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Orthopedics This Week

WEEK IN REVIEW

FOOTING THE BILL FOR HIGH CO-MORBIDITY PATIENTS

BREAKING NEWS

For all news that is ortho, read on.

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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: It's been a rough month for orthopedic equities. The aggregate value of all public ortho stocks fell 5.87% in the last 30 days. It's not a rational valuation change. Institutional buyers see only Middle East and European wars while simultaneously gaming interest rate movements. They are missing essential elements of today's orthopedic business—precisely in front of Q1 sales and earnings reporting season—rising procedure rates and a new generation of innovative leadership at key ortho companies. Here are the top ten orthopedic and spine equities, in our judgement.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	5	Globus Medical	12.74%	(2.86%)	GMED has not been this cheap in years, possibly ever. Management is buying back stock. This is a rare moment. For Q1, analysts are looking at 112% leap in sales. Long-term investors take note.
2	1	Zimmer Biomet	19.31	(5.43)	Probably the most exciting new leader in ortho is ZBH's 44-year-old CEO, Ivan Tornos. For Q1, analysts are expecting sales to grow 9.8%, well above industry average.
3	2	Pacira Biosciences	18.74	(12.56)	The cheapest equity in orthopedics, literally. PCRX expected to report 4% rise in Q1 sales. This is a cash flow machine—check out the operating profit margin.
4	10	Medtronic	19.17	(4.64)	Up significantly in this week's Power Rankings strictly due to valuation and dividend yield. 6th cheapest equity, 3.47% forward dividend yield and the #1 marrket share in spine.
5	8	ConMed	12.24	(4.53)	4th cheapest equity in ortho, CNMD is expected to post up flat-ish sales growth for Q1, but strong earnings: $0.74 vs $0.66 EPS YOY.
6	7	Smith & Nephew	10.06	(8.09)	SNN gets cheaper and cheaper, 3rd least expensive ortho equity. For Q1, analysts are expecting 3.8% sales growth, not great. Big news will be CartiHeal plan.
7	NR	Anika	(14.97)	0.98	The one major bright spot in ortho, rising just 0.98% in a month. Anika's growing by innovating in ortho's fastest growing markets—extremities and innovative pain management.
8	6	Orthofix	(8.51)	(6.83)	CEO Calafiore is another example of the new generation of innovative, inspiring ortho leadership. Been a huge plus for OFIX and the tone is 180 degrees better than a year ago.
9	9	Integra LifeSciences	17.32	(15.92)	OOPs, IART reschedules the Q1 sales and earnings call. Not good news and investors reacted as expected—dumping the stock. It's an overreaction, for sure. Blue light special.
10	4	Johnson & Johnson	19.22	(5.04)	JNJ is one of those equities that investors view as a proxy for the equities market overall. For Q1, investors are expecting flat earnings and an 18% DROP in sales.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Dynatronics Corp	DYNT	$0.53	$3	17.96%
2	OrthoPediatrics Corp	KIDS	$30.31	$721	10.02%
3	Anika Therapeutics	ANIK	$25.84	$384	0.98%
4	Globus Medical	GMED	$50.35	$6,816	-2.86%
5	SI-BONE, Inc.	SIBN	$15.42	$633	-3.81%
6	ConMed	CNMD	$72.64	$2,236	-4.53%
7	Medtronic	MDT	$79.48	$105,535	-4.64%
8	Johnson & Johnson	JNJ	$147.91	$356,431	-5.04%
9	Zimmer Biomet	ZBH	$119.43	$24,493	-5.43%
10	Orthofix	OFIX	$13.10	$490	-6.83%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	SINTX Technologies	SINT	$0.04	$5	-70.38%
2	MicroPort Scientific	0853	$0.68	$1,244	-24.34%
3	Bioventus	BVS	$4.48	$355	-22.09%
4	Xtant Medical Hldgs	XTNT	$0.83	$108	-21.70%
5	AxoGen	AXGN	$6.50	$281	-16.02%
6	Integra LifeSciences	IART	$28.68	$2,254	-15.92%
7	Nevro Corp	NVRO	$12.07	$439	-14.88%
8	Aurora Spine	ASG.V	$0.21	$15	-13.16%
9	Pacira Biosciences	PCRX	$26.25	$1,221	-12.56%
10	Medacta	MOVE	$121.55	$2,431	-11.23%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$147.91	$356,431	17.27
2	Medtronic	MDT	$79.48	$105,535	18.83
3	Pacira Biosciences	PCRX	$26.25	$1,221	23.34
4	Zimmer Biomet	ZBH	$119.43	$24,493	26.21
5	Globus Medical	GMED	$50.35	$6,816	27.79

