VOLUME 20, ISSUE 22 | DECEMBER 10, 2024

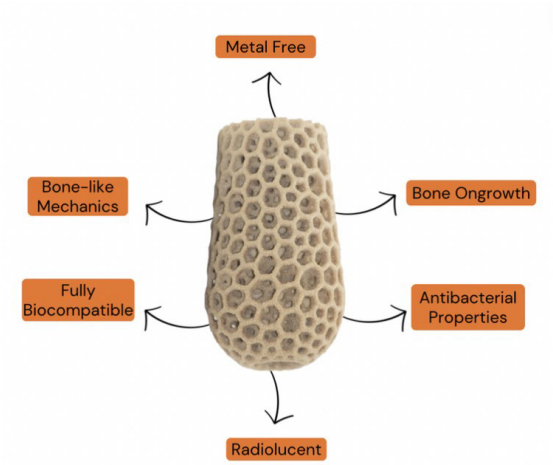
Orthopedics This Week

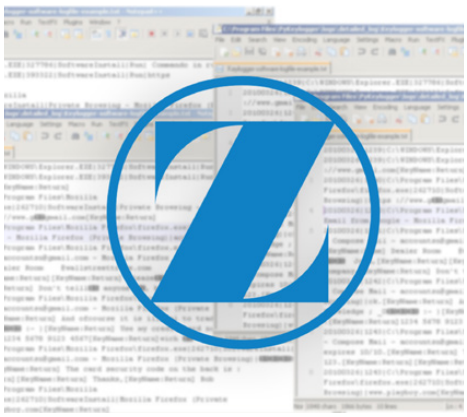
WEEK IN REVIEW

4 Metal vs PEKK – PEKK Wins, It's Not Close >> Time to take a long hard look at non-metal constructs? We're referring to PEKK, not PEEK. PEKK is antibacterial, a biomechanical twin to cortical bone, hypoallergenic, modifiable in the OR, and a friendlier implant than metal. Yes, it's time.

8 ASPN Issues SI Joint Pain Treatment Guidelines >> To put physicians on the same page regarding the diagnosis and treatment of sacroiliac (SI) joint pain and dysfunction, a multicenter team of researchers has developed a new set of guidelines.

10 Female Surgeons Breaking Through One Misperception at a Time >> It's almost 2025 and women still only make up about 7% of orthopedic surgeons across the U.S., according to the American Academy of Orthopaedic Surgeons (AAOS). Why is this? Women who are thriving in the field say that it has a lot to do with misperceptions and a lack of commitment to diversity on staff. When done right though, a diverse medical staff improves patient care.





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: For just the 4th time in a 100 years, equities logged 20%- plus returns for two years in a row, according to BofA research. The overall stock market is up 27% so far this year after rising 24% in 2023. But clouds are gathering in the form of inflation fears. The root cause is, in large measure, the looming probability of widespread Trump Tariffs. U.S. ortho and spine products dominate the global market. We are uniquely vulnerable to tariffs—whether placed on raw materials or finished products. Brick by brick, tariff's super charge inflation. In terms of equity valuations, higher costs without the ability to pass them along to insurance companies, et al., are a real problem for investors.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Pacira Biosciences	13.02%	9.05%	Not only the cheapest equity in ortho, but one of its best performers too. In news, PCRX expanding IP for Exparel, new patent granted in a new family of patents.
2	3	Orthofix	(10.99)	1.20	One of my most effective strategies when I was on Wall Street was to invest in companies who'd recently fired their CEOs. OFIX is up 76% in the last 12 months. Fits the pattern.
3	8	ConMed	12.22	(4.49)	Big jump this week for CNMD, solely on valuation. With the price drop, is now the 3rd cheapest ortho equity. Also, former CEO Harman retired last month, new CEO Beyer in charge.
4	5	Zimmer Biomet	20.70	(1.94)	Investors are willing to pay $21 for each $1 in ZBH earnings. If that seems high, SYK investors pay $41 for each $1 in SYK earnings. Will ZBH ever catch SYK?
5	1	Integra LifeSciences	6.60	(9.74)	IART was cheap when it was #1 in the Power Rankings, now it's even cheaper, by nearly 10%. Investors wonder, is this a falling knife? No, it's not. But investors need a proof point.
6	4	Globus Medical	18.72	0.74	GMED not-so-secret weapon is its steady flood of new products—most recently, the ExceliusHub Navigation system. Turning every OR into a digital cockpit.
7	6	Medtronic	19.17	(6.77)	MDT, like JNJ, is now perceived by institutional investors as a healthcare dividend stock—not as a supplier pushing innovative products for spine and other indications.
8	NR	Stryker Corporation	19.17	4.34	SYK's not cheap, yet, again, reported industry leading sales and earnings for Q3. Latest products: a better lighting platform and a better way to not lose sponges in the OR. Practical.
9	9	Smith & Nephew	19.00	3.59	Unfortunate news from SNN's plant, the former Richards Medical, in Memphis. 150 employees being laid off. Sign of the times? Perhaps. Cost pressures are affecting everyone.
10	NR	Bioventus	4.78	3.55	New management has done a stellar job stabilizing BVS and turning that operating profit margin positive. Where to now? Investors are buying for BVS.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Paragon 28	FNA	$10.03	$840	38.54%
2	SINTX Technologies	SINT	$3.73	$5	31.80%
3	Pacira Biosciences	PCRX	$19.27	$890	9.05%
4	Alphatec Holdings	ATEC	$9.63	$1,365	8.51%
5	Dynatronics Corp	DYNT	$0.16	$1	6.67%
6	Stryker	SYK	$385.02	$146,776	4.34%
7	Smith & Nephew	SNN	$25.36	$11,087	3.59%
8	Bioventus	BVS	$11.68	$948	3.55%
9	Orthofix	OFIX	$18.62	$712	1.20%
10	Anika Therapeutics	ANIK	$17.45	$256	1.04%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Nevro Corp	NVRO	$4.19	$157	-27.51%
2	OrthoPediatrics Corp	KIDS	$23.17	$561	-25.14%
3	Xtant Medical Hldgs	XTNT	$0.40	$56	-23.91%
4	Aclarion	ACON	$0.16	$2	-16.33%
5	SI-BONE, Inc	SIBN	$13.52	$567	-15.76%
6	Integra LifeSciences	IART	$24.10	$1,860	-9.74%
7	MicroPort Scientific	0853	$0.77	$1,417	-9.60%
8	Aurora Spine	ASG.V	$0.29	$23	-7.10%
9	Medtronic	MDT	$84.01	$107,725	-6.77%
10	Johnson & Johnson	JNJ	$149.31	$359,482	-4.67%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Pacira Biosciences	PCRX	$19.27	$890	13.88
2	Johnson & Johnson	JNJ	$149.31	$359,482	19.49
3	Medtronic	MDT	$84.01	$107,725	20.13
4	ConMed	CNMD	$72.24	$2,232	24.47
5	Zimmer Biomet	ZBH	$108.03	$21,506	26.21

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Xtant Medical Hldgs	XTNT	$0.40	$56	85.13
2	Globus Medical	GMED	$83.32	$11,345	57.02
3	Smith & Nephew	SNN	$25.36	$11,087	42.16
4	Medacta	MOVE	$124.96	$2,499	40.96
5	Stryker	SYK	$385.02	$146,776	37.26

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Integra LifeSciences	IART	$24.10	$1,860	-7.63
2	ConMed	CNMD	$72.24	$2,232	1.27
3	Pacira Biosciences	PCRX	$19.27	$890	1.28
4	Medacta	MOVE	$124.96	$2,499	1.47
5	Stryker	SYK	$385.02	$146,776	3.21

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Johnson & Johnson	JNJ	$149.31	$359,482	6.50
2	Xtant Medical Hldgs	XTNT	$0.40	$56	4.26
3	Zimmer Biomet	ZBH	$108.03	$21,506	3.82
4	Smith & Nephew	SNN	$25.36	$11,087	3.73
5	Medtronic	MDT	$84.01	$107,725	3.65

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Dynatronics Corp	DYNT	$0.16	$1	0.04
2	Nevro Corp	NVRO	$4.19	$157	0.37
3	Xtant Medical Hldgs	XTNT	$0.40	$56	0.62
4	Orthofix	OFIX	$18.62	$712	0.95
5	Aurora Spine	ASG.V	$0.29	$23	1.15

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Aclarion	ACON	$0.16	$2	22.69
2	Globus Medical	GMED	$83.32	$11,345	7.23
3	Stryker	SYK	$385.02	$146,776	7.16
4	Medacta	MOVE	$124.96	$2,499	4.89
5	Johnson & Johnson	JNJ	$149.31	$359,482	4.22

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

Metal vs PEKK – PEKK Wins, It's Not Close

BY ROBIN YOUNG

Not likely, right?

You can count on one hand how many base materials are used in orthopedic surgery—titanium, cobalt chrome, PEEK—with metal dominating, particularly for 3D printed titanium implants. And yet.

