VOLUME 20, ISSUE 10 | MAY 21, 2024

Orthopedics This Week

WEEK IN REVIEW

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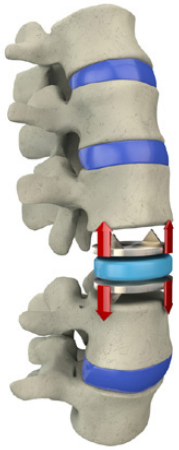
8 Landmark TDR Study: 2,141 Patients, 20-years >> The Texas Back Institute (TBI) team – enrolled 2,141 patients and collected preop data over the course of 20 years (average per patient, 6.55 years). This is a remarkable and immensely valuable study.

10 First-of-Its-Kind Med-Tech Incubator Launched >> Ever have a bright idea for a better retractor, implant, procedure—you name it—but needed engineering, financial and/or operational help to get from step 1 to 100? A new firm, named "pitch sink," aims to make that physician inventor's journey easier and more likely to succeed.

ONKOS SURGICAL



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: Nice rebound for most orthopedic and spine equities. But it was the overall market tide that lifted the MSK boats this past month. Will the FED ease rates? What about inflation? The Bearish analysts seem to be throwing in the towel in face of relentless buying. But that's often the mark of a frothy market. We're probably not there yet. Driving this market is the sense that we're in the midst of another major technology wave. One which will affect most all industries. Including, naturally, MSK.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Pacira Biosciences	9.05%	15.13%	PCRX missed EPS estimates by 17% BUT priced a $250 mililon convertible bond deal—and the stock is up 15% in 30 days. Why? There's an innovation surge in pharma and PCRX has ideas.
2	4	Smith & Nephew	10.06	9.07	Smith and his nephew reported that sales of orthopedic products in Q1 rose 4.4%, sports med + 5.5%. In the U.S., SNN's hip and knees are struggling. #2 on the Power Rankings based on value.
3	1	Globus Medical	12.74	25.78	Big price jump as analysts cheered the Q1 report. Sales up 120% (due to NUVA purchase). GAAP loss was $7.1, but EBITDA was $167 mililon. #3 this week based on valuation—getting more expensive.
4	5	Medtronic	19.17	8.65	MDT reporting trailing 12 months results this week or next. Wall Street expects down earnings and sales. But as 6th cheapest equity in the Power Rankings with a very nice dividend, #4 this week.
5	9	Orthofix	(8.51)	15.38	Nice jump for OFIX as the new management team takes shape and the company starts to flex muscles. For Q1, sales up 7.7%, spine alone is up 16%. Still GAAP losses, but EBITDA was $8 million.
6	6	Conmed	12.24	2.69	Decent Q1 numbers, sales up 5.7% year-over-year and GAAP earnings were a whopping $0.63 vs $0.06 last year. On an adjusted basis, earnings up 20%. Very good value.
7	8	Johnson & Johnson	19.22	6.82	DePuy Synthes posted up 5.8% y/y sales growth, almost double Wall Street's expecations. Hips and knees were standouts, growing 9.7% and 10.3%, respectively. Spine and trauma, less so at +2% each.
8	7	Zimmer Biomet	19.31	(0.92)	Kind of ho-hum results for the first quarter. Sales overall up 3.2% (4.4% constant currency). Hips were notably weak and U.S. overall was tough. OUS was the one bright spot.
9	10	Integra LifeSciences	17.32	(13.78)	Yes, getting cheaper, but the value remains. IART reminds me of the old Zen Koen: Water Flows, River Stays. Today's negative news is just water. The value remains.
10	NR	Bioventus	4.34	35.74	With a price jump like this in 30 days, how can BVS not be on the Power Rankings? At these prices, BVS is STILL 5th cheapest equity in ortho. More upside possible.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	SINTX Technologies	SINT	$0.09	$10	127.88%
2	Bioventus	BVS	$6.38	$508	35.74%
3	MicroPort Scientific	0853	$0.91	$1,665	30.39%
4	Globus Medical	GMED	$64.40	$8,698	25.78%
5	Orthofix	OFIX	$15.00	$563	15.38%
6	Pacira Biosciences	PCRX	$30.82	$1,435	15.13%
7	ZimVie	ZIMV	$17.02	$464	11.02%
8	Smith & Nephew	SNN	$26.09	$11,406	9.07%
9	Medtronic	MDT	$85.92	$114,087	8.65%
10	Medacta	MOVE	$133.48	$2,670	8.12%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Dynatronics Corp	DYNT	$0.42	$2	-27.86%
2	Integra LifeSciences	IART	$27.54	$2,170	-13.78%
3	AxoGen	AXGN	$6.04	$264	-12.97%
4	Alphatec Holdings	ATEC	$11.05	$1,546	-11.67%
5	Xtant Medical Hldgs	XTNT	$0.72	$94	-8.20%
6	Nevro Corp	NVRO	$11.40	$419	-7.24%
7	Aurora Spine	ASG.V	$0.21	$15	-5.35%
8	SI-BONE, Inc	SIBN	$14.92	$615	-2.04%
9	Anika Therapeutics	ANIK	$25.40	$377	-1.13%
10	Zimmer Biomet	ZBH	$120.18	$24,724	-0.92%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$153.40	$372,169	19.92
2	Medtronic	MDT	$85.92	$114,087	20.36
3	Pacira Biosciences	PCRX	$30.82	$1,435	25.09
4	Zimmer Biomet	ZBH	$120.18	$24,724	26.21
5	ConMed	CNMD	$74.72	$2,301	28.27

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Xtant Medical Hldgs	XTNT	$0.72	$94	142.07
2	Globus Medical	GMED	$64.40	$8,698	56.11
3	Medacta	MOVE	$133.48	$2,670	52.06
4	Smith & Nephew	SNN	$26.09	$11,406	43.37
5	Stryker	SYK	$334.68	$127,496	34.63

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Smith & Nephew	SNN	$26.09	$11,406	-5.42
2	ConMed	CNMD	$74.72	$2,301	1.16
3	Medacta	MOVE	$133.48	$2,670	1.87
4	Pacira Biosciences	PCRX	$30.82	$1,435	2.59
5	Stryker	SYK	$334.68	$127,496	3.09

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Xtant Medical Hldgs	XTNT	$0.72	$94	7.10
2	Medtronic	MDT	$85.92	$114,087	5.85
3	Integra LifeSciences	IART	$27.54	$2,170	5.09
4	Johnson & Johnson	JNJ	$153.40	$372,169	3.81
5	Zimmer Biomet	ZBH	$120.18	$24,724	3.72

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Dynatronics Corp	DYNT	$0.42	$2	0.06
2	Aurora Spine	ASG.V	$0.21	$15	0.75
3	Orthofix	OFIX	$15.00	$563	0.75
4	Nevro Corp	NVRO	$11.40	$419	0.98
5	Bioventus	BVS	$6.38	$508	0.99

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Stryker	SYK	$334.68	$127,496	6.22
2	Globus Medical	GMED	$64.40	$8,698	5.55
3	Medacta	MOVE	$133.48	$2,670	5.23
4	OrthoPediatrics Corp	KIDS	$32.02	$763	5.13
5	SI-BONE, Inc	SIBN	$14.92	$615	4.43

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

New Implant Coating Destroys 99.999% Bacteria – The New Standard

BY ROBIN YOUNG

On Friday, April 5, the FDA granted De Novo authorization to a new standard in antibacterial technology.

