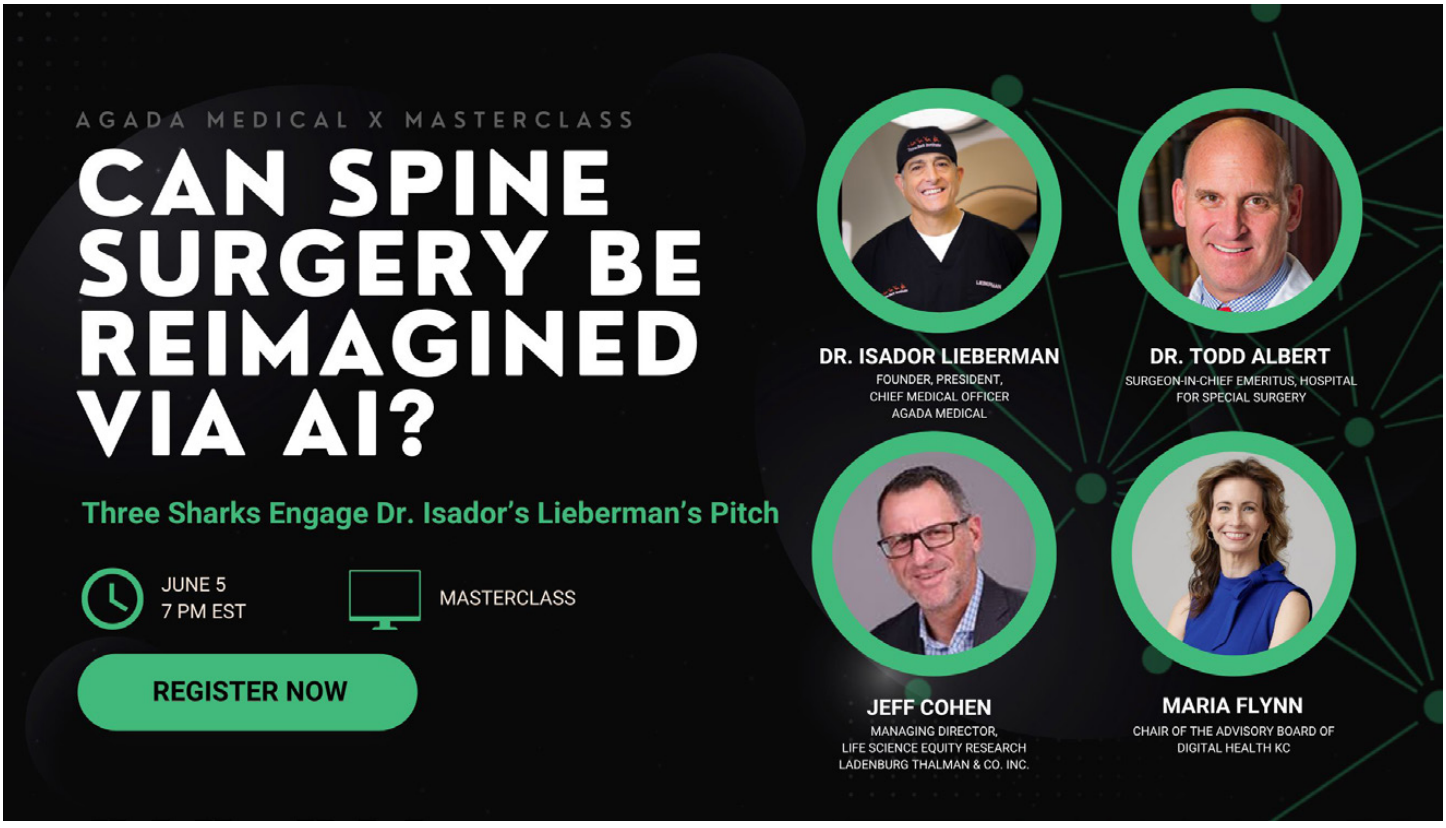
Bernie Haffey / Courtesy of Accelus Corporation

Bernie Haffey, a veteran executive and corporate leader, has joined the Board of Directors of Palm Beach Gardens, Florida-based Accelus Corporation. For over 20 years, Haffey has been CEO of his own firm, Haffey and Co., known for its High-Performance Management System (HPMS), which has transformed performance at more than 50 businesses and organizations.

Prior to launching Haffey & Co., Haffey was president and CEO of two venture-backed start-ups, Nexis Vision, Inc., and NDO Surgical, Inc., both of which achieved structured exits under his leadership. Additionally, he held positions as executive vice president and chief commercial officer at both Summit Technology, Inc., and IntraLase Corp. Under Haffey's leadership, these companies achieved revenues exceeding $100 million and exits of $1 billion and $800 million, respectively.

Haffey serves on the Board of Directors of On Target Laboratories, Inc. and Medevise Consulting and previously served on the boards of WaveTec Vision, Inc., acquired by Alcon Labs, and Ocular Therapeutix, Inc. Haffey holds a B.A. from Colgate University and an M.B.A. from Cornell University.