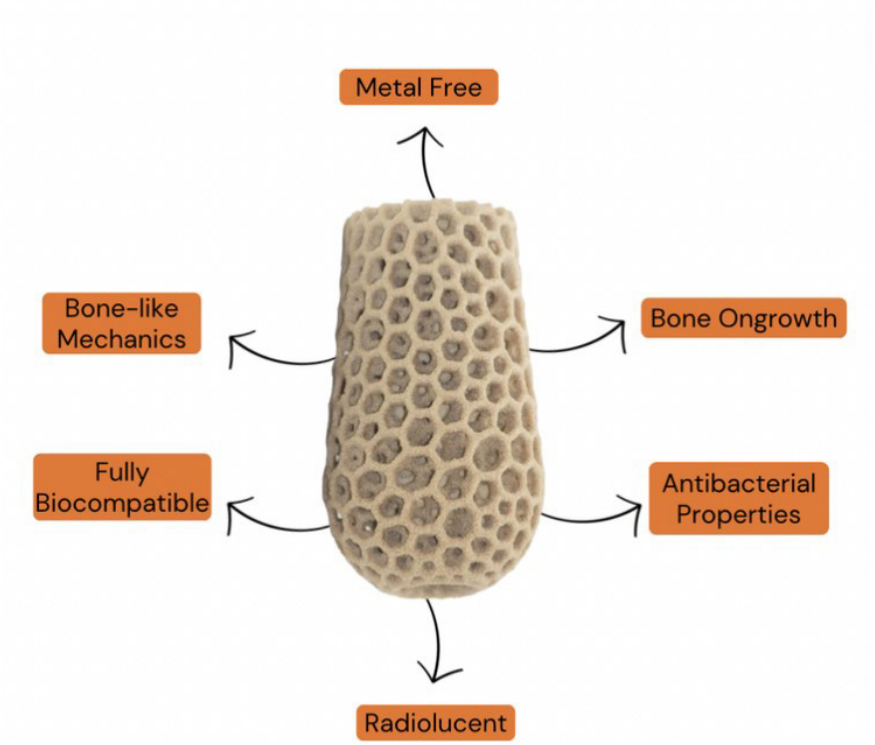
And, yet.

And yet, if there were a way to meet or exceed metal's performance and complex design innovation, most surgeons would take a long hard look at polymer constructs.

For five major reasons:

1. Metal complicates post-op visualization
2. Metal often leads to stress shielding and loosening
3. Metal implants cannot be modified by the surgeon in the O.R.
4. Some patients have an allergic response to metal
5. Biofilm formation and infection risk come with using metal

Which leads us to Scott Defelice's obsession.



Source: Oxford Performance Materials

Scott DeFelice's Obsession

An economist undergrad with a master's degree in marketing from the University of Strathclyde in Glasgow, DeFelice began his formal career in 1988 at Oxford Polymers, a Connecticut-based marketing and sales organization which sold engineering thermoplastics throughout the northeastern part of the United States. Eleven years after he joined Oxford Polymers, the company made a strategic decision to spin out a new company—Oxford Performance Materials (OPM) with Scott DeFelice as its new CEO. His charter? Develop a new line of polymers based on DuPont's polyaryletherketone (PAEK) family of thermoplastics. DeFelice's two-decade-long fascination with poly-ether-ketones took root.

If you stick 'aryl' between poly and ether, you get polyaryletherketone, or PAEK, which was originally designed to meet structural strength and performance requirements of the aerospace industry.

In the early 1980s, ICI (Imperial Chemical Industries) developed PEEK (polyetheretherketone), which was later spun out to become Victrex and its biomedical subsidiary Invibio. Today, PEEK is the most commonly used polymer for spinal implants.

DeFelice, however, was focused on another version of PAEK, one that changed the formula by doubling up on the 'ketone' to create a polyetherketoneketone or PEKK. PEKK was originally developed by DuPont, and OPM

has subsequently developed its own patented "low temperature" synthetic method.

OPM's OXPEKK® technology, which DeFelice has been steadily improving since 2000, is arguably equal or superior to metal constructs in musculoskeletal surgery.

PEKK in 2024

Here's a partial list of PEKK's attributes as a musculoskeletal implant:

1. Antibacterial properties; no biofilm formation
2. A near bio-mechanical twin to cortical bone
3. Hypoallergenic
4. Modifiable for a more precise anatomical fit
5. Better inherent osseointegration than metal

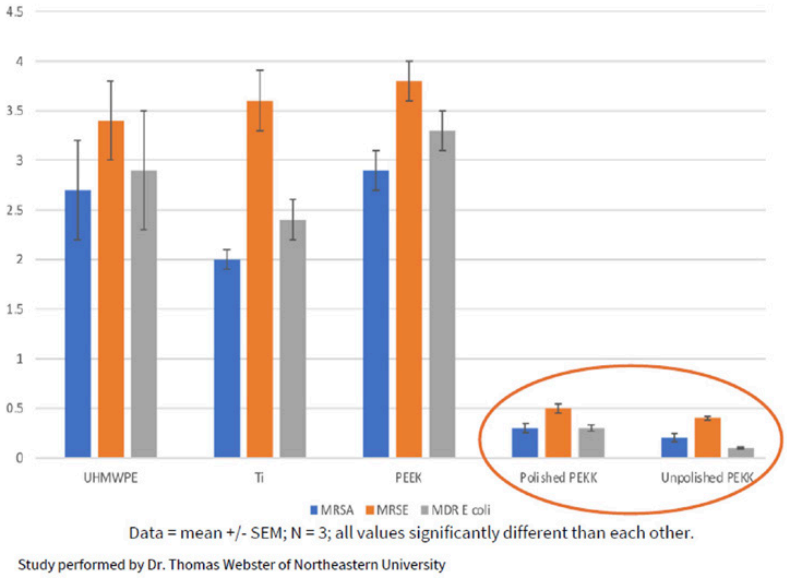
Strategically, this combination of features could improve outcomes (fewer periprosthetic infections, reduced rates of stress shielding or allergic reactions, and a better anatomical fit) and reduce revision surgeries saving musculoskeletal care providers hundreds of millions of dollars.

Since 2006, DeFelice has been piling up key PEKK milestones:

- 2006: first machined PEKK spinal cages
- 2010: FDA clears first PEKK tissue marker
- 2012: FDA clears first PEKK craniomaxillofacial device (OsteoFab®)
- 2015: FDA clears first OsteoFab PEKK VBR spinal implant
- 2016: PEKK Wins *Best Technology in Spine Award*
- 2017: FDA clears PEKK spine implants made with OsteoFab process
- 2019: FDA clears PEKK suture anchor for multiple indications

In addition to 3D printing PEKK implants, OPM sells PEKK in powder, rod, and pellet forms. *(See graph on page 6.)*

As Scott DeFelice explained to *OTW*: "We're basically saying, 'this $60 billion orthopedic industry that's built upon this metal platform is starting to show its warts'. Titanium and cobalt chrome have serviced millions of patients in the industry for decades, yet we now know that metal constructs can be too strong, too stiff, limit the surgeon's ability to modify in the O.R., and can raise infection risk."



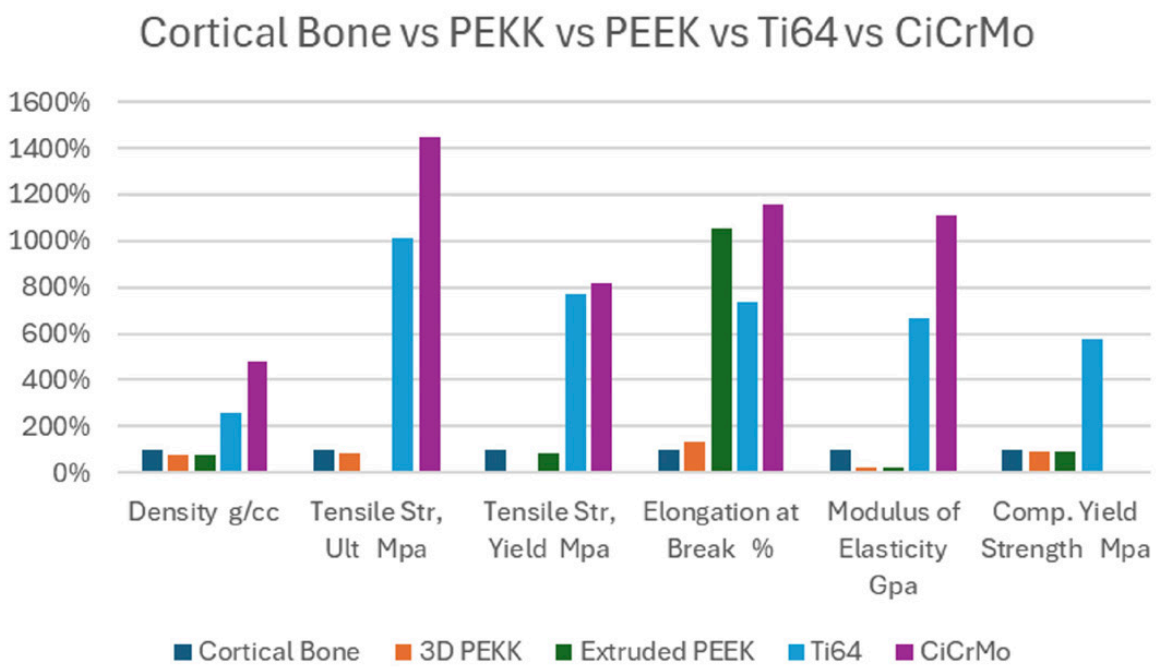
PEKK OSTEOFAB® Platform—Decreased Antibiotic Resistant Bacteria Colonization / Courtesy of Oxford Performance Materials

"PEKK essentially solves all these problems. Mechanically, it's just right for the human body. It's biologically right. Bone grows on it. It prohibits infection. There's either no or very limited bacterial colonization. We've implanted more than 100,000 PEKK spinal implants, over 5,000 personalized PEKK implants for CMF, lower & upper extremity and oncology, and our material has been used for dental implants for over a decade."