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Xtant Medical Hldgs	XTNT	$0.83	$108	163.76
2	Medacta	MOVE	$121.55	$2,431	47.41
3	Smith & Nephew	SNN	$23.84	$10,422	39.63
4	Stryker	SYK	$325.43	$123,816	35.03
5	Integra LifeSciences	IART	$28.68	$2,254	33.28

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Smith & Nephew	SNN	$23.84	$10,422	-4.95
2	ConMed	CNMD	$72.64	$2,236	1.27
3	Medacta	MOVE	$121.55	$2,431	1.70
4	Globus Medical	GMED	$50.35	$6,816	1.72
5	Pacira Biosciences	PCRX	$26.25	$1,221	2.24

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Xtant Medical Hldgs	XTNT	$0.83	$108	8.19
2	Medtronic	MDT	$79.48	$105,535	5.41
3	Zimmer Biomet	ZBH	$119.43	$24,493	3.78
4	Integra LifeSciences	IART	$28.68	$2,254	3.78
5	Johnson & Johnson	JNJ	$147.91	$356,431	3.30

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Dynatronics Corp	DYNT	$0.53	$3	0.06
2	Orthofix	OFIX	$13.10	$490	0.66
3	Bioventus	BVS	$4.48	$355	0.69
4	Aurora Spine	ASG.V	$0.21	$15	0.78
5	ZimVie	ZIMV	$15.43	$420	0.92

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Stryker	SYK	$325.43	$123,816	6.04
2	OrthoPediatrics Corp	KIDS	$30.31	$721	4.85
3	Medacta	MOVE	$121.55	$2,431	4.76
4	SI-BONE, Inc.	SIBN	$15.42	$633	4.56
5	Globus Medical	GMED	$50.35	$6,816	4.35

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

Structure vs Chemistry in 3D Printed Spinal Implants

BY ROBIN YOUNG

The logical argument goes like this: if fusion is the goal—and many factors can frustrate a spine surgeon in pursuit of that goal, diabetes, smoking, age, comorbidities—then which of these two factors—structure or chemistry—is your osseointegration ace in the hole?

And how do such innovative designs as, for example, Camber Spine Technologies, LLC's Spira implants, which could never have been produced prior to additive manufacturing techniques, affect osseointegration, support and fusion?

Courtesy Camber Spine Technologies, LLC

Better Osseointegration (Fusion) Through Chemistry?

By definition, osseointegration is the connection between living bone and a load-bearing implant. Strong osseointegration means that the implant becomes so fused with the bone, it can't be separated without breaking. Osseointegration is one of the key definitions of stability and long-term spine fusion clinical success.

From experience, surgeons know osseointegration is complex. In the formative years of spine fusion (1990s) more than one early implant developed fibrous capsules, osteolysis or barely detectable traces of wear debris on or around interbody implants instead of integrating with the surrounding bone.

In addition to using osteoconductive or inductive bone void fills, the other early strategies were to coat or bind thin layers of various metals or osteoinductive ceramics such as hydroxyapatite, titanium, gold, titanium dioxide, diamond-like carbon, or even tert-butoxides to the implant's surface. And those strategies worked to a certain extent.