The new technology, being brought to market by New Jersey-based Onkos Surgical, covered by 27 patents and tested in 63 studies, obliterates 99.999% of both gram-negative and gram-positive bacteria that land on an implant surface.

Several authors and researchers have described "the race to the surface" theory which characterizes the contest between the body's natural healing response and the potential for microbial colonization on the surface of an implant.

With this announcement, that race to the surface, by virtue of Onkos Surgical's technology, is tilted 99.999% against bacteria commonly found in the OR.

Onkos Surgical announced this groundbreaking news on April 5 and *OTW* had the opportunity to interview Onkos CEO and Co-founder Patrick Treacy, and Chief Commercial Officer Sean Curry shortly after their announcement.

"We'd been looking at anti-bacterial technologies for a very long time. We wanted to find a technology that would address bacterial contamination but not contribute to bacterial resistance. Also, we wanted to find a technology that did not elute and that could be considered a Class II medical device regulatory pathway," said Patrick Treacy.

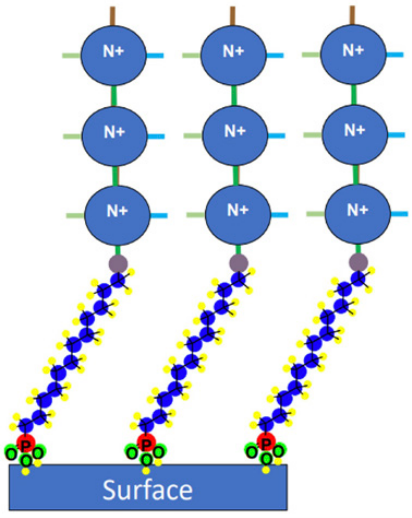
Source: Shutterstock and Onkos Surgical

Onkos and Orthobond Partnership

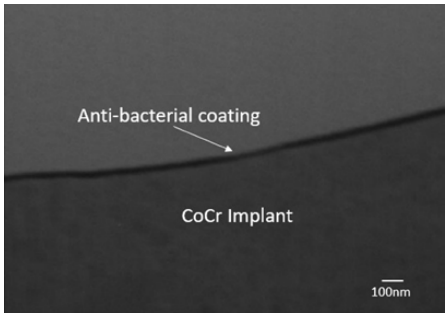
Treacy and his team found this technology at New Jersey-based Orthobond Corporation. "The fundamental technology came from intellectual property spun out of Princeton University and Orthobond had been advancing the platform. Throughout this process, Orthobond has been a great partner to work with," recalled Treacy. Onkos became Orthobond's technology partner.

"Onkos has an exclusive license with Orthobond for musculoskeletal oncology, pelvic reconstruction and modular revision implants," said Curry. "This field of use is particularly valuable in patients with bone loss due to tumor, trauma, and revision procedures where there is a higher rate of complication due to sickness and prolonged procedural time."

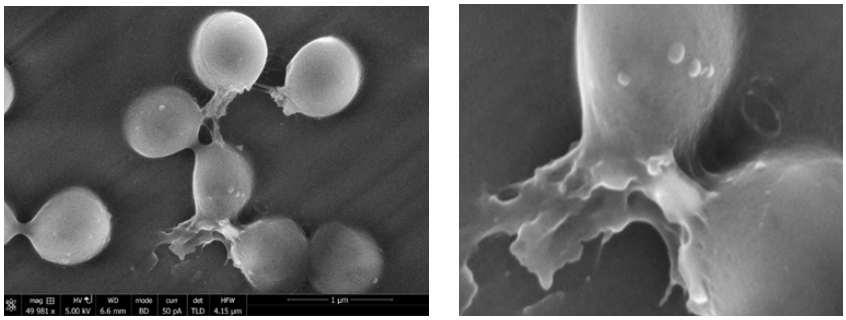
Onkos developed applications of the technology to their products using translational research and preclinical data to support their own De Novo application. The technology covalently



Schematic showing the chemical structure of the quaternary ammonium compound with positively charged nitrogen ions. / Source: Onkos Surgical



Scanning Electron Microscope image of a cross sectioned CoCr implant with the quaternary ammonium coating



CoCr Surface Treated with Onkos Technology, bacteria with disrupted cell wall

Source: Onkos Surgical

bonds an anti-bacterial compound to an implant's surface—effectively making the implant itself anti-bacterial.

"Covalent bonding is effectively permanent bonding to the implant. Our anti-bacterial technology essentially becomes an integral part of the implant. This formulation of the coating creates a polymeric chain and on the end of that chain we attach quaternary ammonium. All of this happens at the nanoscale," said Treacy.

"The coating is about 70 nanometers thick. Human hair is about a hundred thousand nanometers. Extremely thin but devastatingly effective against any bacteria that lands on the implant surface. When bacteria come into contact with this coating, its cell walls disrupted, and the bacteria die." *(See table above.)*

Onkos Surgical

When Patrick Treacy and Tony Koblish founded Onkos in 2015, they made

complex orthopedic problems—revision and limb salvage surgeries—the target of their research and product development. "When we started Onkos, we did some research that put a spotlight on addressing three key areas of innovation:

1) reducing procedural complexity

2) advancing the value of personalization in complex procedures and

3) addressing clinical challenges.

That same data pointed to unmet needs in reattaching soft tissue implants, aseptic loosening, and bacterial contamination.

Onkos has demonstrated a cadence of innovation over the past several years using new technologies to address soft tissue reattachment to implants and address aseptic loosening, which are common modes of implant failure.

With the April 2024 announcement, Onkos dramatically took a major step forward in its third major innovation goal—bacterial contamination.

Bacterial Reduction at the Implant Surface

"Bacterial contamination is a complex, multifactorial, and multivariate problem. Surgeons and staff have struggled over the years to reduce bacterial contamination in the operating room—double gloving, draping, gowning, laminar flow, ultraviolet lights, reducing traffic, skin prep, amongst others. And yet, despite all that, the problem of bacterial contamination in the operating room remains," explained Treacy.

Onkos's anti-bacteria coating, which have now been authorized for commercial sale by the FDA, are indicated for reduction of bacterial contamination on the implant in the operating room at the time of surgery prior to implantation.

FDA De Novo Authorization and 63 Studies

A De Novo designation means that the device is a first-of-its-kind.