To cap it all off, DeFelice told *OTW*, OPM is now offering patient-matched spine and trauma implants. With 3D printed PEKK, DeFelice gives surgeons patient specific, anatomically precise musculoskeletal implants.

Proof Points and Study Data

In 2019, *The Spine Journal* published a head-to-head, PEEK vs titanium vs PEKK, osseointegration comparison. **Conclusion:** "PEKK implants demonstrated bone ingrowth, no radiographic interference, no fibrotic tissue membrane formation, significant increase in bony apposition over time, and significantly higher pushout strength compared to standard PEEK. The



Courtesy of Oxford Performance Materials

PEKK implant displayed bone growth characteristics comparable to Ti-coated PEEK with significant improvements in implant integrity and radiographic properties."

In a 2021 Northeastern University study PEKK was compared to titanium vs UHMWPE (ultra-high-molecular-weight polyethylene) vs PEEK and showed significant antibiotic resistance in contrast to the other three materials. This chart illustrates the study conclusions:

- The surface energy of PEKK increased the adsorption of key antibacterial proteins: mucin, casein and lubricin
- Significantly decreased colonization of antibiotic-resistant bacteria on both polished and unpolished PEKK samples compared to PEEK, Ti and UHMWPE

Comparing Cortical Bone to 3D-Printed PEKK

This study, conducted by Northeastern University, concluded that PEKK, when compared to PEEK, titanium and cobalt chrome, was most similar to cortical bone in terms of:

- Density
- Tensile strength – 2 measures
- Elongation at break point
- Modulus of Elasticity
- Yield strength

Metal: Too Stiff, Too Strong, Too Much Infection Risk

As OPM's CEO Scott DeFelice told *OTW*: "Titanium and cobalt chrome have serviced the industry for decades for millions of patients, and we know that metal constructs can be too strong, too stiff, and the endemic formation of biofilm on metal implants substantially raises infection risk."

"PEKK essentially solves all these problems. It's mechanically right. It's biologically right. Bone grows on it. It prohibits infection. There's either no or very limited bacterial colonization."

With more than 100,000 PEKK spinal implants successfully implanted, could a metal-free MSK surgery future be unfolding?

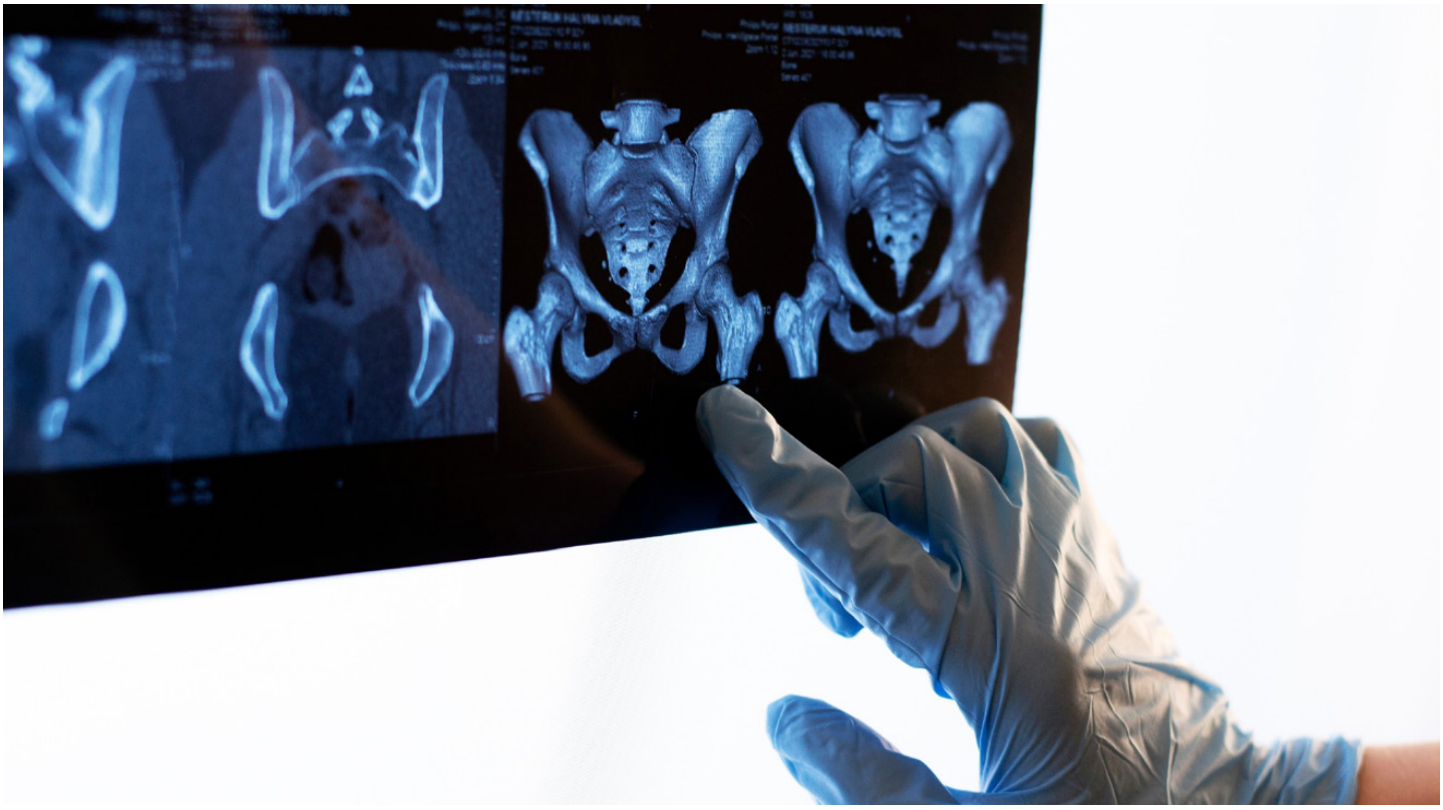
The simple answer is "Yes."

Furthermore, when considering OPM's ability to customize and personalize implants using 3D printed PEKK (I believe I saw that OPM had only a 3-day turnaround on patient-matched CMF cases) then why wouldn't surgeons begin using a more compatible, infection resistant material like PEKK?

For more information: https://www.oxfordpm.com/ ♦

ASPN Issues SI Joint Pain Treatment Guidelines

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



Source: Shutterstock

To put physicians on the same page regarding the diagnosis and treatment of sacroiliac (SI) joint pain and dysfunction, a multicenter team of researchers has developed a new set of guidelines. Their work, "American Society of Pain and Neuroscience Best Practice (ASPN) Guideline for the Treatment of Sacroiliac Disorders," appears in the May 2024 edition of *The Journal of Pain Research.*

Co-author Timothy Deer, M.D., founder of the Spine and Nerve Center of the Virginias, told *OTW,* "We identified a need for guidance on the treatment of SI joint disease. The treatment was heterogeneous, and the outcomes for both surgeons and interventional spine physicians were often not optimal. We took a look at the evidence and clinical experience and gave a decision tree for treatment. This is a living document that will change with time, as more studies are done."

According to the authors, the goal of this paper was "to better define the anatomy, diagnosis, and best practices for treatment of this common and often poorly misunderstood pathology."

OTW asked Dr. Deer for his opinion regarding the lack of consensus surrounding the appropriate clinical management of sacroiliac pain. According to Dr. Deer, "This area, like many others, has been complicated by turf battles. This is unfortunate, and whether you are an orthopedic surgeon, neurosurgeon, interventional radiologist, or interventional spine physician, we should have a goal of a collaborative discussion and decision-making."

"That is the goal of this type of paper. In addition, the American Society of Pain and Neuroscience has invited many of the world's top surgeons and interventional radiologist physicians to both our annual meeting and to our collaboration council meetings in Nashville."

The American Society of Pain and Neuroscience Guideline Process

The American Society of Pain and Neuroscience commissioned a systematic guideline process whereby members of the consensus group were selected from experts across a range of specialties interested in the treatment of sacroiliac joint disease. Work groups conducted literature searches and examined the evidence for the topics developed by lead authors in outline form.

After the literature search, each author was asked to provide cited references, and evidence rank. The section leaders then formulated the recommendation grades, based on the evidence, which were reviewed by at least three different, nonconflicted working group members. Agreement by at least 80% of the contributing authors was considered a quorum. Consensus strength was defined, as described in previous ASPN guidelines. If a recommendation was proposed with <50% consensus, based on assigned evidence rank and recommendation grade, then no consensus was achieved.

How well supported, *OTW* asked, is a minimally invasive approach to treating SI Joint pain? Dr. Deer explained, "The minimally invasive techniques are well supported by biomechanical studies. The progress made by physicians like Dr. Kasra Amirdelfan, Dr. Corey Hunter and Dr. Steven Falowski have been very impressive and have led to a better understanding."