Haffey joins Accelus at a particularly opportune time. Not only has the company recently hired a new CEO, but it



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also closed on new financing. Among the key products in Accelus's portfolio are:

- Adaptive GeometryTM technology, used in its flagship product, the FlareHawk® Interbody Fusion System
- Toro®-L biplanar-expandable lateral implant
- LineSider® Spinal System, a posterior screw system that gives surgeons the ability to tailor their surgical construct to each patient's pathology
- BioNest® allograft bone matrix, a 100% human allograft demineralized bone matrix designed for ease of flow for post-pack graft delivery into the surgical site.

Haffey, who will be bringing his HPMS system into Accelus, told *OTW*, "I believe that HPMS firmly lays the groundwork for cultivating a culture of excellence. This is achieved through the establishment of shared values and ensuring organizational alignment."

"Our approach is distinctive because of our focus on the Vital Few, which sharpens Accelus's ability to execute with excellence. This focus, when integrated with our Breakthrough Process, positions Accelus uniquely by executing through a management system that is deeply rooted in proven quality principles."

"As I step into this role, my initial focus will be on acquiring a profound understanding of our technology, customers, markets, and competition. This foundational knowledge is crucial for me to effectively support and lead the company forward." — *EH*

LEGAL

Former Mazor Robotics VP Guilty of Insider Trading

Doron Tavlin, the former vice president of business development at Mazor Robotics, has been found guilty for his role in an insider trading conspiracy.

Source: Unsplash and Matthew Ansley

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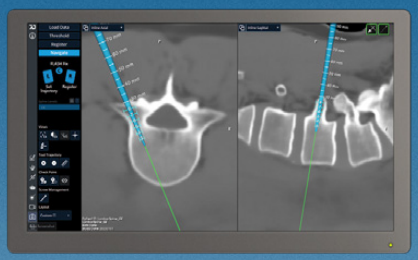

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seaspine.com

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Mazor Robotics was a medical device company based in Israel focused on robotics for spinal procedures. In 2018 it was acquired by Medtronic, Inc., a medical device company based in Ireland with executive headquarters in Minneapolis.

The conspiracy involved both Tavlin and his friend Afshin Farahan. In 2018, based on information from the nonpublic acquisition negotiations, Tavlin, per the Department of Justice press release, "tipped this information about the acquisition to his friend, Farahan, and instructed him to keep the information secret."

During August 2018 and September 2018, Farahan bought more than $1 million of Mazor stock. Farahan then sold all of the stock he had purchased the morning after the acquisition announcement. This "resulted in a combined profit of over $500,000 for himself and one other individual."

After the acquisition, the Financial Industry Regulatory Authority (FINRA) investigated certain trades of Mazor securities. Tavlin falsely responded to FINRA's inquiry by "denying that he recognized any names on a list of persons and entities that purchased Mazor securities, which included Farahan."

Evidence at trial also showed an agreement between Tavlin and Farahan regarding the disclosure of the material, nonpublic information. In October 2019, per that agreement, Farahan gave $25,000 to Tavlin for the information.

After a nine-day trial, Tavlin was found guilty of one count of conspiracy to commit insider trading and 10 counts of securities fraud and aiding and abetting securities fraud. Last year, Farahan pled guilty to one count of conspiracy to engage in insider trading. Sentencing hearings for Tavlin and Farahan will take place at a later time.

A third individual, David Gantman, also faced charges related to the conspiracy. Gantman was found not guilty for those charges. — *KD*

CMS Finalizes Interoperability and Prior Authorization Rule

The Centers for Medicare & Medicaid Services (CMS) has published its CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F), reflecting its efforts to improve access to health information and the prior authorization process.

The final rule includes the following provisions: patient access API (application programming interfaces), provider access API, payer-to-payer API, and prior authorization API. The final rule does not apply to prior authorization decisions for drugs.

Under the final rule, impacted payers will be required to provide information about prior authorizations via the patient access API. Per the CMS Fact Sheet, impacted payers will be required to "implement and maintain a provider access API to share patient data with in-network providers with whom the patient has a treatment relationship." This is meant to "facilitate care coordination and support movement toward value-based payment models."

To facilitate care continuity, impacted payers will be required to implement and maintain a payer-to-payer API to make available certain data including information about certain prior authorizations. Beginning in 2027, impacted payers will also be required to, per the CMS Fact Sheet, "implement and maintain a prior authorization API that is populated with its list of covered items and services, can identify documentation requirements for prior authorization approval, and supports a prior authorization request and response."

The final rule also includes a provision on improving prior authorization processes which includes the following: prior authorization decision timeframes; provider notice, including denial reason; and prior authorization

Source: Shutterstock

metrics. The prior authorization policies have a compliance date starting January 1, 2026. Impacted payers will be required to provide prior authorization decision within 72 hours for urgent requests and 7 calendar days for non-urgent requests. In 2026, impacted payers will also have to provide a specific reason for any prior authorization denial decisions. Impacted payers, per the CMS Fact Sheet, will be required to "publicly report certain prior authorization metrics annually by posting them on their website."