In FDA terms, it's a device for which there is no predicate. Furthermore, the FDA has also determined that this novel medical device provides "reasonable assurance of safety and effectiveness for the intended use." (Source: FDA).

This work is groundbreaking. Since the FDA launched its De Novo program in 1997, only 9 orthopedic implants have received De Novo authorization. This technology represents the 10th De Novo authorization. By contrast, approximately 12,000 orthopedic devices received 510(k) decisions during the same period of time.

"We worked closely with the Agency. The technology is regulated as a Class II medical device", explained Treacy. "The data generated to support this De Novo submission is in many ways on par with what is required for a PMA [pre-market approval], with one exception: we were not required to do human clinical trials. Our team completed 63 distinct studies to support the safety and efficacy profile of the technology. Several of those studies were novel and required scientific breakthroughs to achieve the desired results. We achieved a lot of 'firsts' in the process," said Treacy.

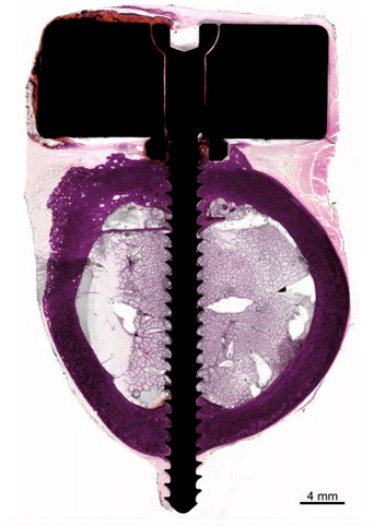
This technology is not a drug; the implant is classified as a device that leverages a proprietary coating to reduce bacterial contamination. "With the global concern of the healthcare community regarding the development of resistant organisms, it was crucial to support antibiotic stewardship in the forefront of the technology development," explained Treacy.

Cross sectional histology image of an antibacterial coated Onkos surrogate implant and screw demonstrating bone and soft tissue apposition in an ovine femur. / Source:Onkos Surgical

"To validate that the technology did not create bacterial resistance, Onkos and Orthobond developed highly sophisti-

In *OTW*, we've covered Onkos's remarkable journey so far.

1. https://ryortho.com/breaking/onkos-surgical-fda-clearance-adds-options-to-limb-salvage-system/
2. https://ryortho.com/breaking/onkos-acquires-system-to-treat-pediatric-bone-cancer-patients/
3. https://ryortho.com/breaking/onkos-launches-personalized-instrumentation-trays/
4. https://ryortho.com/breaking/onkos-surgical-launches-ortho-oncology-platform/



Cross sectional histology image of an antibacterial coated Onkos surrogate implant and screw demonstrating bone and soft tissue apposition in an ovine femur. / Source:Onkos Surgical

cated testing models to validate that the technology not only killed bacteria but did not lead to resistance over time. The studies we conducted demonstrated that gram-negative and gram-positive bacteria exposed to the surface, through multiple generations, did not show any evidence of increased resistance to the surface. Further, these bacteria, over the course of the multiple generations, did not demonstrate any resistance to multiple classes of commonly used antibiotics."

Onkos will be introducing its new anti-bacterial coated implants later in 2024 starting with the ELEOS™ Limb Salvage System and the company will proliferate it across its entire portfolio of implants.

Next Steps

The Onkos team is, understandably, excited about the FDA's authorization and the promise the technology holds for patients. "With this technology, we've achieved something that nobody else has in the history of orthopedics and multiple surgeons have told us this could be one of the most meaningful advancements in orthopedics over the last 30 years," said Patrick Treacy.

Onkos is now scaling up manufacturing from laboratory scale to full production. Surgeons should expect to see the ELEOS™ Limb Salvage anti-bacterial coated implant by the end of 2024.

For more information: https://onkos-surgical.com/. ♦

Landmark TDR Study: 2,141 Patients, 20-years

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

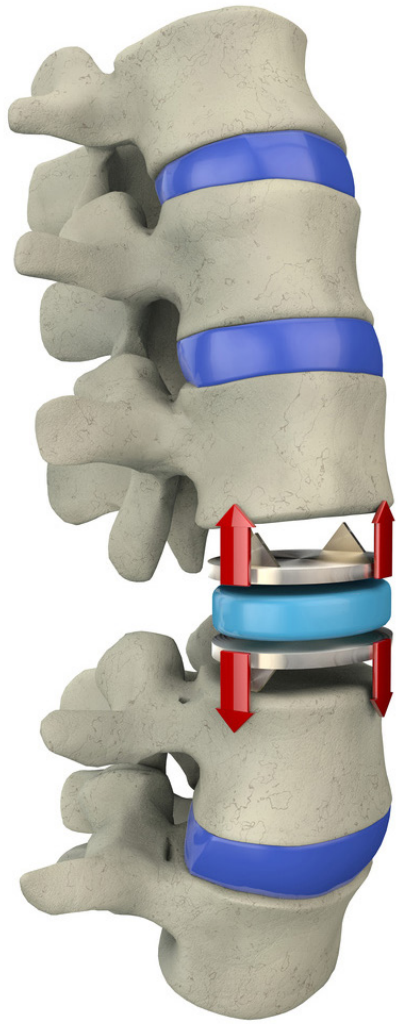
Since 2000, yes, more than two decades ago, Texas Back Institute surgeons have been treating spine surgery patients with total disc replacements (TDR). This is, frankly, the best longitudinal data from THE top disc arthroplasty center in the United States, if not globally.

This data, this remarkable study, "Lumbar Total Disk Replacement Device Removals and Revisions Performed During a 20-Year Experience with 2141 Patients," appears in the May 15, 2024 edition of *Spine*.

The Texas Back Institute (TBI) team—notably Richard Guyer, M.D. and Jack Zigler M.D. and Scott Blumenthal M.D.—enrolled 2,141 patients and collected pre-op data over the course of 20 years (average per patient, 6.55 years). This is a remarkable and immensely valuable study.

The study's team enrolled 2,141 patients and followed them for, on average, 78.6 months or 6.55 years.

What did they find? Extraordinarily low rates of revision or removal. Of 2,141 patients, a mere 1.26% (27) returned for implant revision or removal—mostly for removal (only 3 representing 0.14% of the total returned for a revision of their implant.



Source: Texas Back Institute

As study co-author Dr. Richard Guyer explained to *OTW,* "I think the most important finding of this paper is the fact that the longevity of the lumbar artificial disc far exceeded what we thought when we first started doing these over 24 years ago (first one being done in March 2000). We used to tell patients—much like total hips and total knees—that we were hoping to get 10 years out of these discs before a revision. And then they kept going and going. With our 20-year follow up we had a 1.2% revision rate which included 40% of them attributed to our learning curve of the 1st 25 cases of each of the three primary surgeons (myself, Dr. Scott Blumenthal, and Dr. Jack Zigler) giving less than a 1% revision rate."