"The need to adhere to strict diagnostic cues such as physical exams, imaging, and diagnostic contrast guided injections to assure it is the joint are the most important. New studies show that less invasive methods have a better safety profile than the older larger methods and equal one year term outcomes. Additional work will allow better decision-making." ♦

Female Surgeons Breaking Through One Misperception at a Time

BY TRACEY ROMERO

It's almost 2025 and women still only make up about 7% of orthopedic surgeons across the U.S., according to the American Academy of Orthopaedic Surgeons (AAOS). Why is this?

Women who are thriving in the field say that it has a lot to do with misperceptions and a lack of commitment to diversity on staff. When done right though, a diverse medical staff improves patient care.

Many of the medical schools and hospitals that are committed to gender diversity participate in The Perry Initiative which offers free hands-on events to female high school and medical school students to encourage them to pursue careers in engineering and surgery, particularly orthopedic surgery. (The Perry Initiative: Inspiring Women to Be Leaders in Orthopaedic Surgery and Engineering)

Outreach programs like The Perry Initiative help dispel common misperceptions about the life and work of orthopedic surgeons.

It has been proven that when young women see female orthopedic surgeons thriving in their field, they are more likely to consider training in that field as well.

While there are still some orthopedic surgery programs across the country that still haven't trained a woman, some places like the University of Minnesota in Minneapolis, Minnesota, make it a priority. At the University of Minnesota not only do they recruit and train women orthopedic surgeons but many of the graduates of the program come back to teach, inspiring new generations of women to step into the OR.

Orthopedic surgeons performing a hip replacement . Source: Wikimedia and U.S Army Sgt. Meleesa Gutierrez.

The University of Arkansas for Medical Sciences in Little Rock, Arkansas, is also committed to promoting gender diversity. The school recently participated in a Perry Initiative outreach program to Central Arkansas female high school students teaching them how to suture using pigs' feet and how to break and fix fake bones using the same tools found in the operating room.

Four female orthopedic surgeons recently spoke to *Orthopedics This Week* about the importance of encouraging more female medical students and residents to consider a career in orthopedic surgery.

A big part of this they say is increasing the exposure to female orthopedic surgeons, crushing any misperceptions about the field, and adopting policies that support both the men and women in the department.

Increasing Exposure

Teresa Wyrick, M.D., an orthopedic/hand and upper extremities surgeon at The University of Arkansas for Medical Sciences told *OTW*, that women orthopedic surgeons are among the best and the brightest in the field, but they still are largely underrepresented in the specialty.

"Orthopedic surgery is traditionally a man's field so it not always on a female medical student's radar," she explained.

"It is also a physical field with a lot of hands-on work and long hours. Some may question, am I strong enough? There's also a bit of an imposter syndrome because orthopedic surgery is very competitive."

When she mentors female students, she said one of the most common concerns they have are whether it is possible to fulfill their desire to be both an orthopedic surgeon and a wife and mother.

The answer of course is yes and that is why she enjoys participating in Perry Initiative programs and giving them a glimpse into a day in the life of a female orthopedic surgeon.

Jacqueline Geissler, M.D., and Jessica Downes, M.D., are two of five female orthopedic surgeons on staff at Hennepin Healthcare in Minneapolis.

Geissler grew up on a farm in Wisconsin. Downes is the daughter of an electrical contractor.

Downes told *OTW*, "If you look at what we do, it is really carpentry with nuances of anatomy and patient care."

Because they learned to enjoy working with their hands and with power tools at an early age, they felt drawn to orthopedic surgery, but not all girls grow up with the same experiences.

Geissler explained, "Exposure continues to be something we work to increase. Not seeing orthopedic surgeons that look like you makes it hard to visualize it for yourself. When you look at the field and see 93% are men, you might not consider it for yourself."

"As women go through medical school, there is some stigma, and they are advised against specializing in orthopedic surgery and steered toward more traditionally female specialties instead," Downes added.

"The assumption is that women surgeons are not welcome in orthopedic surgery but that is not true."

Geissler emphasized, "Women do hard things all the time. We need to show it is possible to have a good work-life balance as an orthopedic surgeon. Men want to have families too. Better policies like a 6-week parental leave will help recruit both men and women."

Johns Hopkins Medicine in Baltimore, Maryland, also has five female attending surgeons in the orthopedic surgery department. Erin Honcharuk, M.D. is one of them. She is a pediatric orthopedic surgeon.

"I was drawn to orthopedic surgery because I enjoyed working with my hands and the long-lasting impact I can have on a child's and parents' life," she told *OTW.*

She agrees that there are certain misperceptions about the field that keep more female doctors from pursuing orthopedic surgery.

"Many are concerned with work-life balance, long hours, late nights, being on call and balancing all that with other life aspirations like having children," she explained.

There is also the concern that most women don't have the brute strength needed for fixing and setting bones. Honcharuk, however, pointed out that women can still get the job done using different techniques that sometimes work better for patients.

Honcharuk said she is always very open about her life. She likes to show that breastfeeding is still possible with a tight OR schedule and that even though she isn't as strong as some of her male counterparts, she can still find effective techniques that don't require heavy muscle.

Importance of Supportive Admin

Honcharuk, Geissler, Downes, and Wyrick all say that a supportive culture both in medical school and at the hospitals they work is an essential ingredient for more diversity in orthopedic surgery departments.

There needs to be a commitment to recruit, train, and promote a diverse group of doctors, Geissler said. At Hennepin Healthcare, Dr. Dick Kyle and Dr. Andrew Schmidt, former department chairs, during their tenure were committed to hiring a diverse staff that included both men and women during their tenure.

"The success we have built on makes us welcomed and valued," she said.

Honcharuk added those orthopedic surgery departments that encourage a good work-life balance are also important.

She said that the residency director at Johns Hopkins is a big proponent of

both male and female residents taking a few weeks off when having a child. She herself is currently pregnant with her second child.

The great thing about working at Johns Hopkins, she added, was that the administration's baseline approach is to want diversity. They recognize it adds value for everyone.

"Having different types of people on staff will bring different life experiences, different solutions, different ways of looking at things, different ways of communicating. How I communicate with families may be different than the way my male counterparts do," she explained.

On ways hospitals can be more supportive of their female surgeons, Honcharuk said hospitals need to improve access to fertility treatments for women who may choose to delay starting a family until after their training. For instance, give them the ability to store their eggs during medical school and allow them the time off to do in vitro fertilization.

The Value of Diversity

On why a diverse medical staff is better for patients, Wyrick said, "Some patients prefer a doctor of a specific gender because they feel better connected to a doctor that is just like themselves. This increases patient compliance.

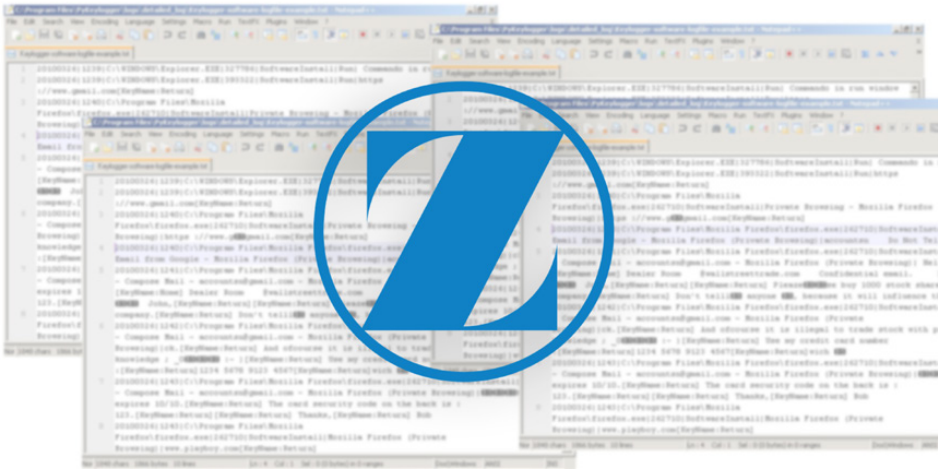
Studies continue to show that diversity is important for patient care. One study found that hospitals with more than 35% female surgeons and anesthesiologists on staff had better patient outcomes.

Studies also continue to show that patients at hospitals committed to not just gender diversity, but diversity in general, have better outcomes. Patients do better when they can connect to their caregivers on a more personal level.

"Fifty percentage of the U.S. population is women. If we want the best and the brightest, some of them will be women," Wyrick pointed out. ♦

COMPANY

ZBH's Q3 Report: OK, Despite Software Bugs



Source: Wikimedia Commons and Zimmer Biomet Holdings, Inc.

Zimmer Biomet Holdings, Inc. reported $1.824 billion in sales and $279.5 million in operating profit for the quarter ending September 30, 2024, which was above both Wall Street's expectations and management's guidance. *(See table on page 15.)*

There's an old Wall Street maxim that goes like this: "See one cockroach, expect dozens more in the baseboards."

So it goes with software bugs, as Zimmer Biomet's management reported to investors in the third quarter earnings call.

Zimmer Biomet President and CEO Ivan Tornos, David DeMartino, senior vice president of investor relations, and Suketu Upadhyay, CFO and EVP, Finance, Operations and Supply Chain reported to investors and other stakeholders that Q3 sales were strong despite Enterprise Report Planning (ERP) software issues.

Net sales for the 3Q 2024, were $1.824 billion. U.S. sales rose 2% year-over-year while international business grew 7.1%.

During the earning call, Tornos highlighted sales performance in three principal areas—knee and hip treatment and cranial care. He also pointed out that this third quarter marked

the "11th consecutive quarter of mid-single-digit (or better) constant currency revenue growth for Zimmer Biomet."