In the American Medical Association (AMA) press release, AMA President Jesse M. Ehrenfeld, M.D., MPH, expressed support for the reforms. Dr. Ehrenfeld commented, "The American Medical Association applauds Centers for Medicare & Medicaid Services Administrator Brooks-LaSure for heeding patients and the physician community in a final rule that makes important reforms in government-regulated health plans' prior authorization programs for medical services."

Dr. Ehrenfeld added, "Today's final rule requires impacted plans to support an electronic prior authorization process that is embedded within physicians' electronic health records, bringing much-needed automation and efficiency to the current time-consuming, manual workflow."

Dr. Ehrenfeld continued, "The AMA also appreciates that the rule will significantly enhance transparency around prior authorization by requiring specific denial reasons and public reporting of program metrics as well as requiring that prior authorization information be available to patients to help them become more informed decision makers." — *KD*

LARGE JOINTS

Phase 2B Study Data for 4-Week TKA Analgesic

Results from a Phase 2B study of a novel, ultra-sustained pain management for post total knee arthroplasty

Source: Shutterstock

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(TKA) pain management and recuperation drug have been announced. The study, which took place at 13 sites in Australia, Canada, and the United Kingdom, determined that this new compound, ATX101, achieved "sustained post-surgical pain relief for up to four weeks for patients following total knee arthroplasty (TKA) and outperformed a standard of care active comparator, bupivacaine, on durability of effect, use of opioids to support pain relief and the potential for patients to return to day-to-day activities earlier."

ATX101 is a novel configuration of a bioresorbable polymer and bupivacaine that contains a high density of bupivacaine within a biodegradable polymer designed to deliver an ultra-sustained analgesic effect over weeks before dissolving.

Study participants were randomly assigned to either one dose of 1,000 mg (n=37) or 1,500 mg (n=37) ATX101, a control group (saline placebo (n=4), or bupivacaine standard of care active comparator (n=34)).

The bupivacaine comparator was administered once by way of local infiltration or adductor canal block; two or three 500 mg ATX101 implants were placed within the knee capsule prior to surgical closure. Opioids were used as needed for postoperative pain, and all patients received around-the-clock celecoxib and acetaminophen to simulate a real-world multimodal analgesic protocol.

David Hewitt, M.D., CMO of the study sponsor, Allay Therapeutics, told *OTW,* "Allay's ATX101 product was designed by surgeons to ensure ease of administration, form factor that fits within anatomy and simplifies the surgical workflow. Yet it was then developed by scientists with a long history of drug elution technologies to safely deliver small amounts of drug in a controlled fashion over a long period."

"The drug and polymer technology started in Singapore with Lightstone Singapore and the Foundry incubator (Menlo Park, CA) seeding and acquiring the technology and built Allay around those capabilities. Initially the team started with antibiotics and then moved to focus on post-surgical pain relief using bupivacaine, the mainstay of analgesic protocols and a well-defined Poly (lactic-co-glycolic acid) polymer. We then developed implants that treat the pain anatomically at the source, instead of pharmacologic approaches like opioids."

"The results from the 112-patient Part A study against bupivacaine standard of care showed rapid and durable pain relief out through 30 days, with less opioids used, earlier opioid-free recovery, and never-before-seen functional improvements at 30 and 60 days."

"These results will give patients a gentle active recovery, critical for successful long-term results after TKA. Clinicians will save time in their operating room with favorable reimbursement, and payers will benefit from less resource utilization. Importantly, we saw a favorable safety profile—by using a local anesthetic and polymers that are commonly used in surgery, we can hopefully demonstrate weeks of pain relief but without the development risk of many new chemical entities."

"We now move into the final registration studies for FDA approval with a Phase 2B planned this year in the U.S., and a global Phase 3 against standard of care or leading competition that will take us to FDA approval in 2027. We have a pipeline of other products with different shapes, forms, and drug release to target other soft and hard tissue applications, all under a shared platform in Singapore and the U.S."

The company indicates that this data informs the design of a pivotal Phase 2B study projected to start in 2024. If successful, this study would support a new drug application filed with the FDA. — *EH*

SPINE

98,000 Patient Study Links Diabetes to Spinal Stenosis

According to the Centers for Disease Control and Prevention, 38.4 million people in the U.S. have diabetes, 97.6 million people 18 or older have prediabetes and 27.2 million people 65 and older have prediabetes.[1] As our population stands at roughly 336,377,915

Source: Wikimedia Commons and Biswarup Ganguly

people, those in the above categories represent nearly half of the country.[2]

To what extent is diabetes a risk factor for lumbar spinal stenosis? An international team of researchers designed a massive study to quantify the connection between diabetes and lumbar spinal stenosis. Their work, "Diabetes Mellitus and Poor Glycemic Control Are Associated With a Higher Risk of Lumbar Spinal Stenosis: An Analysis of a Large Nationwide Database," was published in the May 1, 2024 edition of *Spine*.