The principal cause of removal was migration and/or loosening.

"Repeat anterior exposure is obviously very, very challenging and it's one that

we try to avoid unless there are no other alternatives," said Dr. Guyer, fellowship director and co-director of the Center for Disc Replacement at TBI. "For example, if there is infection or in a very, very rare event, a fracture at the replacement level, we may have to carry out a revision anterior exposure. One needs to have a very experienced anterior access surgeon because of the scarring of the great vessels that is the aorta, and more importantly, the vena cava."

"Special precautions and pre-op imaging studies are needed to help make this surgery as safe as possible. At L5/S1 a revision exposure is possible and a little bit easier than L4/5, but it is still fraught with difficulty due to the scarring of the vessels. In general, if there are not mitigating circumstances requiring an anterior approach, we will utilize a posterior fusion depending on the indications."

"The three revisions were for core repositioning (technique error), device repositioning after displacement, and core replacement due to wear/failure. With respect to timing, 37.0% of removals/revisions occurred within one-month postimplantation. Of note, 40.7% of removals/revisions occurred in the first 25 TDR cases performed by individual surgeons. There was one significant vascular complication occurring in a patient whose TDR was removed due to trauma. This was also the only patient among 258 with ≥15-year follow-up who underwent removal/revision."

"This is consistent with Dr. Marney from France who found in his 21-year follow up a revision rate of less than 1%. When one looks at the data of the 20-year follow up with total hips and total knees the revision rates are 15% and 10%, respectively. What this proves to me is that the stresses on the lumbar disc are very different from the hips and knees and that we can safely tell our patients that unless there was a fracture from severe trauma or infection, which is extremely rare, the likelihood of them needing a revision at that particular disk level is very, very rare up to 20 years!"

"As further work, we need to continue to follow these patients and begin to look at different groups of patients as we have started to do. Such as, how do patients over the age of 60 fare? What are the ideal groups candidates? Previous surgery, etc. I recently presented on these topics at the International Society for the Advancement of Spine Surgery." ♦

First-of-Its-Kind Med-Tech Incubator Launched

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

Ever have a bright idea for a better retractor, implant, procedure—you name it—but needed engineering, financial and/or operational help to get from step 1 to 100?

A new firm, named "pitch sink", was officially launched on May 1, 2024, to make that physician inventor's journey easier and more likely to succeed.

According to pitch sink's (lower case) CEO and Founder Steven Flutie-Davis, pitch sink is a two-way talent marketplace which is a first-of-its kind medtech-focused collaborative platform dedicated to carrying early-stage ideas through the journey to market-ready solutions.

"Our goal is to transform how medical devices are developed by returning autonomy to physicians, independent innovators and lean startups," said Flutie-Davis to *OTW*. "pitch sink connects medical professionals and device innovators to industry leaders and investors, untangling the innovation process and allowing inventers to achieve maximum efficiency."

pitch sink's process is based on a platform of vetted consultants where ideas and feedback can be shared, ultimately resulting in an accelerated path from concept to reality.

Often, would-be entrepreneurs are reluctant to even get started given the daunting hurdles required to bring med-tech to market. "Throughout my career I've noticed several obstacles for surgeons wanting to develop a product", said Flutie-Davis, "and while a lot of the ideas are not necessarily very large concepts, these smaller projects sometimes make a larger impact on surgical procedures."

Courtesy of pitch sink

"If a physician wants to develop a product in the current environment, they have only a few options. One is to pitch their concept to whatever medical device company they can access…but 9 times out of 10 the company will use the 'slow no' concept, meaning it takes around four months to be told 'we love the concept, but we can't take that on board at this time.'"

"Alternatively, the surgeon can try to find a developmental agency and hope their concept fits. These agencies aren't typically easy to find, and they typically have a long response window from the initial inquiry."

One of pitch sink's key features is that it connects innovators to specific funding resources—specifically Physicians First Bancorp, Inc, a Des Moines, Iowa-based financing firm which offers loans and other resources (private banking, for example) for physician inventors.

"The landscape of physician reimbursement and overhead is changing, and we believe that by empowering physicians to take a more active role in the economics of their practices, we can drive positive, sustainable change," said Marty Nichols, co-founder of Physicians First

Bancorp, Inc., a 30-year medical device veteran.

Nichols, who began his career at DePuy Orthopedics, holds three patents in robotic-assisted surgery and collaborates with doctors to design and manage physician-owned outpatient surgical hospitals.

"Physicians, their patient relationships and hard work is the basis of most of the business verticals in MSK [musculoskeletal]," Nichols told *OTW.* "Our collaboration with pitch sink aligns perfectly with our mission, leveraging their innovative platform to give physicians the tools and opportunity to better capture the revenue they drive and need to thrive."

Funding, Logistics and Manufacturing

"Partnering with Physician First Bancorp was a strategic move to ensure physicians have all the necessary resources to develop their product from concept to commercialization," explained Flutie-Davis, "during the job flow process a physician will inquire about financing opportunities and will then be connected to Physicians First Bancorp, Inc., where they will receive access to a private banker to address any financial needs."

pitch sink is also creating a network of strategic partnerships across various sectors including finance, inventory management, and manufacturing. These partnerships are designed to ensure that innovators have access to all the necessary tools and resources at every stage of the development and commercialization process.

Finally, according to Flutie-Davis, "pitch sink also features a Physician Advisory Consulting Committee, which includes some of the leading minds in the orthopedic sector. This committee plays a crucial role in mentoring up-and-coming innovators and ensuring that all products developed through pitch sink meet the highest standards of efficacy and safety."

"With pitch sink, the future of medical device innovation is bright, and most importantly, it's in the hands of those who understand patient needs the most—our physicians." ♦