Tornos also emphasized Zimmer Biomet's latest innovations—notably the Z1 Femoral Hip System for total hip arthroplasty, a triple-taper femoral system that can be used in junction with Biomet's G7 Acetabular System.

Zimmer Biomet has also recently completed the acquisition of OrthoGrid Systems Inc., a privately held medical technology focused on artificial intelligence guidance systems for total hip replacement.

He added, "Zimmer Biomet is the only orthopedic company offering both a CT scanless robotic system in ROSA," and "a smaller footprint handheld CT scan-based system in Tamini."

Zimmer Biomet Holdings *$ in 000s*

Quarterly Report: 3 mos and 9 mos ended 9/30/24

3 Month SALES		
2023	2024	% Change
$ 1,750,000	$ 1,824,200	4.24%
Op Profit		
2023	2024	% Change
$ 266,600	$ 279,500	4.84%
15%	15%	
EPS		
2023	2024	% Change
$ 0.77	$ 1.23	59.7%
2024 Sales Estimate		
Consensus		Change
$ 7,670,000		3.00%

9 Month Sales		
2023	2024	% Change
$ 5,450,000	$ 5,655,400	3.77%
Op Profit		
2023	2024	% Change
$ 886,700	$ 896,700	1.13%
16%	16%	
EPS		
2023	2024	% Change
$ 2.88	$ 3.25	12.85%
2025 Sales Estimates		
Consensus		Change
$ 8,020,000		3.20%

Source: RRY Publications LLC

Upadhyay explained that Zimmer Biomet had implemented a new ERP system during the third quarter and it had adversely affected shipping levels in North America which reduced U.S. sales growth rates by 60 to 80 basis points (0.6 – 0.8%) of annual sales. He said, "Despite ERP-related heads, we grew sales over 4%, while maintaining steady operating margins generating $1.74 in adjusted earnings per share and $310 million in free cash flow."

Because of the ERP issues, the company changed its guidance for investors to a 2024 constant currency revenue growth rate of 4.25% to 4.75%, year-over-year, down from 5.0% to 6.0%.

Wall Street Analysts Grill Management Over Shipping Issues and M&A Prospects

Bank of America's medical technology analyst Travis Steed, as well as other analysts, grilled management over the change in 2024 forecast and questioned specifically whether ERP would also lower 2025 guidance.

Tornos said that he and the team were simply being conservative. He highlighted, of course, the ERP issues, but noted being late with certain new product introductions because of those challenges.

"In Quarter 4, all kinds of things happen. We want to see where we end up with pricing. Pricing has been positive for the entire year," he explained.

Steven Lichtman with Oppenheimer asked about other important product launches on the horizon.

Tornos highlighted the Oxford Partial cementless system, a projected mid-2025 product, which would be the only PMA (Pre-Market Approval) approved partial cementless knee in the U.S. In addition, Tornos highlights three new ROSA indications, including ROSA shoulder, for 2025 and 2026.

Wells Fargo's Vikramjeet Chopra questioned Tornos about the apparent paucity of merger and acquisition activity. Tornos took some exception with the premise of Chopra's question, saying that Zimmer Biomet does not need M&A to grow sales. Zimmer, in Tornos's words, would only pursue transactions that make strategic and financial sense.

Shagun Singh Chadha with RBC Capital Markets, however, echoed Chopra's questions and asked Tornos for more specificity, saying, "On M&A, you did note that you don't need to do large deals to maintain that mid-single-digit growth outlook. And I was wondering how you think about diversification and pushing that top line beyond the mid-single-digit growth longer term?"

Tornos's answer: "What I said was we do not need to do it. But certainly, we like to do it. And we got the optionality from a balance sheet standpoint to do it."

Mike Matson with Needham & Company lastly brought up the challenges of volume-based purchasing in China.

Tornos said that China is about 3% of global sales for Zimmer Biomet and they have been monitoring the situation in China for the last few years.

"We understand fully the impact of volume-based procurement. We have the right level of investment with the right level of returns. Right now, we've not seen anything that can change the way we think about revenue contribution from China."

Analysts have given Zimmer Biomet Holdings, Inc., an average rate of "Hold." Two analysts recommended selling the stock and six have given a "Buy" rating. — *TR*

Team Stryker Slam Dunks the Q3 Report

Stryker reported $5.5 billion in sales and $1.9 billion in operating profit for the quarter ending September 30, 2024, which was above both Wall Street's expectations and management's guidance.

Kevin Lobo, chair and chief executive officer of Stryker Corporation, and his management team, reported strong sales growth in its third quarter, leading Team Stryker to bump up organic sales growth from 9.5% to 10%.

Leading the quarter's strong sales report was Medical/Surgical and Neurotechnology's 12.8% year-over-year growth rate and Orthopedics and Spine 10% year-over-year report. The company also reported an adjusted quarterly Earnings Per Share of $2.87 (2.16 fully diluted), up 16.7% from 2023's Q3.

Lobo said, "Our growth was well-balanced between the U.S. and international, with both rising double digits organically. All international regions showed strength in the quarter, and we continue to see international markets as key catalysts for our long-term growth."

STRYKER CORPORATION *$ in 000s*

Quarterly Report: 3 mos and 9 mos ended 9/30/24

3 Month SALES		
2023	2024	% Change
$ 4,910,000	$ 5,494,000	11.89%
Op Profit		
2023	2024	% Change
$ 931,000	$ 1,090,000	17.08%
19%	20%	
EPS		
2023	2024	% Change
$ 1.80	$ 2.16	20.0%
2024 Sales Estimate		
Consensus		Change
$ 22,520,000		3.00%

9 Month Sales		
2023	2024	% Change
$ 14,690,000	$ 16,159,000	10.00%
Op Profit		
2023	2024	% Change
$ 2,631,000	$ 3,112,000	18.28%
18%	19%	
EPS		
2023	2024	% Change
$ 5.27	$ 6.35	20.49%
2025 Sales Estimates		
Consensus		Change
$ 24,070,000		3.20%

Source: RRY Publications LLC

Source: Shutterstock and Stryker Corporation

The commercialization of the Pangea Plating system, which will be fully launched in the U.S. by second half 2025 and the LIFEPAK 35 monitor/defibrillator also contributed to Styker's strong sales growth.

Lobo also mentioned three recent acquisitions:

- Care.ai, an artificial intelligence platform to support healthcare teams,
- NICO Corporation which specializes in minimally invasive surgery

for tumor and intracerebral hemorrhage procedures, and

- Vertos Medical, which specializes in minimally invasive treatments for chronic lower back pain caused by spinal stenosis.

Wall Street Analysts Grill Team Stryker: 'You *can't* keep this up, can you?'

On the earnings call, Robbie Marcus a JPMorgan analyst, pointed to the large growth in Stryker's medical business and asked, is this a one-off or is it sustainable?

Lobo responded, "If you look over the past five years, it's probably been our highest growing division pretty consistently. Now from quarter-to-quarter, it does move around a little bit given the capital equipment nature of the business, but it's not unusual for us to post an 18% growth."

He pointed to ProCuity wireless bed series, LIFEPAK 35 and Vocera Edge as being behind the momentum, and he expects the double-digit growth to continue.

Marcus also questioned why the fourth quarter implied guide was below the current sales growth pattern and asked if weather was a factor.

According to Lobo, Team Stryker wasn't factoring in any weather-related disruption, explaining, "I think it's a reasonable guide. We moved it up. But clearly, we are hoping and aiming to finish at the high end of that guide closer to the 10%."

Questions of sustainability were one of the biggest concerns for the analysts for all business segments. Richard Newitter with Truist Securities asked about plans to turn around the ischemic stroke business.

Lobo explained that there had been some supply issues and a lot of competition, but that they are working on a number of solutions, including more product launches and changes in sales force.

Analysts were also excited to see that the third quarter was the first quarter for positive orthopedic pricing growth. Glenn Boehnlein, vice president and chief financial officer, said that was mostly driven by international markets, and that while their U.S. orthopedic market had a good performance, they aren't seeing positive orthopedic pricing growth in the U.S. yet.

Joanna Wuensch with Citi particularly questioned the sustainability of the current growth in orthopedics.

Lobo reassured that this growth is expected to be the new normal based on surgery schedules, aging demographics, and positive outcomes from the procedures.

Wuensch also asked for early feedback on Mako spine, but Lobo said that it was too early to report anything, but that it is performing as expected so far. He cautioned though that it won't have a noticeable impact on sales for a while because they want to make sure that all the training goes well first before full launch.

Because of the quarter's strong performance, Richard Newitter from Truist Financial and JMP Securities' David Turkaly gave Stryker a "Hold" rating while Canaccord Genuity issuing a "Buy" rating. Overall, out of 28 recommendations, 18 were "Strong Buy" ratings and two "Buy" ratings.

Newitter said, "Stryker demonstrated a solid Q3 with an organic revenue beat and possesses one of the more robust growth profiles in the large cap MedTech sector. There are several new product launch areas expected to boost momentum as the company moves in Quarter 4 and looks toward Fiscal Year 25. These recent developments bolster the optimism surrounding Stryker's trajectory, flagging potential opportunities for investors." — *TR*

LEGAL

Are Whistle Blower Qui Tam Provisions Constitutional?