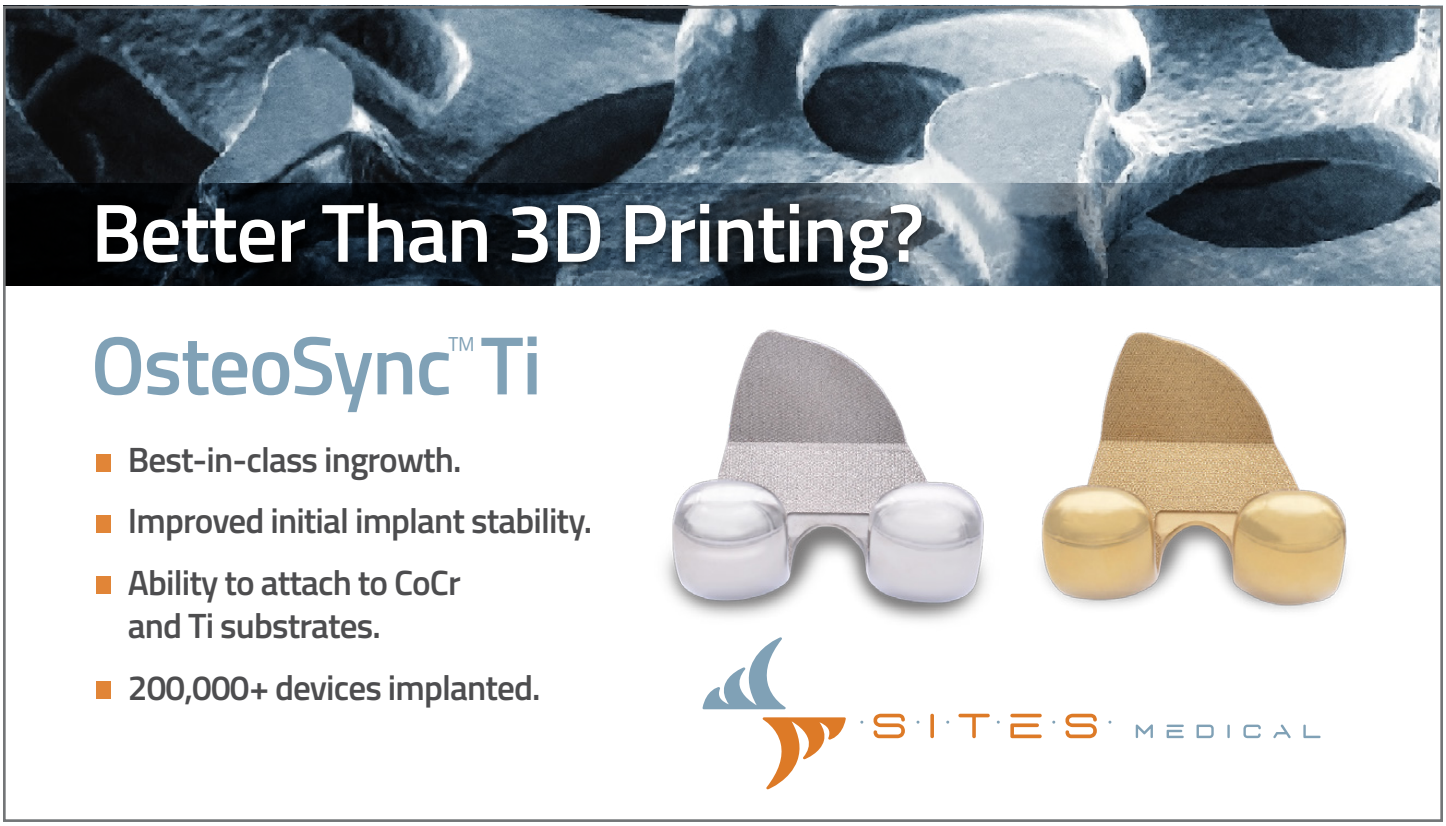
Co-author Assaf Kadar, M.D. an orthopedic surgeon at the Rabin Medical Center, Beilinson Hospital, Petah Tikva, Israel, told *OTW*, "Dr. Shai Shemesh, who is the lead author, postulated that the ligamentum flavum, the culprit of spinal stenosis, is in fact an overlooked 'target organ' for diabetes. The effect of diabetes on other target organs (nerves, retina, kidney and more) have been extensively studied, but there is scarce literature about spinal stenosis."

In total, 49,576 patients diagnosed with lumbar spinal stenosis were matched with controls of the same number based on age and sex. The researchers found a higher likelihood of lumbar spinal stenosis in diabetic patients; those with hemoglobin A1c ≥7% and ≥1 diabetes-related complication also had an elevated likelihood of having this diagnosis. The team determined that prolonged diabetes exposure increased the risk.