The most common of these bioactive coatings was hydroxyapatite—which is well known and well characterized.

The other strategy was to create a rough nanometer surface which, again, was able to demonstrate improved bony fusion. Titanium and gold coatings were also able to promote osteoblast adhesion on the implant.

But, as studies have demonstrated, these coatings have trade-offs—their modulus of elasticity, for example, can range from 10 GPa to 100 GPa (compared to 1.0–2.4 GPa in cortical bone), depending on the density of the coat.

Better Osseointegration (Fusion) Through Structure?

3D printing has unleashed a flood of creative implant design energy—struts, curves, arches—and opened the implant real estate for more bone graft material. As 3D printing changed the geometries of each implant, they also altered the implant's biomechanics. Change biomechanics, change osseointegration?

If you're a fan of chemistry over structure and your tools of the trade include, for example, hydroxyapatite, surface modification or other chemical interface, you may think all these new designs are fine, but they're just suspenders, while you still rely on chemistry to be your "belt" in this analogy.

In a 2022 review and analysis of spinal implant osseointegration and the role of 3D printing which was published in the *Journal of Bioengineering* by authors Kia, Antonacci, Wellington, Makanji, and Esmende wrote: "3D printed implants have come into the market, providing mechanical stability with increased surface design for bony ingrowth. While clinical outcomes studies are limited, early results have demonstrated more reliable and quicker fusion rates using 3D custom interbody devices."[i]

In a recent *Orthopedics This Week* Master Class, Bill Walsh, Ph.D., Professor at the University of New South Wales and head of one of the most active bioengineering and testing labs in the world, said: "The geometry of the implant dictates or drives the biomechanics" and biomechanics drives osseointegration and fusion.

Dr. Walsh has been doing osseointegration studies in his lab since the late 1990s and has looked at the osseointegration capabilities of more implants and materials than most surgeons see in their lifetime. Furthermore, Dr. Walsh's model for testing implants and materials has been validated repeatedly over the years.

The New Geometries OVER Chemistry for Osseointegration

Dr. Walsh has looked at the chemistry and coatings of implants as well as the mechanical geometries of the implants. "We've looked at the mechanical proper-

ties, adding hydroxyapatite," explained Dr. Walsh, "different coating thicknesses, traditional manufactured implants, additive manufactured implants from different groups, different companies over those years and we tested them all with the exact same model."

"What we see is that the geometry of the implant dictates or drives the biomechanics."

It's the Macro Topography, Stupid.

"Bone will grow into the available geometry of the implant. I think it is important to realize that macro features can often achieve stability independent of the material. Geometry of the implant is a very, very important component. The porosity and macro topography almost makes the material irrelevant for osseointegration."

"Macro topography is an important component for osseointegration."

Dr. Walsh continued, "Once you achieve some level of biomechanical stability at the implant interface be it at the aperture or at the porous walls, the biomechanics of the whole environment changes. We're not just talking about how strong a cage is, we're talking about a motion segment that you want to stabilize and as soon as you start to fuse especially in the aperture, the stresses go off the implant and down the aperture."

"The cages companies are now designing have elegant features that will hopefully provide better ways for the body to integrate into and facilitate the clinical outcome. The opportunity to make complex shapes with titanium is there. Surface roughness or macro topography? I'll take macro topography any day."

Using Arches, Expanding the Space for Bone Graft and Changing the Macro, Micro and Nano topography