United States District Judge Kathryn Kimball Mizelle for the United States District Court for the Middle District of Florida recently ruled that the qui tam provisions of the False Claims Act are unconstitutional.

The defendants had argued that the False Claims Act's qui tam provisions violated Article II of the Constitution's Appointments Clause. In the order, Judge Mizelle granted the defendants' motion for judgment on the pleadings and dismissed the case with prejudice as to Clarissa Zafirov, M.D.

The case was initially filed by Dr. Zafirov against her employer Florida Medical Associates, LLC d/b/a VIPcare in 2019. Other defendants include the following: Physician Partners, LLC; Anion Technologies, LLC; Freedom Health, Inc.; and Optimum HealthCare, Inc.

From October 2018 through March 2020, VIPcare employed Dr. Zafirov as a primary care physician. Dr. Zafirov alleged that the physician practice group violated the False Claims Act. According to court documents, Dr. Zafirov alleged that the defendants "acted in concert to falsely increase the risk adjustment scores of thousands of Medicare Advantage patients for the purpose of obtaining more funding from the United States than was rightfully owed."

The defendants moved for judgment on the pleadings. Per court documents, the defendants argued that the False Claim Act's qui tam provision violates "Article II's Appointments Clause, Take Care Clause, and Vesting Clause." The United States had initially declined to intervene in the matter. However, the government did intervene to contest the constitutional arguments.

Judge Mizelle found that "[a]n FCA [False Claims Act] relator is an officer of the United States" and was "not constitutionally appointed" and, therefore, "dismissal is the only permissible remedy."

The case is captioned as United States ex rel. Zafirov v. Fla. Med. Assocs. and is case number 8:19-cv-01236-KKM-SPF.

The matter is far from resolved. Despite an initial refusal by the United States to intervene, last month the United States filed a notice of appeal of dismissal order. The notice was filed in the U.S. Court of Appeals for the Eleventh Circuit.

At present, the decision is not binding authority. However, there is the potential that other defendants will raise similar Article II arguments. Additionally, the appeal could lead to a circuit split and potential review by the U.S. Supreme Court. If this case eventually proceeds to the U.S. Supreme Court, it could have a significant impact on False Claims Act litigation. *OTW* will continue to monitor the litigation. — *KD*

Source: Pixabay and WikiImages

FDA Clears Dr. Betz's Vertebral Body Replacement Device

The U.S. Food and Drug Administration (FDA) has granted 510(k) clearance to a novel spinal vertebral body replacement device indicated for partial replacement of a diseased or damaged vertebral body.

According to the FDA's clearance order, the new device, brand named Vertiwedge® Intraosseous System and supplied by Foundation Surgical Group, Inc., the company founded around technologies developed by one of the giants of spine surgery, Randal Betz, M.D.

The device is indicated "for use in the thoracolumbar spine (T1-L5) for partial replacement of a diseased or damaged vertebral body resected or excised to replace a portion and/or restore the height of a collapsed vertebral body for the treatment of previous trauma (i.e., fracture or tumor) or degenerative spine disease."

According to Foundation Surgical CEO Dr. Betz, "With the FDA clearance of the Vertiwedge® and the launch of the VBO® procedure, we are ushering in a new era of spine surgery."

Dr. Betz continued, "Our approach allows for the treatment of degenerative conditions while preserving the spine's natural motion, a significant step forward in patient care."

According to the FDA, "The system is to be placed within the vertebral body following an osteotomy

Source: Foundation Surgical Group, Inc.

and supplemented with autograft or allograft and to be used with its contralateral staple; should a physician choose to use fewer than the maximum number of screws, then supplemental fixation must be used to augment stability."

Additionally, Foundation's Vertiwedge is intended to "restore the integrity of the spinal column even in the absence of fusion in patients with advanced stage tumors involving the thoracolumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion."

In order to qualify for shorter and earlier 510(k) clearance the device must be substantially equivalent to a predicate device. Here, the primary predicate device is the PILLAR SA PEEK Spacer System with Blackstone Medical, Inc. listed as the manufacturer. In 2006, Blackstone Medical Inc. was acquired by Orthofix International NV.

Foundation Surgical is an Arizona-based spinal implant company. The company announced this device was its second cleared device in the past few months.

According to the Foundation Surgical press release, "The Vertiwedge® is the first intraosseous device designed to facilitate and maintain vertebral body correction of partially collapsed vertebrae via the groundbreaking VBO® [Vertebral Body Osteotomy] procedure." Additionally, this "novel single position, motion-sparing technique, allows for effective treatment through a conventional lateral or oblique lateral approach and facilitates indirect decompression of the nerve roots while preserving the natural motion of the disc and facet joints without the need for intervertebral fusion." — *KD*

LARGE JOINTS

TKA: Obesity Up—But Outcomes Are Better!?

A Mayo Clinic team decided to take a new look at reoperation, revision, and infection risk rates for high body mass index (BMI) patients. In total, the team pulled data from 13,919 total knee arthroplasty (TKA) patients who were treated between 1990 and 2019.

Their work, "Outcomes of Obese Patients Undergoing Primary Total Knee Arthroplasty: Trends Over 30 Years", November 6, 2024, edition of *The Journal of Bone and Joint Surgery (American)*.

"We became interested in the study of obese TKA patients as a result of the increasing number of patients with obesity and end-stage knee arthritis that we are seeing in our clinics for evaluation for TKA," said co-author Nicholas A. Bedard, M.D., associate professor of orthopedic surgery at Mayo Clinic in Rochester, Minnesota, to *OTW*.

For the study, the Mayo team stratified patients according to body mass index using the World Health Organization (WHO) classification to wit:

- non-obese (BMI, <30 kg/m 2),
- WHO Class-I and II obese (BMI, 30 to 39.9 kg/m 2), and
- WHO Class-III obese (BMI, ≥40 kg/m 2).

Rate of Increase in Obesity

Rates of obesity, the team found, had increased dramatically during the near 30-year test period.

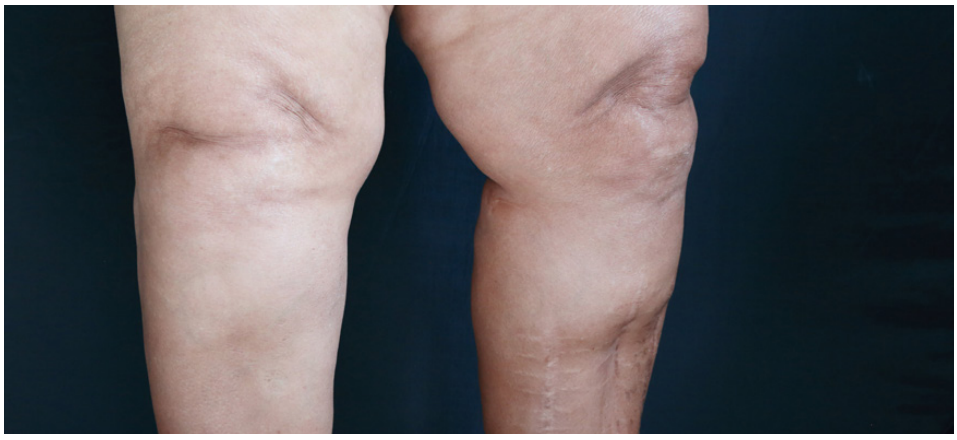
- Class-II obesity (13% to 25%), up 90%
- Class-III obesity (3% to 12%), up 300%!

But, that did NOT correlate into a comparable increase in reoperations, revisions or infection rates.

Rates of Change in Reoperations, Revisions and Infection Rates

Overall, across the entire cohort of patients in the study, the researcher found that the two-year risk of any reoperation, any revision, and periprosthetic joint infection (PJI) declined.

For non-obese patients, that same risk decreased significantly.



Source: Shutterstock

For Class-III obese patients, also a significant decrease, except with respect to infection rates.

For Class-I and II obese patients, however, the risk of reoperations, revisions or infection remained stable.

Focusing specifically on periprosthetic infection risk, the Mayo team found that it decreased from 1990 to 2019 for non-obese patients, but did not change significantly for either obesity group.

"The most interesting finding from this project was that despite increasing rates of obesity amongst our TKA patients, we were able to observe a decreased risk of infection following TKA over the last 30 years at our institution," explained Dr. Bedard to *OTW.*

"However, when we looked specifically at non-obese and obese patients, we found that the improvement in PJI risk was largely a result of decreased risk for non-obese patients as there were no significant changes in infection risk for any obesity over time."

OTW asked Dr. Bedard if Mayo employed a preoperative weight loss program for obese TKA patients. "At Mayo we take a multidisciplinary approach to optimize our patients prior to hip and knee arthroplasty surgery to minimize the risk of postoperative complications, particularly the risk of infection," Dr. Bedard explained.

"Part of those optimization efforts include weight loss for patients who are at a body weight that places them at increased risk for complications. We work with our nutrition team, endocrinology, and occasionally bariatric surgery to try and ensure a successful surgery for our patients." — *EH*

New 300 Patient PJI Study: How to Cut Failure Rates

"Rare but devastating" are words often used to describe periprosthetic joint infection (PJI). To make a substantial dent in this ongoing issue, researchers from what is likely the only official Prosthetic Joint Infection Center in the U.S.—OrthoCarolina—along

Featured from left to right: Thomas K. Fehring, M.D., Keith A. Fehring, M.D., Brian M. Curtin, M.D., Bryan D. Springer, M.D., Jesse E. Otero, M.D., Ph.D. / OrthoCarolina

with researchers from Atrium Health and OrthoCarolina, got to work.