Having a diabetes diagnosis reduced median survival by around 4.5 years for both stenotic and non-stenotic patients; spinal stenosis diagnosis alone minimally impacted survival. A multivariate analysis revealed a significantly increased risk of all-cause mortality in patients with diabetes and lumbar spinal stenosis and those with diabetes without stenosis compared with controls.

Dr. Kadar, also affiliated with the Roth|McFarlane Hand & Upper Limb Centre, St. Joseph's Hospital and Western University in Canada, explained to *OTW*, "This work established the causal relationship of poor glycemic control and long-standing diabetes to high risk of spinal stenosis. In essence, this finding confirms the hypothesis that glycosylation (the effect of high glucose levels on tissues) effects the ligamentum flavum in a dose dependent manner."

"The study will help surgeons and physicians educate their patients on the



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deleterious effect of poor diabetes control on spinal stenosis. All physicians like to quote that 'Prevention is better than cure.' We feel that with our findings, clinicians have a powerful prevention tool that can be specifically applied to diabetic patients with early spinal stenosis."

Going forward, Dr. Kadar told *OTW*, "We need to have basic science studies defining the mechanism of the effect of high glucose levels on the ligamentum flavum. In addition, we need large-scale prospective clinical trials looking at the various diabetes treatment options and its effect on spinal stenosis." — *EH*

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1. https://www.cdc.gov/diabetes/data/statistics-report/index.html
2. https://www.census.gov/popclock/

Study: Discharge to Postop Facility Not Always Helpful

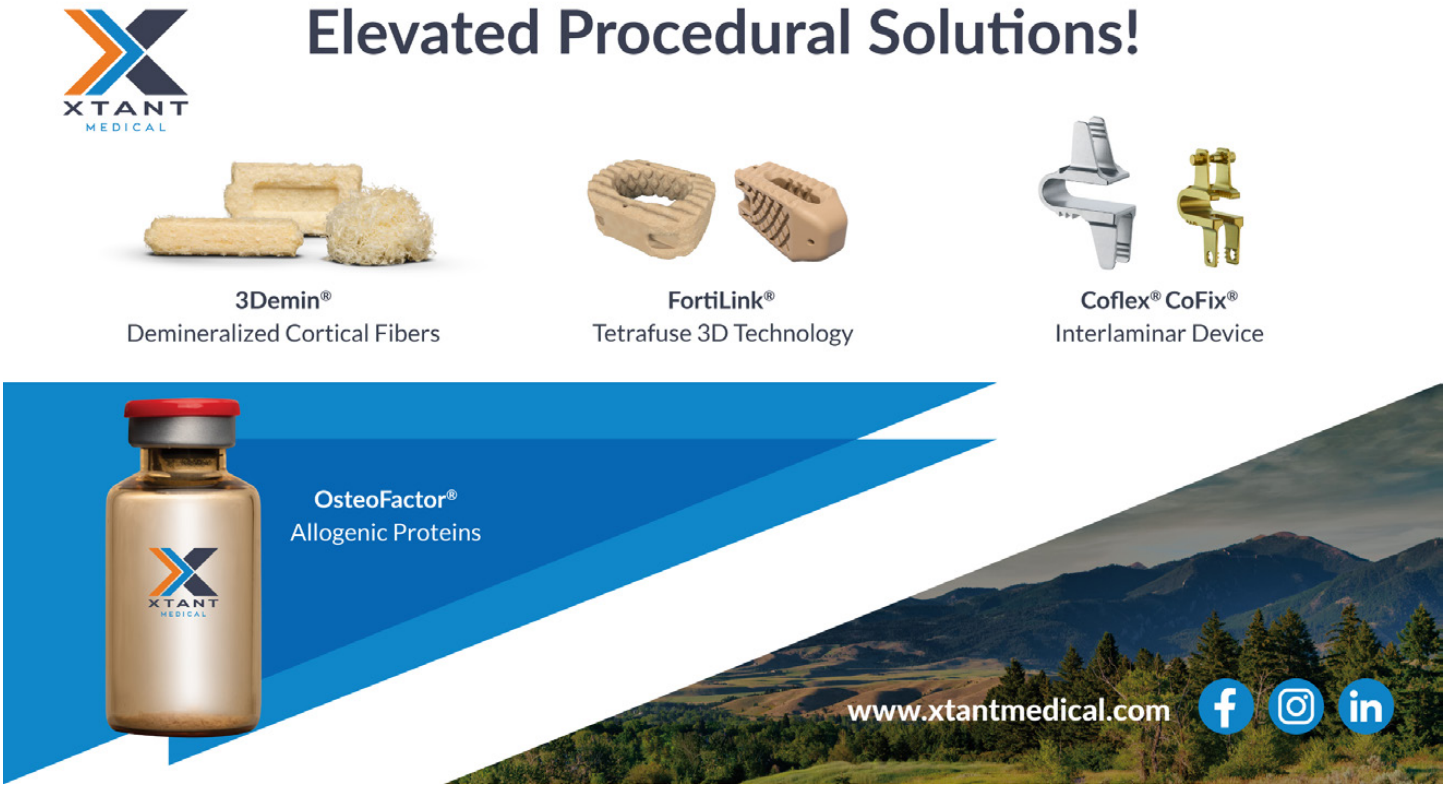
Discharge home or a postop facility? What does the data show?