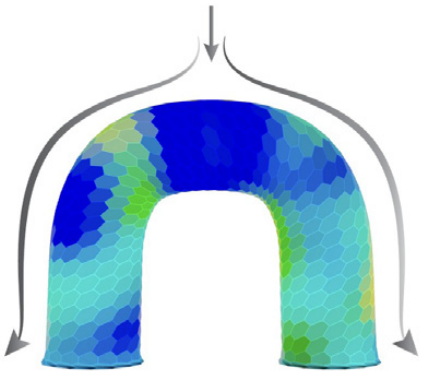
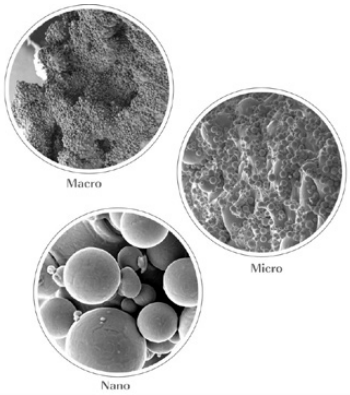
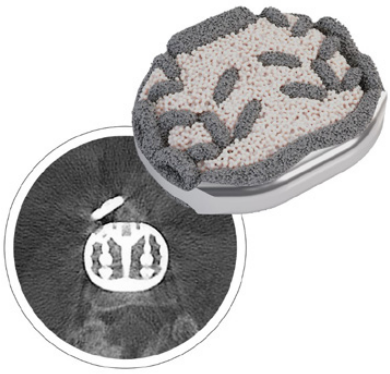
One spinal implant manufacturer that has won Orthopedics This Week's Best Technology in Spine award did so by creatively changing the design of interbody implants to drive improved biomechanics (along with other attributes).

The company, Camber Spine, has combined design, surface macro, micro and nano topography and more space for bone graft into a truly one-of-a-kind implant.

Here are its key features: *(See table on page 7.)*

For more information about Camber Spine's bone graft, here's a link: www.cambermedtech.com/spira-technology ◆

[1] *Spinal Implant Osseointegration and the Role of 3D Printing: An Analysis and Review of the Literature Cameron Kia 1,* , Christopher L. Antonacci 1 1 , Ian Wellington 1 , Heeren S. Makanji 2 and Sean M. Esmende 2*

The Arch Design. Camber's Spira implants employ a series of arches which distribute loads and stresses throughout the implant itself—and, in the process, take advantage of Wollf's Law to help improve osseointegration.	
Macro, Micro and Nano Surface Topography. Because of Camber's additive manufacturing approach, the implant's surface topography extends down three levels, macro, micro and nano, providing cells with multiple ways to attach and proliferate. The implant's surface design is trabecular bone-like with an average pore diameter of just 500µm.	
Subsidence Resistance. It's called the "snowshoe effect." As you can see in the attached images, these designs distribute loads widely across the endplates. More surface area, decreases bone stress (load/area) and reduces subsidence risk.	
More Bone Graft per Implant. Finally, because of the 3D printing process, Camber, like all companies using 3D printing, can create more space within each implant for bone graft.	

Source: Camber Spine Technologies, LLC

Representation and Editorial Boards, Does it Affect the Science?

BY ROBIN YOUNG AND ELIZABETH HOFHEINZ, M.P.H., M.ED.

Yes, Science Knows / Courtesy of Wikimedia

We've documented, as have numerous journals, the latest being *The Journal of Bone and Joint Surgery,* that editorial boards, surgeon society boards and, indeed, the membership of most orthopedic and surgeon societies do not match the gender, ethnic or racial characteristics of the patient populations they serve.

In addition, we've written extensively about the struggle to bring objective, non-biased scientific research to the practicing physician.

Medicine is a mission critical occupation—which is obvious, but unfortunately not so powerful a concept as to change medicine's incentive structure which rewards publishers who reject 60% of all research submitted for publication and seems to push more dollars to the same labs year in and year out.

Perhaps it's time to ask another simple question. What is the connection between lack of representation and the quality of the science being published in these journals or being included on programs at surgeon society meetings?

Is this yet another type of clinical study bias that can be defined and mapped? Maybe the answer is "yes," because how you define a problem, particularly if it is based on your personal frame of reference, can affect how you articulate a "solution." The answer may also be "no," because the connection between gender, race and ethnicity, and the quality or rigor of orthopedic or spine research, does not have an immediately recognizable link.

Do we really think that only certain genders or ethnicities or races can do rigorous research? Hardly.