Their study, "Regional Periprosthetic Joint Infection Centers: The Time Has Come for a Paradigm Change in the Treatment of Periprosthetic Joint Infection," appears in the July 30, 2024, issue of *The Journal of Arthroplasty.*

"Five years ago, I initiated a prospective randomized OREF [Orthopaedic Research and Education Foundation]-funded study comparing 1-stage vs 2-stage treatment for PJI," co-author and director of the OrthoCarolina Prosthetic Joint Infection Center Thomas Fehring, M.D. told *OTW.*

"Over 300 patients needed to be enrolled in this study to have enough statistical power to determine which treatment path was best for patients with a PJI. Since this complication is rare (approximately 1%), most orthopedic surgeons only treat a few PJIs per year. In order to obtain sufficient numbers for our 1-stage, 2-stage study, I contacted all the orthopedic surgeons in North and South Carolina offering to see their patients afflicted with this serious problem. We implemented a system for rapid access and care coordination for their PJI patients. Since its inception, we have been referred over 1,000 patients for treatment."

Using the OrthoCarolina PJI registry, the researchers identified 172 patients (182 joints) who had a chronic PJI treated with a 2-stage exchange arthroplasty from 2017 to 2021.

Sooner Is Absolutely Better – Reduces Failure 50%

"Because this complication is relatively rare," stated Dr. Fehring to *OTW,* "most orthopedic surgeons who only treat a few PJIs per year are frequently unaware of the latest evidence-based guidelines concerning the diagnosis and treatment of prosthetic joint infection. Therefore, delayed referral to our PJI Center was common. We found that there was a significantly higher failure rate in patients referred greater than 90 days after the diagnosis of chronic PJI (23%) compared to those patients referred in a timely fashion less than 90 days from diagnosis (11%)."

Cut 90-day Mortality to Zero?

"We also noted a significant decrease in the mortality rate of patients treated at our PJI Center compared to national averages. There were no deaths within 90 days of surgery at our PJI Center. This compares favorably to the national 90-day mortality rate of 5%. Our 1-year mortality rate was 3.9%, which also compares favorably with the 1-year national mortality rate of 9.7%."

"Finally, we found that the cost of treatment prior to referral was substantial. The cost of nonevidence-based treatments such as multiple irrigation and debridements, multiple rounds of IV antibiotics, and long-term wound Vacuum-Assisted Closure therapy averaged approximately $80,000 per patient before they were referred to us. If one projects this cost over the 20,000 or so patients treated for PJI in the U.S., the cost to our healthcare system for ineffective PJI treatment prior to referral is nearly $800 million dollars."

To Succeed, Follow Best Practices

"Currently in the United States there is well-documented precedent for improved outcomes when patients are treated in Centers of Excellence such as Trauma Centers or Cancer Centers. These improved outcomes are directly related to higher volumes seen in these Centers, which results in improved surgical techniques and familiarity with complex care. Given the significant morbidity and mortality associated with treatment of PJI, it is reasonable to expect that similar benefits can be seen by establishing Centers of Excellence specifically for the treatment of this complex problem."

"In France, they have established a 24-Center National Network of PJI Centers concentrating surgeons, infectious disease consultants, microbiologists, radiologists and internists in order to optimize patient care, promote education and bolster research efforts. A similar national effort has been instituted in the Netherlands."

"I am currently working with CMS [Centers for Medicare and Medicaid Services] to help establish Regional Prosthetic Joint Infection Centers across the country that would improve patient care and provide significant cost savings to the healthcare system as a whole. Our proposed model of care serves as an example for other healthcare institutions throughout the United States seeking to optimize PJI treatment, improve the patient experience, and reduce spending in the healthcare system. A National Network of PJI Centers, like the successful network established in France, would accomplish these goals. The time has come for a paradigm change in the treatment of PJI."

"As far as I know," commented Dr. Fehring to *OTW*, "we are the only formalized Prosthetic Joint Infection Center in the U.S. In other areas of the country, tertiary academic orthopedic departments have been the de facto referral choice for PJIs when encountered by general orthopedists." — *EH*

EXTREMITIES

Vitamin E Blended Ankle Replacement Launched

Enovis™ Corporation, based in Wilmington, Delaware, is debuting its Scandinavian Total Ankle Replacement (STAR® Ankle), now with new e+™ Polyethylene.

According to Enovis the STAR Ankle is the first and only mobile bearing ankle system with e+ Polyethylene in the U.S. Blending vitamin E into the implant's polyethylene's insert will, according to Enovis, offer improved durability, stability, and longevity.

"With e+ Polyethylene, we uphold our commitment to the advancement of our total ankle portfolio, merging full oxidative resistance with the time-tested design of the STAR Ankle," said Gary Justak, president and general manager of Enovis Foot & Ankle. "Building upon the proven success of the STAR Ankle epitomizes our culture of advancing foot and ankle solutions and elevating patient treatment options. We don't just set the standard—we redefine it."

In its public releases, Enovis pointed out that vitamin E is a free radical-neutralizing antioxidant and will, as a result, resist oxidation and maintain consistent wear rates and stable mechanical properties over time. In contrast, according to the company, other highly crosslinked polyethylenes are remelted during manufacturing to neutralize free radicals, a process that can reduce their mechanical strength by up to 12%.

"After extensive clinical experience with this superior material in knee and shoulder implants, along with years of laboratory testing, I expect improved patient outcomes through increased polyethylene longevity. This builds on the outstanding STAR Ankle long-term metal-component survival rates seen in multiple clinical studies," explained Dr. Gregory Lundeen, a foot and ankle orthopedic surgeon at Reno Orthopedic Center.

Gary Justak told *OTW* that the company had to innovate a new bench testing method in order to precisely replicate clinical oxidation fractures. "Traditional tests fell short in replicating the real-world failure modes, so we developed a sophisticated wear cycle with a spine test frame incorporating flexion/extension, varus/valgus angulation, and internal/external rotation."

"This breakthrough approach has allowed us to authentically simulate oxidation-driven fractures and rigorously validate the durability and performance of e+ Polyethylene, ensuring it meets the highest standards of durability and stability. In fact, through this extensive mechanical testing, the e+ Polyethylene did not fracture in even the most extreme situations (increased load and extreme angulation), further proving that this great implant, with the longest history of clinical outcomes and survivorship, is even stronger with this material change."

"An important element of our development process was overcoming the challenge of reproducing failures observed in standard polyethylenes. Unlike traditional materials, our vitamin E-blended e+ Polyethylene insert demonstrated remarkable resilience under extreme testing conditions. Moreover, FDA reviewers acknowledged the unique and novel testing performed to assess the improvements with e+ Polyethylene. This recognition highlights the significance and originality of our work." — *EH*

Scandinavian Total Ankle Replacement (STAR® Ankle) / Courtesy of Enovis™ Corporation

REIMBURSEMENT

Category 1 CPT Code for Barricaid Annulus Closure

The American Medical Association (AMA) CPT Editorial Panel has accepted the addition of a new Category 1 CPT Code for bone anchored annular closure. This is significant news for patients, surgeons, clinics, and hospitals.

The new Category 1 CPT Code sets the stage for reimbursement for the Barricaid® Annular Closure Device. It is the first CPT Code, according to the company, to "describe closing large annular defects using the Barricaid device."

The new CPT code will go into effect on or after January 1, 2026. The addition of this CPT Code is a significant milestone for Barricaid since it puts in place a reimbursement for the leading annular closure device.

Intrinsic Therapeutics, Inc., the Woburn, Massachusetts developer and manufacturer of Barricaid, explained that the device "prevents reherniation and reoperation in patients with large annular defects following lumbar discectomy surgery."

The AMA Board of Trustees has authorized the CPT Editorial Panel to, "revise,

New Category 1 CPT Code Effective January 2026 / Source: Intrinsic Therapeutics, Inc.

update, or modify CPT codes, descriptors, rules and guidelines." The CPT Editorial Panel's primary responsibility is the maintenance of the CPT code set. A proposal for a new or revised Category I code must meet specific criteria.

Serena Hu, M.D. is a board-certified, fellowship-trained orthopedic spine surgeon and chief, orthopedic spine service, department of orthopedic surgery at Stanford. Dr. Hu commented, "A new Category 1 CPT code represents a significant milestone for any new technology. Category 1 codes are intended to describe procedures that demonstrate high levels of clinical evidence and efficacy. Most importantly, this distinction demonstrates that Barricaid has met the rigorous criteria the AMA sets forth, including robust clinical data and widespread adoption by physicians, further substantiating the medical necessity of this critical therapeutic alternative."