A new, multi-center study has generated new data about longer term post op facilities for adult spinal deformity patients. Their work, "Postoperative Discharge to Acute Rehabilitation or Skilled Nursing Facility Compared With Home Does Not Reduce Hospital Readmissions, Return to Surgery, or Improve Outcomes Following Adult Spine Deformity Surgery," appears in the May 1, 2024 edition of *Spine*.

"This paper emanated from ongoing research by the International Spine Study Group," stated co-author Pierce Nunley, M.D., director of the Spine Institute of Louisiana, to *OTW*. "There has been a longstanding question of the utility of non-home discharge vs home discharge. We were part of the Medicare Bundle program that shed a light on the high costs of overutilization and began to find ways for patients to be able to transition from the hospital directly to a home environment."

"Combined with heightened awareness surrounding the COVID pandemic, we believed there may not be as much a

Source: Wikimedia Commons and USNS Mercy Medical Support at Skilled Nursing Facility Orange County



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need for rehab and skilled nursing facilities and therefore queried out prospective database to see the results."

The researchers looked at surgically treated adult spinal deformity patients who were prospectively enrolled in a multicenter study, assessing them for "non" or "home" status following hospital discharge. "Non" was further divided into "rehab" or "skilled nursing facility." They then matched "non" patients to "home" patients, leaving 158 patients for evaluation.

Dr. Nunley: "The study was conducted at 11 centers with 18 surgeons that worked with the patients, therapists, and social workers to determine the best discharge placement. It is important to point out that we used propensity score matching to match the identified non-home and home patients to reduce the influence of confounding variables."

Patients in the "non" and "home" had similar preoperative age, frailty, spine deformity magnitude, surgery performed, and duration of hospital stay. Thirty-day readmissions, 90-day return to surgery, and postoperative complications were similar for "non" versus "home" and similar for "rehab" (N=64) versus skilled nursing facility (N=42) versus "home". At 1-year and minimum 2-year follow-up points, those in the "home" group demonstrated similar to better patient-reported outcome scores including Oswestry Disability Index, Short-Form 36v2 questionnaire Mental Component Score and Physical Component Score, and Scoliosis Research Society scores versus "non", "rehab", and skilled nursing facility.

"There does not appear to be a clear benefit of non-home discharge after adult spinal deformity surgery," said Dr. Nunley to *OTW*. "Note that this study was not randomized, thus some of the data was not as granular as we would like. We clearly believe that certain patients need to discharge to skilled nursing facility and rehab, so the message is not to have this paper be used for denial of care."

"It used to be 'one size fits all' and most adult spinal deformity patients would go to rehab. This is no longer necessary. The message is really to individualize each discharge and work more actively to see if the patient is able to be discharged safely home. That takes the surgeons being actively involved in these expectations starting before surgery during the surgical consultation. Setting these expectations with the patients and very importantly, the family as well, is crucial." — *EH*

Advertisement

REMEMBRANCES

Former Chairman of Malawi Orthopedic Overseas Dies at Age 94

Richard Joseph Kemme, M.D., former chairman of Malawi Orthopedic Overseas and orthopedic surgeon at the Greeley, Colorado Medical Clinic, passed away on Sunday, March 31, 2024, at the age of 94.

Dr. Kemme earned his medical degree at the St. Louis University School of Medicine in St. Louis, Missouri, and stayed to complete his orthopedic surgery residency at St. Louis University.

Dr. Kemme became the first orthopedic surgeon in central Colorado when he joined the Greeley Medical Center in Greeley, Colorado in 1961. As joint arthroplasty emerged as a practice during the 1960s and 1970s, Dr. Kemme became a joint arthroplasty pioneer in a service area that included, of course, Greeley, but also Boulder and surrounding communities.

Kemme was born on March 20, 1930, in Denver, Colorado, to Theodore and Sarah Kemme. An avid adventurer, he earned his pilot's license at the age of 15 while attending Regis High School in Denver and took up Nordic skiing in college at Regis University.

He was also a businessman and a philanthropist. He developed and owned 270 affordable apartment units in Greeley and helped found the Greeley Area Chapter of Habitat for Humanity in 1978. He served on the board and served as president for a one-year term.

After retiring from his surgical practice, for 25 years he worked with Malawi Orthopedic Overseas, an orthopedic training program in Malawi, Africa. For 12 of those years, he served as chairman. In 1994, he was honored by the White House for his work in Malawi.