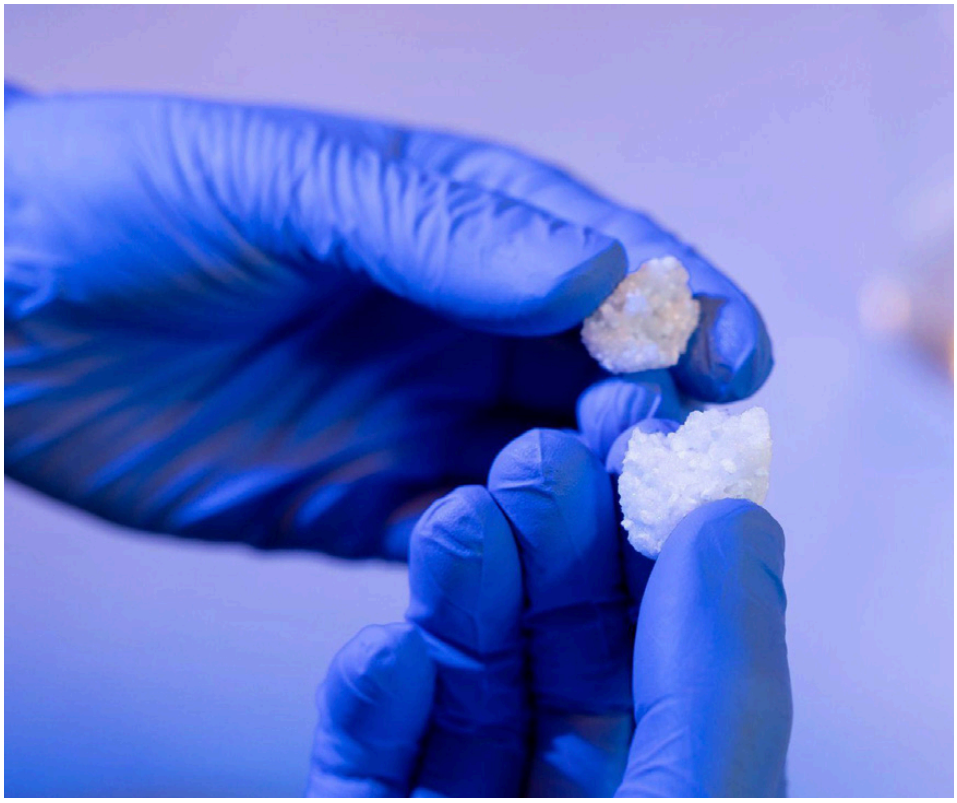
COMPANY

£9.2M Raised for a Time Release BMP2

UK-based orthobiologics company, Locate Bio Limited, a spin out from the University of Nothingham, (see The Interesting Turn Bmp2 Bone Grafting Is Taking) has successfully completed an oversubscribed £9.2 million funding round to advance the clinical study of its bone graft substitute, LDGraft, for spinal fusion.

Locate Bio is a privately held UK-based orthobiologics company. The funding will be used for a randomized study of LDGraft in single level anterior lumbar interbody fusion. The clinical trial is called RESTORE.

Locate Bio received U.S. Food and Drug Administration (FDA) breakthrough



LDGraft / Source: Locate Bio Limited

device designation for LDGraft last year. Per the press release, Locate Bio uses a "proprietary protein encapsulation method to deliver a powerful therapeutic protein called rhBMP-2" which is combined with an "osteoconductive scaffold in LDGraft."

OTW spoke with Locate Bio CEO John von Benecke about how LDGraft is different from other alternatives out there. Von Benecke told *OTW*, "Other rhBMP-2 products in development focus exclusively on the retention of the rhBMP-2 to various biomaterials, using a variety of attachment mechanisms. At Locate Bio, we recognize the delay in peak BMP-2 expression in bone healing as you move up the species order. It is much slower in humans than in mice. This has informed our development approach."

Von Benecke continued, "LDGraft is based on not only 'where' the rhBMP-2 is delivered but also 'when' it becomes available to bind to specific cell receptors and activate the signaling cascade, and our design intent is the improved biomimicry of that signaling process."

New and existing investors participated in the funding round including Mercia Ventures and BGF. Mercia Ventures is a venture capital investor that is part of Mercia Asset Management PLC. Established in 2011, BGF is the most active equity investor in the UK and Ireland.

In the press release, von Benecke commented, "This oversubscribed funding round underscores the significant investor confidence in the company's vision and the potential of LDGraft to become the most relied-on bone graft substitute globally." — *KD*

LEGAL

Ortho Association Sues Marriott, LA Rams, and NFL

Western Orthopaedic Association (WOA) has filed a lawsuit against Marriott for allegedly cancelling accommodations for the group's annual meeting to accommodate the Los Angeles Rams.

WOA is a medical professional organization with over 1,500 members comprised of orthopedic professionals in the Western United States. It filed suit in Maryland federal court and listed the following as defendants: Marriott Acquisition 2002, LLC t/a VEA Newport Beach; Marriott International, Inc.; Marriott International Hotels, Inc.; The Los Angeles Rams, LLC; and The National Football League.

For the past 87 years WOA has, according to the complaint, "hosted an annual meeting for its 350 members, orthopedic surgeons and their families and associates." These annual meetings are a venue for professionals to gather and exchange information as well as for professional development and continuing medical education.

In 2022, WOA purportedly entered into a sales agreement with VEA and Marriott for the use of VEA Newport Beach for the 2024 WOA Annual Meeting. The agreement purportedly provided WOA with over 1,300 rooms during a specific range of nights in August 2024 as well as other associated benefits and rooms related to the annual meeting.

In early December 2023, VEA allegedly notified WOA via telephone that VEA Newport Beach was no longer available for the August 2024 dates. VEA and Marriott purportedly "advised the WOA that the Newport Beach VEA was no longer available for the WOA Annual Meeting because the Rams had determined that the football team required use of VEA Newport Beach during the contracted time period of the Marriott Sales Agreement."

WOA is also alleging that the Rams and the NFL had knowledge of the original sales agreement. WOA claims that even with this knowledge "the Rams and the NFL, jointly and/or severally, demanded that the Marriott Defendants accom-

Source: Western Orthopaedic Association, Freepik and brgfx, Marriott, LA Rams, NFL

modate the Rams and the NFL instead, and provide VEA Newport Beach to the Rams and the NFL during the dates of the Annual Meeting set forth in the Marriott Sales Agreement."

WOA is claiming breach of contract against VEA and Marriott. WOA is claiming tortious interference with contractual relations against the Rams and the NFL. WOA is demanding compensatory damages in excess of $75,000.00 as well as other fees and costs.

As of the date of this article VEA, Marriott, the Rams, and the NFL have not yet filed a response.

According to the WOA website the 88th WOA Annual Meeting is scheduled for August 7-10, 2024. It is being held at the Hyatt Regency Huntington Beach in Huntington Beach, California. — *KD*

510(k) Clearance for a 'BowTie' SI Joint Fixation Device

This is a truly novel SI Joint fixation design.

And the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance to its "BowTie" designed sacroiliac fusion system.

According to the FDA 510(k) summary document, the novel sacroiliac joint (SI) fusion system is "intended to provide stabilization of the sacroiliac joint until fusion occurs." It includes an implant and a set of ancillary instruments. The implant is comprised of an "interarticular component, an iliac screw, and a transfix screw."

Again, referring to the FDA summary document, the BowTie is indicated for "sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis." When

BowTie SI Joint Fusion System / Source: SAIL Fusion, LLC

the system is implanted, "both the iliac and transfix screw components must be used."

It looks like a BowTie and it is brand named, BowTie™ SI Joint Fusion System. SAIL Fusion, LLC submitted the 510(k) application. According to the company, BowTie™ "is the first SI fusion technology to be based on long-standing, validated joint fusion principles established by the AO Foundation and is now the sole commercially available device that incorporates both intra-articular and transfixing components."