The newest study we've seen documents, again, the lack of racial/ethnic and gender representation on orthopedic journal editorial boards and found that it mirrors the lack of diversity and representation in academic orthopaedics overall. The study, "Racial/Ethnic and Gender Diversity of Orthopaedic Journal Editorial Boards," appears in the March 6, 2024, edition of *The Journal of Bone and Joint Surgery.*

"In the current era of evidence-based medicine, scientific publications play a crucial role in guiding patient care," said co-author, David Forsh, M.D., Chief of Orthopaedic Trauma, Associate Professor of Orthopaedics, Icahn

School of Medicine, Mount Sinai Health System, to *OTW.* "While the lack of diversity among orthopaedic surgeons has been well documented, little is known about the diversity of orthopaedic journal editorial boards. The purpose of this study was to assess the racial/ethnic and gender diversity of U.S. orthopaedic journal editorial boards."

The researchers included 876 editorial board members of 13 subspecialty and general orthopedic journals, using the 2021 journal impact factor to identify the most prominent U.S.-based journal in the field. Of the members of the editorial boards, 14.0% were Asian, 1.9% were Black, 1.9% were Hispanic, 2.4% were multiracial/other, and 79.7% were White.

They found no significant differences in minority representation between the different orthopedic subspecialties. The representation of racial/ethnic minority groups on journal editorial boards was similar to their representation in academic orthopedics (14.0% versus 14.1% for Asian, 1.9% versus 2.2% for Black, and 1.9% versus 2.1% for Hispanic). Asian representation was higher than that observed in the general U.S. population (6.0%), while Black and Hispanic representation was lower than that observed in the U.S. population (12.4% and 19.0%, respectively).

The overall representation of women was 7.9% (69 of 876). They determined that lower female representation was evident in adult reconstruction, spine, sports medicine, and trauma when compared with general orthopedics.

"In this study, the representation of racial/ethnic minorities and women on editorial boards was similar to their representation in academic orthopaedics," said Dr. Forsh to *OTW.* "However, these values remain low in comparison with the population of patients treated by orthopaedic surgeons. Given the importance of scientific publications in the current era of evidence-based medicine, orthopaedic journals should continue working to diversify the membership of their editorial boards."

In conclusion, this study along with several others, has established that editorial and surgeon society or foundation boards in orthopedics and spine do not have the same gender, ethnic or racial diversity profile as the patient populations they serve.

Is that a difference with a distinction or not? It's time someone tackles that question, rigorously and objectively. ♦

AAOS Best Paper Award Goes to NYU Langone Research Team

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

FOOTING THE BILL FOR HIGH CO-MORBIDITY PATIENTS

Source: Shutterstock and RRY Publications LLC

The best paper in all of orthopedics for practice management and/or rehabilitation, according to the American Academy of Orthopaedic Surgeons (AAOS), for 2024 came from a team of researchers at New York University's Langone Orthopedics hospital.

The paper, "The Financial Burden of Patient Comorbidities on Total Knee Arthroplasty Procedures – A Matched Cohort Analysis of High-Comorbidity Burden to Non-High-Comorbidity Burden Patients," looked into the reimbursement issues surrounding the treatment of total knee arthroplasty (TKA) patients with multiple comorbidities.

This study, which collected data from 10,647 patients (1,186 high-comorbidity patients and 9,461 non-high-comorbidity patients), found that high-comorbidity patients undergoing TKA incurred significantly higher total and direct costs compared to non-high-comorbidity patients patients—BUT without an increase in hospital revenue for high-comorbidity burden patients.

"Direct costs were 12.5% greater (95% CI, 8.8-16.2%) among high-comorbidity patients," said Ran Schwarzkopf, M.D., senior author of the study and professor at NYU Langone Orthopedics, to *OTW*. "Similarly, total costs were 15.6% greater (95% CI, 11.6-19.5%) in this patient group as well."