In 1994, he also chaired the Northern Colorado Medical Center Foundation and was instrumental in the building of the Monfort Children's Clinic.

Kemme was preceded in death by his wife, Mary, his parents and his siblings Theodore Kemme, Marie Helene Raleigh, and Kathleen Raleigh.

He leaves behind his children Mary Pat, Sarah, Doug, Frank, Kathleen, and Tom as well as nine grandchildren and two great grandchildren. — *TR*

Wooster Orthopaedics' Michael Knapic Dies Unexpectedly at 55

Michael Steven Knapic, D.O., a beloved physician at Wooster Orthopaedic & Sports Medicine Center for 24 years passed away unexpectedly on March 15, 2024, while golfing with his wife. He was 55.

Dr. Knapic specialized in general orthopedics, adult joint reconstruction, and sports medicine. He was board certified by the American Osteopathic Board of Orthopaedic Surgery. He earned his Doctor of Osteopathy at the Ohio University College of Osteopathic Medicine in Athens, Ohio.

Dr. Knapic's medical training included internships and orthopedic surgery residency at the Ohio University College of Osteopathic Medicine in Athens and at Doctors Hospital of Stark County in Massillon, Ohio.

He was a member of the American College of Osteopathic Surgeons, American Osteopathic Association, Ohio State Medical Association and Wayne County Medical Society. He also helped found the Wooster Ambulatory Surgery Center.

Upon his passing his colleagues wrote, "A beloved physician and friend to all in our community, especially to his peers and coworkers, Dr. Knapic served WOSMC and his patients for 24 years and is an irreplaceable loss to us all."

Kathy Rakovec, Knapic's clinical manager and close friend described him as "a great person, friend" and said he had a "heart of gold." She added, "Mike had his hands in so many different things. It was amazing. You can't replace him whatsoever."

Knapic was born on January 2,1969. He and his wife of 32 years first met when they were five years old when they were the ring-bearer and flower girl in a wedding. By age 12, they were "boyfriend and girlfriend." Together they raised two sons Trevor and Garrett and a daughter Hannah.

In 2017, Knapic suffered a stroke, but made a complete recovery and was able to return to his practice.

Besides his wife and children, he also leaves behind his mother, three sisters and many nieces, nephews and great nieces and nephews. He will also be missed by his mother-in-law Sharon and sister-in-law Pam Chipps. — *TR*

Jack Sewell Cooper, M.D. of Miami Dies at Age 85

Jack Sewell Cooper, M.D., military veteran and former chief medical officer of Doctor's Hospital in Miami, Florida, passed away on March 31, 2024, in Miami at the age of 85.

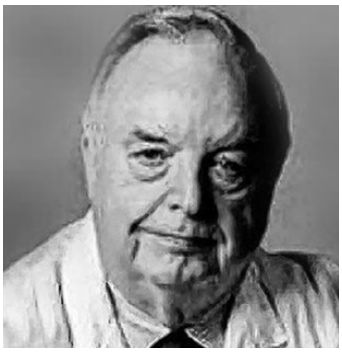
Dr. Cooper knew from a young age that he wanted to be a doctor, and the dream became a reality in 1965 when he completed his medical degree from the University of Virginia School of Medicine.

Dr. Cooper completed an internship at Jackson Memorial Hospital in Miami and then completed his residency in orthopedics and rehabilitation at the University of Miami School of Medicine. He also served as a clinical assistant professor there.

During his tenure at the Doctor's Hospital in Miami, Florida, he served in various leadership roles, including president of the medical staff, and chief medical officer.

Cooper was born on January 26, 1939, to Jack Ellis and Mary Ruth Cooper. He graduated from Appalachia High School in Appalachia, Virginia in 1957.

"Jack was diagnosed with polio when he was in high school which reinforced his desire to become a doctor. He guided his family and patients through broken bones, replaced knees and joints, shoulder injuries, and surgeries," his family wrote.



In between his training for orthopedic surgery, he served in the United States Navy Corp. for four years.

When Dr. Cooper wasn't in the operating room, he enjoyed woodworking, photography, and spending time on his boat swimming and deep-sea fishing.

Cooper was predeceased by his parents, his grandmother, Doni Sewell, and three brothers, Joe Cooper, Ben Cooper, and Tom Cooper.

He leaves behind his wife Debbi, his son Mark, and his granddaughter Kaylynn Lee. He will also be missed by his sister Doni Cooper Duckett, brother Sid Pat Cooper and many nieces and nephews. — *TR*

Michael Eugene Ralston, M.D., Department Chair, Dies at 75

Michael Eugene Ralston, M.D., FACS, former chair of Mount Carmel East Hospital in Ohio and a well-respected orthopedic surgeon in Indianapolis, Indiana, passed away on March 30, 2024, in Indianapolis at the age of 75.

Dr. Ralston earned his medical degree from The Ohio State University College of Medicine and completed his general surgery residency at the University of Florida in Gainesville from 1974 to 1977.