SAIL Fusion President and CEO David Jansen explained to *OTW*, "The BowTie device, with its trademark bowtie shape, was designed to help achieve the AO's other significant joint fusion principle of rigidly fixating the joint to provide a biologic environment favorable for bone growth. We reinforced its rigidity by adding both integrated iliac and transfixation screws to address the complex biomechanics of the pelvis."

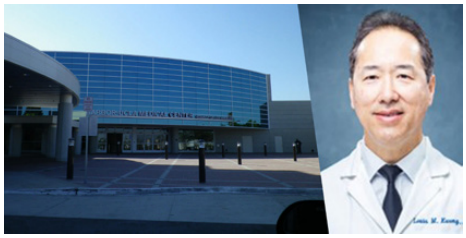
Jansen continued, "We are pleased that BowTie's multiplanar approach to fixating the joint also closely aligns with both the Transfixation and the recently established Intra-Articular CPT codes. This is an exciting time for surgeons, and especially for patients struggling with chronic SI joint pain."

The primary predicate device for BowTie's clearance was the SILO TFX MIS Sacroiliac Joint Fixation System by Aurora Spine, Inc. According to the 510(k) summary document, the device is substantially equivalent to the primary predicate device "in all facets including function, design, performance, material, and intended use." — *KD*

Harbor-UCLA Medical Center Fires Ortho Surgeon

Los Angeles County-based Harbor-UCLA Medical Center has fired the former head of its orthopedics department following a two-year investigation into misconduct allegations.

The hospital's investigation into the alleged misconduct by Louis Kwong,



Harbor–UCLA Medical Center and Louis Kwong, M.D. / Source: Wikimedia Commons and Biochemistry2016

M.D. began in the fall of 2021. The following year Dr. Kwong was placed on paid leave while the investigation was conducted. This allowed Dr. Kwong to purportedly receive more than a million dollars during the time he was not working.

There are a number of misconduct allegations that led to Dr. Kwong's termination, some of which involve alleged sexual misconduct over many years. Among these claims includes the assertion that Dr. Kwong would look at and commented on the genitalia of anesthetized patients.

In the discharge notice, Harbor-UCLA Medical Center Chief Medical Officer Griselda Gutierrez, M.D. reportedly said, "Your [Dr. Kwong] inappropriate, disparaging comments and actions were offensive, and created an uncomfortable, hostile, and demoralizing work environment for others."

The discharge notice also claims that Dr. Kwong failed to disclose that he was being paid by medical device company Zimmer Biomet. Dr. Kwong purportedly received more than $700,000 from Zimmer Biomet which was never disclosed to the county. In addition to the payments, Dr. Kwong also allegedly flew on the Zimmer Biomet private plane to the company's private headquarters.

Another issue that was highlighted in the discharge notice involved Dr. Kwong's failure to disclose his alleged employment with the Lundquist Institute, a nearby research facility. The termination notice reportedly said, "Zimmer Biomet and Lundquist not only compensated you for your work but provided you with financial incentives for business referrals, which created a clear conflict of interest since the Department had contracts with them. Your [Dr. Kwong] decision to hide your employment with these companies for 6 years demonstrates your propensity for dishonesty."

This matter is far from resolved. Dr. Kwong apparently disagrees with the decision to terminate his employment and recently filed an appeal with the Civil Service Commission.

In addition to his employment woes, Dr. Kwong is facing litigation involving his alleged misconduct. For *OTW*'s previous coverage of allegations against Dr. Kwong, see "LA County Ortho Surgeon Faces Sexual Misconduct Allegations." — *KD*

EXTREMITIES

FAI Journal Says 'No' to Learning Curve Studies

Source: Shutterstock

Foot & Ankle International senior editors have announced that the journal will no longer consider learning curve manuscripts for publication.

Foot & Ankle International is the official journal of the American Orthopaedic Foot & Ankle Society. The announcement appeared in a recent editorial entitled "The Fallacy of the 'Learning Curve.'" The editorial was authored by the following editorial board members: John T. Campbell, M.D.; George B. Holmes Jr., M.D.; Christopher P. Chiodo, M.D.; Thomas O. Clanton, M.D.; Ellie Pinsker, Ph.D.; Stefan Rammelt, M.D., Ph.D.; Robert A. Vander Griend, M.D.; and Charles L. Saltzman, M.D.

The learning curve is also known as a surgeon's attainment of expertise for specific procedures. The senior editors highlighted a number of reasons for their decision including those discussed below.

First, the senior editors looked at the "focus on surgical time as the main measure of proficiency." The editors discussed how this focus could be problematic because "surgical time

does not necessarily equate to surgical competence or to quality outcomes." Additionally, surgical time is a complex measure that involves countless variables. Other benchmarks used in learning curve studies were also seen as potentially arbitrary "such as predefined checklists of skills needed for proficiency."

Next, the senior editors emphasized that learning curve data is not generalizable across all practitioners. This means that data may not equally apply to all groups. For example, if the learning curve studies come from those with more familiarity to the new procedure (such as in an academic setting) it would not necessarily translate to surgeons outside of the realm of familiarity.

Finally, the senior editors found it problematic that many learning curve studies encourage case volume thresholds for surgical proficiency or technical expertise. Notably, where surgeons must have documented case volumes before being allowed to perform new procedures. They emphasized that this could potentially create a "Catch-22" whereby "surgeons cannot perform the procedures to attain the necessary experience." This could also potentially create legal risks if the thresholds are upheld.

The senior editors concluded by stating that "surgeons rightly strive for continual improvement and expertise rather than for 'good enough' thresholds defined by overly simplified or flawed methods." They emphasized that their decision was made with "the hope that all surgeons will strive for lifelong learning and continuous refinement of their surgical proficiency in the relentless pursuit of excellence."

In the press release, *Foot & Ankle International* Editor in Chief Dr. Saltzman commented, "The goal of a surgeon is to always get better—and that can be measured in terms of clinical outcomes."

Dr. Saltzman continued, "Each surgeon has the responsibility to review their own results rather than compare the number of cases they have done to some published paper with a conceptually flawed benchmark." — *KD*

PEOPLE

'Engineering' OA Treatment Lands $31M Research Award

The Advanced Research Projects Agency for Health (ARPA-H) has awarded up to $31 million to researchers at Washington University in St. Louis to support the development of non-surgical osteoarthritis treatment.

The award is part of the Advanced Research Projects Agency for Health's program for novel innovations for tissue regeneration in osteoarthritis (NITRO). The Advanced Research Projects Agency for Health is part of the U.S. Department of Health and Human Services. In 2022 it was created to enhance the government's ability to, per the press release, "accelerate biomedical and health solutions."

The research will be led by Washington University Mildred B. Simon Professor of Orthopaedic Surgery and Shriners Children's St. Louis Director of Research, Farshid Guilak, Ph.D. Dr. Guilak's research has focused on advancing therapeutics to prevent or reverse OA progression. The funding will enable a team of scientists to focus on, per the press release, developing "a single-injection treatment that promotes tissue regeneration and restores joints."