Dr. Hu continued, "For physicians, achievement of a CPT code not only offers a pathway to reimbursement, but also is a strong indicator of clinical acceptance and a new standard of care within the surgical community." — *KD*

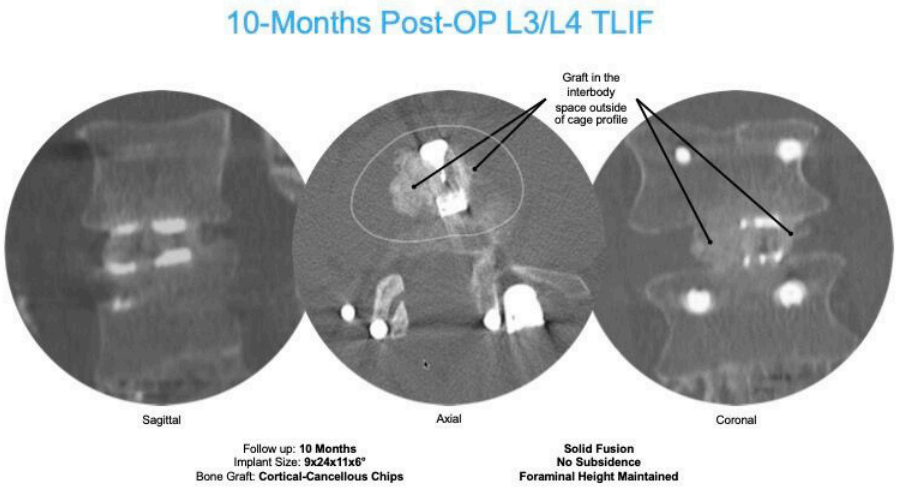
The answer, and it is an intriguing one when you dig into the "why," is "yes."

The device in question, KG™2-Surg(r) Flow-Thru, invented by spine surgeon Jeff Kleiner, M.D., is the subject of a couple of new studies and anecdotal data which support not only that proposition that a rectangular cannula combined with a biportal conduit for graft delivery will put more graft in the disc space but that it will also improve fusion rates and by extension patient outcomes.

Minnesota-based orthopedic surgeon, Nathan Wanderman, M.D. told *OTW*, "I have been using KG2 for a year and have yet to encounter a pseudoarthrosis. I have been surprised at how much more graft I can get into disc spaces with the device, and there is an appreciable difference in graft volume compared to products I have used in other settings."

As Dr. Kleiner explained to *OTW*, "The KG2 system relies upon a rectangular graft cannula pre-attached to an I-Beam implant that doubles as a biportal conduit for graft delivery. It has no pinch points and allows implant insertion and grafting with a single pass of an instrument. This is distinct from the multi-step process involving round, end-dispensing funnels that poorly distribute graft, are prone to underfill the disc space and give surgeons a feeling of 'graft insecurity.' These archaic systems require flowable graft, frequently jam and are prone to diminished endplate-to-endplate contact, which ultimately results in a failure to heal."

"This example of a patient CT scan 10 months post-surgery (see images above) utilizing the KG2 Surge for a TLIF procedure shows obvious fusion and demonstrates the value of a biologic foundation of graft between vertebral end plates, maintaining disc height, preventing implant subsidence and preservation of foraminal height", said Dr. Jeff Kleiner, founder and CEO of Kleiner Device Labs. "The importance of that biologic foundation was highlighted in the recent



CT Images Ten Months Post-Op L3/L4 TLIF / Source: Kleiner Device Labs

SPINE

New Data for More Graft and Nerve Avoidance in TLIF

Does changing the shape of the cannula, to a rectangular shape, for example, deliver a consequential improvement in spine surgery, in a transforaminal lateral interbody fusion, for example?

release of a study by the University of Toledo showing the higher failure rate of spinal fusions in diabetic patients."

75% More Cross-Sectional Area for Graft

Dr. Kleiner says he was frustrated by this flawed technology and knew there was a better way.

"I set out to eliminate some headaches for my colleagues—and for myself," Dr. Kleiner told *OTW.*

"I knew it would be important to use a dispensing device that matches the annulotomy—hence, the KG 2 rectangular cannula that has 75% more cross-sectional area for graft, and biportal delivery in a distracted disc space that prevents jamming. With the KG 2 Surge, surgeons can deliver a variety of graft materials, meaning that the graft material doesn't have to have a primary characteristic of flowability. Surgeons are free to select a graft that has the greatest osteogenic and osteoconductive properties."

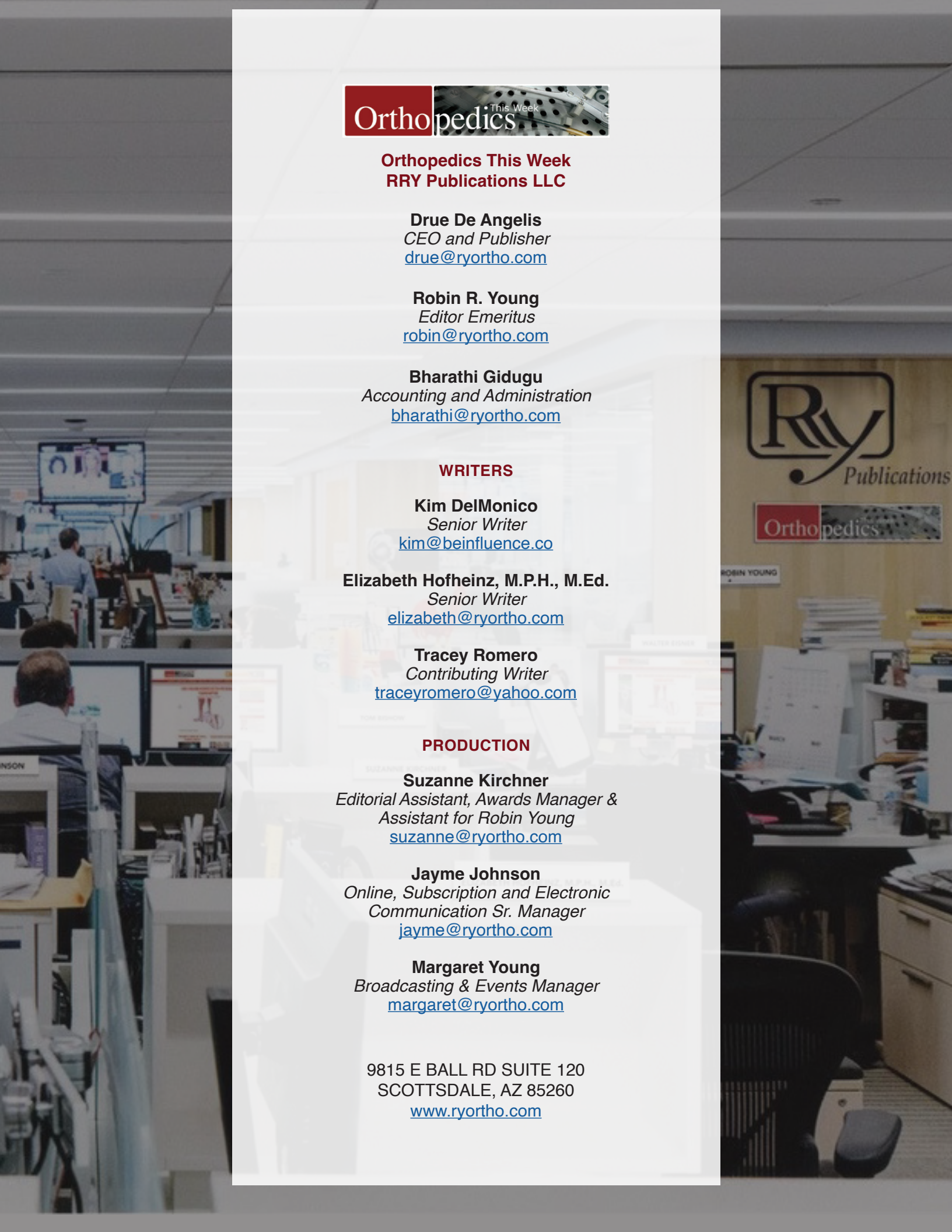
"While BMP may be an alternative, it has a prohibitive cost and is associated with substantial risk. There are many potential deleterious side effects of BMP that can be obviated by maximizing the graft volume that the KG 2 system provides."

Concerning diabetic patients, Dr. Kleiner told *OTW*, "We know that diabetes and other endocrinopathies impact the patient's ability to heal a fusion. The KG2 Surge offers optimal placement and quantity of bone graft with a single instrument pass. This is especially important for individuals with diabetes, who are prone to fusion failure and infection."

2.5x More Graft, No Touching, Nerve Avoidance

Dr. Kleiner: "With our system, if you 'do good carpentry,' i.e., clear out the disc material to make more room for the graft, then you can put in 2.5x more bone graft than with conventional means. In addition, because this is a 'touch free' technology and since the implant and disc are not pre-packed, the risk of implant cross-contamination is essentially eliminated. With the pre-assembled, single patient use KG2 Surge, redundant operative steps are reduced, diminishing the risk from multiple passes by the nerve tissue and reducing the risk of soft tissue irritation/damage.

Dr. Kleiner told *OTW*, "In 2016 I published on my minimally invasive spine surgeries done with a typical round dispensing device, finding that my fusion rate was 75%. I have found that by using our rectangular cannula I can put in more graft material and my fusion rate increased by 17%! To date, the KG2 Surge has been used in 130 patients—and although it is early in the process, no fusion failures have been reported." — *EH*



Orthopedics This Week
RRY Publications LLC

Drue De Angelis
CEO and Publisher
drue@ryortho.com

Robin R. Young
Editor Emeritus
robin@ryortho.com

Bharathi Gidugu
Accounting and Administration
bharathi@ryortho.com

WRITERS

Kim DelMonico
Senior Writer
kim@beinfluence.co

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

Tracey Romero
Contributing Writer
traceyromero@yahoo.com

PRODUCTION

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

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

Margaret Young
Broadcasting & Events Manager
margaret@ryortho.com

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