Afterwards, he moved to Missouri to complete his residency in orthopedic surgery at the University of Missouri in Columbia from 1977 to 1981. Dr. Ralston then completed a fellowship in total joint replacement at The Ohio State University Affiliated Hospitals.

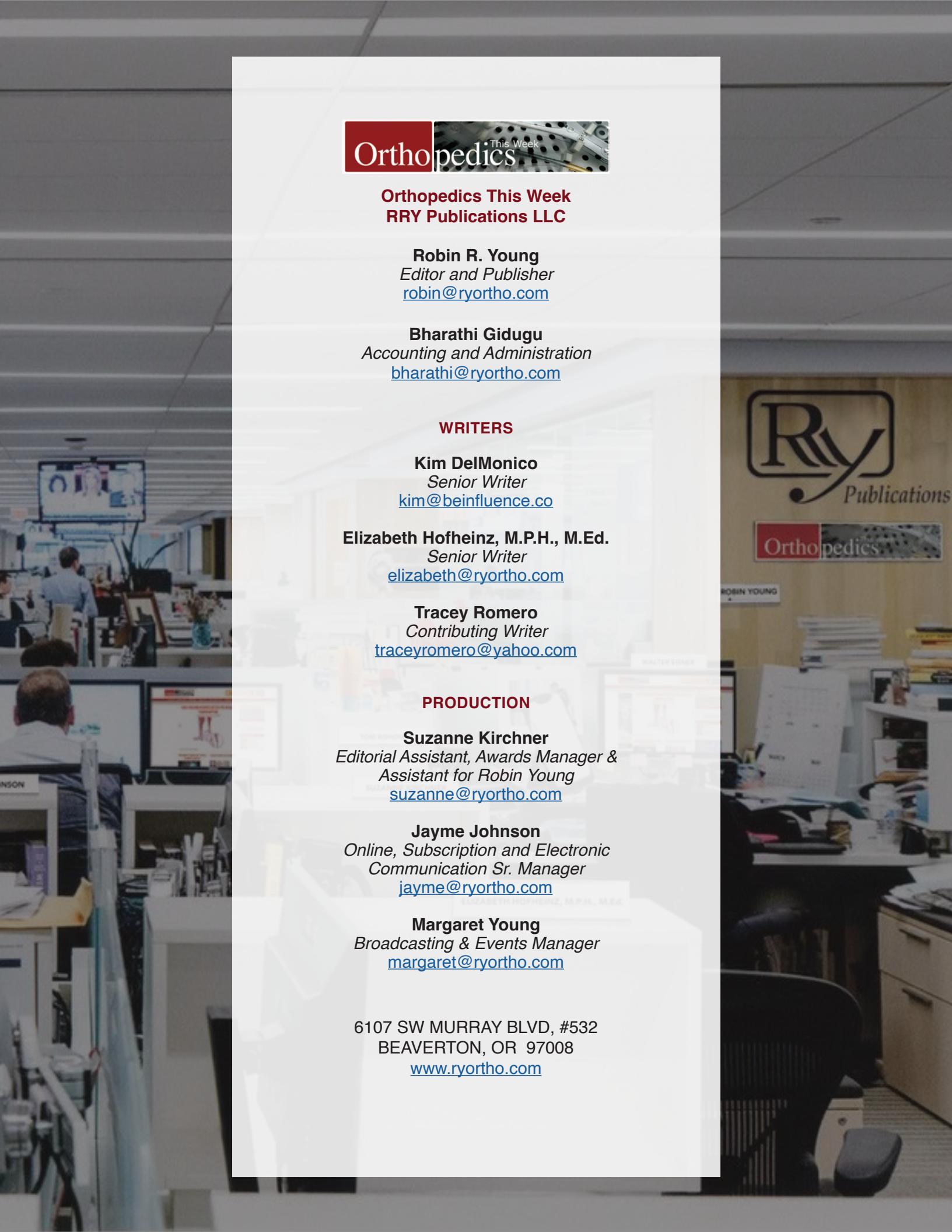
Ralston was also a fellow in the American College of Surgeons and in the American Academy of Orthopaedic Surgeons.

He served patients at Mount Carmel East Hospital and St. Ann's Hospital in Columbus, Ohio, and at the Franciscan Health System in Indianapolis.

Ralston was born on October 8, 1948, in Van Wert, Ohio, to the late Dorothy Ralston and Myron "Mike" Ward Ralston. He grew up in Van Wert and graduated from Van Wert High School in 1967. He then attended The Ohio State University for his undergraduate and medical degrees.

Ralston was a devoted family man and very much involved in his community. He was a member of the Sons of the American Revolution, First Families of Ohio, The Military Order of The Loyal Legion, and the Society of the Descendants of Washington's Army at Valley Forge.

He is survived by his wife Mary Ann and his children Elizabeth Clark and Geoffrey Ralston as well as his brothers and their families and many nieces and nephews. — *TR*



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