In the press release, Dr. Guilak commented, "Osteoarthritis has one of the greatest disease burdens of any disease in the world. But we have no drugs that can reverse the joint damage it causes."

Farshid Guilak, Ph.D. and Christine T. N. Pham, M.D. / Source: Washington University in St. Louis

Dr. Guilak continued, "This award is a moonshot initiative, funding high-risk projects with the goal of developing a single-injection treatment or even a cure for osteoarthritis. If successful, we could potentially affect the quality of life for millions of people and lessen the economic impact due to the billions of dollars spent treating pain caused by osteoarthritis."

The project will be driven by a multidisciplinary team focused on developing the single-injection treatment. The team's investigators will include the following: Christine T.N. Pham, M.D., the Guy and Ella Mae Magness Professor of Medicine and director of the Division of Rheumatology within the university's Department of Medicine; Hua Pan, Ph.D., an associate professor of medicine; Xiaoxia Cui, Ph.D., an associate professor of genetics; Lori Setton, Ph.D., the Lucy and Stanley Lopata Distinguished Professor and chair of the Department of Biomedical Engineering; and Erik Herzog, Ph.D., the Viktor Hamburger Distinguished Professor in Arts & Sciences in the Department of Biology.

The award will fund a team effort to "develop advanced nanoparticles intended to deliver snippets of genetic code into human joint cells and treat osteoarthritis with a single, yearly joint injection." In the press release, Dr. Herzog explained, "We are putting knobs on the cells that will allow the body to self-tune drug production according to the severity of the inflammation, degree of mechanical load and the time of day."

OTW had the opportunity to speak with Dr. Guilak about the award. Dr. Guilak explained that his team "was selected by ARPA-H for funding based on the innovation of our approach to develop a new treatment for osteoarthritis, and the potential to move it to clinical trials within five years."

Dr. Guilak continued, "The goal of this is study is to reprogram the cells in the knee joint to be 'smart,' meaning we will use advanced bioengineering methods to rewire their genes so that they automatically produce biologic drugs to fight pain and inflammation and regenerate the cartilage and bone in the joint that was lost to arthritis."

"The team is currently testing the ability of these cell reprogramming methods in the lab to show that they produce enough biological drugs on demand, whenever the cells sense inflammation or arthritic changes in the joint." — *KD*

REMEMBRANCES

Dennis Watkins Wise, M.D. Dies at Age 84

Dennis Watkins Wise, M.D., a former orthopedic surgeon with Winchester Orthopedic Associates in Winchester, Virginia, passed away on January 18, 2024, at his home in Winchester, Virgina at the age of 84.

Wise practiced orthopedic surgery for 40 years as a member of Winchester Orthopedic Associates. His son Tom joined the firm in 2000 and continues his father's legacy.

Before his retirement in 2014, Wise served thousands of patients at the Winchester Medical Center.

His family wrote, "His care for patients was given with compassion and a commitment to excellence and he felt rewarded each time he helped a patient feel better."

He received his medical degree from Cornell University Medical College in New York City in 1967 and then did his internship at New York Hospital Cornell Medical Center. While there he served as an assistant surgeon.

Dr. Wise completed his general surgery residency at the New York-Presbyterian Hospital Cornell Hospital and his orthopedic surgery residency at the Hospital for Special Surgery (HSS) also in New York City. After completing his orthopedic residency in 1973, he then did a hand surgery fellowship also at HSS which he completed in 1974.

Dr. Wise was born in 1939 in Greenville, Illinois, to Dale and Grace Watkins Wise. He spent parts of his childhood near Pittsburgh, Pennsylvania, and Warren, Ohio. His parents owned Wise Florists in Warren and he worked there as a teen until he went away to college.

He attended Howland High School in Warren and Wheaton College in Illinois, playing basketball for both schools. Wise continued his passion for sports by volunteering as team physician for both the Handley High School and James Wood High School football teams and for serving as chairman of the Winchester Parks. He was also team physician for Team USA at the Deaflympics from 1995 to 2009.

Wise leaves behind his wife of 62 years Kay, daughter Laura, sons Tom and Andrew and his two grandsons Gus and Sam. He is also survived by his daughter-in-law Mary Margaret, his brother and sister, and many nieces and nephews. He was preceded in death by his brother Jerry Wise, sisters-in-law Catherine Wise and Barbara Bergland, and brothers-in-law James Bergland, Richard Bergland and Tom Bergland. — *TR*

Holzer Medical Center Orthopedic Surgeon Edwin Hissa II Dies at 70

Edwin A. Hissa II, M.D., an orthopedic surgeon at Holzer Medical Center in Jackson, Ohio, passed away on Wednesday, April 17, 2024, at the age of 70.

Hissa practiced orthopedic surgery for 32 years before his recent retirement. He specialized in joint replacement, arthroscopy, sports medicine, adult reconstruction, and trauma. He earned his medical degree from the University of Cincinnati and did his surgical internship and orthopedic residency at The Cleveland Clinic in Cleveland, Ohio.

Hissa served patients at Cleveland Clinic's Hillcrest Hospital in Mayfield Heights, Ohio, and at Lake Hospital System in Painesville, Ohio, before joining Holzer in 2008. He also ran his own practice.

He returned to Holzer in 2012 and served patients at the Gallipolis and Jackson locations. He was a member of the American Academy of Orthopaedic Surgeons, the American Medical Association, Ohio Medical Association, and the Academy of Medicine in Cleveland.

Hissa was born on October 20, 1953, in Cleveland, Ohio. He spent his formative years in Burton, Ohio.

He most recently lived in Jackson and attended St. Helen Catholic Church in Newbury and Holy Trinity Catholic Church in Jackson.

Hissa is survived by his wife, Evelyn Woolman Hissa, his children Erin Cunningham, Edwin Hissa, Julia Hissa and his stepchildren, Thomas Enerva, Samuel Enerva and Joseph Enerva. He also leaves behind his sisters, Ann Humphrey and Alisa Humphrey, his brothers Michael Hissa and Mathew Hissa and his five grandchildren, nieces, and nephews. He was preceded in death by his parents Edwin and Joan Hissa and his brother Mark Hissa. — *TR*

Former Chief of Orthopedic Surgery at St. Luke's West Dies at 91

Roger L. Mell, M.D., 91, former chief of orthopedic surgery at St. Luke's West in Chesterfield, Missouri, and a well-respected leader in orthopedics, passed away on Sunday, April 14, 2024, in Kirkwood, Missouri.

Mell earned his medical degree from Washington University in Saint Louis, and then completed orthopedic surgery internships at Barnes Hospital, St. Luke's Hospital, Shriners Hospital, and the John Cochran Veterans Hospital.

Once his medical training was completed, he joined St. Louis Clayton Orthopedic Group from 1971 to 1979 and then started his own private practice in Chesterfield, Mell Orthopedics, Ltd, which later became Mell & Jones Orthopedics.

Mell was affiliated with St. Luke's West and served as chief of orthopedic surgery there from 1980 to 2005.

He served as president of Southern Medical Association, Washington University Medical Alumni Association, and St. Luke's Hospital Medical Staff Association.

He also belonged to the American Academy of Orthopaedic Surgeons, St. Louis Orthopedic Association, and the St. Louis Rheumatism Society.

Mell was born on March 19, 1933, in Bonne Terre, Missouri, to Myrtle Alice Mell and Henry Charles Mell.

He has three older siblings, and they all grew up in Farmington, Missouri, where their father owned the Mell's Hardware & Furniture store.

After graduating from Farmington High School, Mell initially embarked on an electrical engineering path. He earned a B.S. in Electrical Engineering from the University of Missouri College of Engineering in 1956 and worked as an electrical engineer at the Esso Oil Refinery in Baton Louge, Louisiana, after serving as a commissioned officer in the U.S. Air Force for two years, attaining the rank of First Lieutenant. He piloted the T-34, T-28, T-33 and trained in the F-86 D & L models.

After marrying his wife Joan White Mell, the couple moved to St. Louis, Missouri, so he could begin medical school. When Mell wasn't in the hospital, he was devoted to his faith as a member of Central Presbyterian Church. He was also a member of the St. Louis Club.

After he retired, he built and flew two experimental aircrafts: an RV-7 and an RV-12. Mell passed away just two weeks after his wife Joan did. They are survived by their four children, Mike, David, Julie, and Peter as well as their seven grandchildren and their great grandson. — *TR*

Beloved Fayetteville VA Orthopedic Surgeon Dies at 83

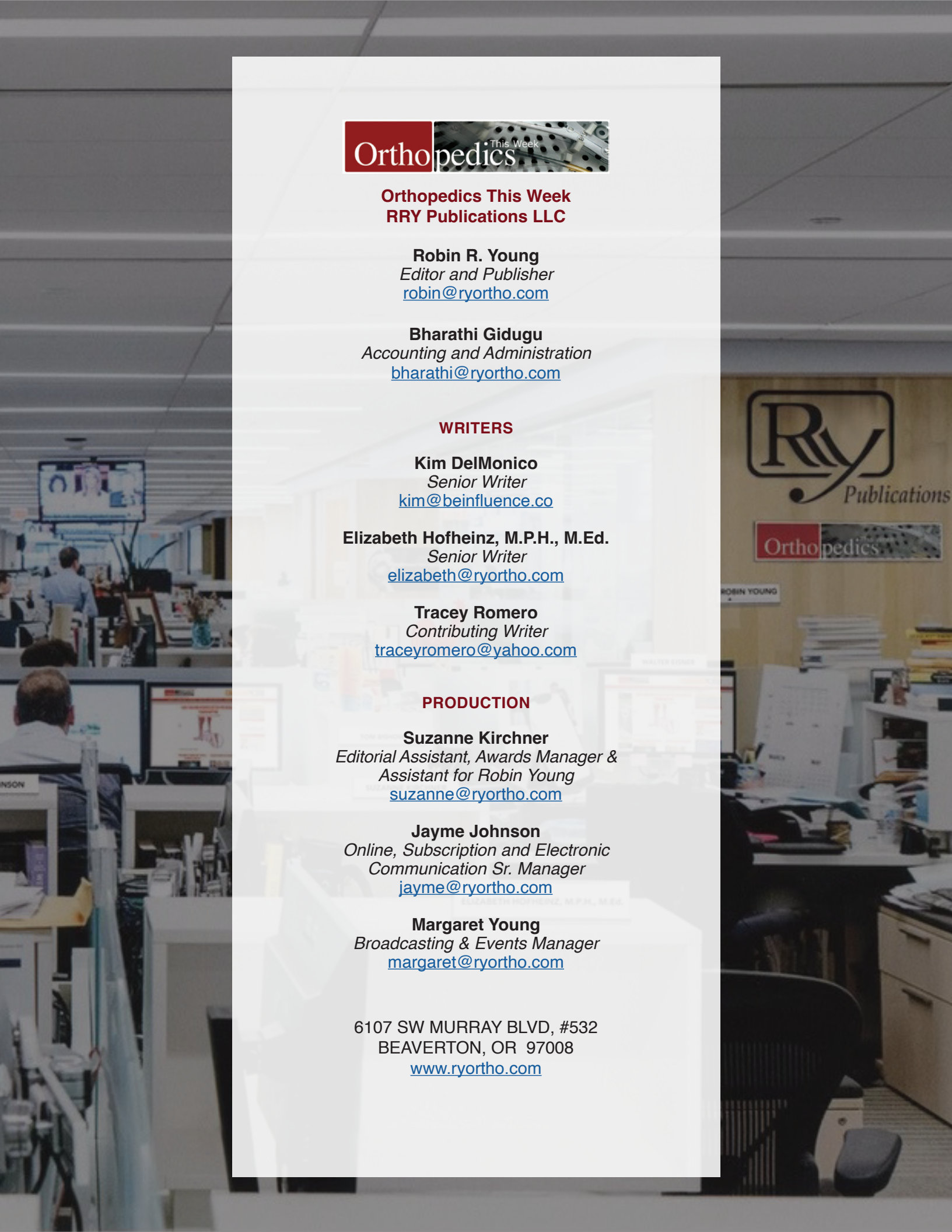
Paul Muenzner, M.D., who practiced orthopedic surgery in Wisconsin, Ohio, and North Carolina, passed away on April 13, 2024, at the age of 83 in Fayetteville, North Carolina.

Dr. Muenzner specialized in treating osteoarthritis, internal derangement of knee, intervertebral disc degeneration, scoliosis, and bunions. Muenzner earned his medical degree from the University of Kentucky Medical School in 1973. He completed an internship at Akron General Medical Center from 1973 to 1974, and did his orthopedic residency there as well.

Once he finished his medical training, he established a private practice in Superior, Wisconsin. He was the only orthopedic surgeon in the area. Later, he moved his practice to Dayton, Ohio, and after closing that one he continued to serve patients at the Veteran Hospital in Fayetteville, North Carolina. He retired in 2016.

Muenzner was born in Salem, Massachusetts, to Harriett and Henry Muenzner. He spent most of his childhood in Ashland, Kentucky, graduating from high school there in 1959. He earned his undergraduate degree from Dartmouth College in Hanover, New Hampshire, but didn't head straight to medical school.

Before deciding on a career in orthopedic surgery, he worked in the lab of Armco Steel in Ashland for five years. He is survived by his wife Elizabeth; his sister Elizabeth; his three sons, Chris, Pat, and Dave and his four grandchildren, Jamie, Zach, Patrick, and Erin. — *TR*



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