"And while no significant difference was found between groups with respect to hospital revenue (-1.5%; 95% CI, -80 to 4.9%), the cost differences between the two resulted in a significantly decreased contribution margin among high-risk patients (-19.9%; 95% CI, -34.9 to -4.9%)."

"Perhaps not surprisingly, more high-risk patients (15 vs 7) also experienced hospital readmission within the first 90 days after surgery."

"Reasons for these readmissions included sepsis, surgical site infection, fracture, prosthetic join infection, dehiscence, hematoma, mechanical failure, pain, and non-surgical site orthopedic complications."

"Hospital length of stay was also greater among those in the high-risk group (3.3 vs 2.7 days). On the other hand, no differences were found between groups with respect to operating room time or 90-day revision rates."

OTW asked Dr. Schwarzkopf to opine on how reimbursement programs might adjust for patient comorbidity burdens. Dr. Schwarzkopf responded: "I think we need to define what comorbidity burden justifies the higher diagnosis-related group for inpatient status."

"After seeing the decreased contribution margin in the high-risk patient group, we then tried to calculate the percentage of patients who would need to be classified in the higher acuity diagnosis-related group to at least keep the contribution margin equal."

"We found that it was about 25%, which means that one-fourth of our patients have to get the higher diagnosis-related group for TKA to still be fiscally viable in these patients without a decrease in the contribution margin. Less than 4% of our patients got the higher paying diagnosis-related group in the study."

"It will be important for hospitals to try to get diagnosis-related group 469 vs. 470 for these high comorbidity patients. We need to advocate, and we need to push for this, but we have to continue caring for these patients because, surgically, they do well."

Dr. Schwarzkopf: "This imbalance in contribution margins poses a significant threat to the financial sustainability of healthcare institutions, impacting their ability to provide quality care to these vulnerable patient populations." ♦

COMPANY

$20M Series B Extension Boosts ACL Implant

Miach Orthopaedics, Inc. has closed a successful $20 million Series B extension financing round.

The financing will be used to continue to support and expand commercialization and clinical activities for its Bridge-Enhanced ACL Restoration (BEAR®) Implant.

OTW spoke with Miach Orthopaedics President and CEO Patrick McBrayer about the financing. McBrayer told *OTW*, "We are at an exciting time in the growth of Miach Orthopaedics, having recently closed on a record first quarter in terms of number of patients treated.

BEAR® Implant / Source: Miach Orthopaedics, Inc.

This financing will enable us to further commercialization for the BEAR Implant while continuing to expand the extensive base of clinical evidence through our Bridge Registry real-world study."

New investors joined this round including the Major League Soccer Players Association, SV Health Investors, and Aperture Venture Partners. Concurrent with the funding is the announcement that SV Health Investors will now be represented on the Miach Orthopaedics BOD. Existing investors include the following: Amzak Health, Smith & Nephew, DSM Venturing, Sectoral Asset Management, Endeavour Vision, and the NFL Players Association.

McBrayer added, "The BEAR Implant has been embraced by athletes of all skill levels and ages to restore the natural function of their knee following an ACL [anterior cruciate ligament] injury. We are excited to welcome the Major League Soccer Players Association to our esteemed roster of investors, which also includes the National Football League Players Association. We believe investment by these leading organizations is indicative of the impact that ACL tears have on professional soccer and football players, and the potential for their ACL tears to be treated more naturally with the BEAR Implant."

The BEAR implant differs from current ACL tear treatments. Instead of replacing the ACL with another tendon, the BEAR implant, per the press release, utilizes the body's own blood to enable the body to "heal its own torn ACL." Nearly 3,000 ACL patients suffering from tears have already been treated with the BEAR Implant.

For *OTW*'s coverage of the initial Series B, see "Miach Orthopaedics Raises $40M." — *KD*

ZimVie Closes Sale of Spine Business – Re-Named Highridge Medical

ZimVie Inc. has completed the sale of its spine business to an affiliate of H.I.G. Capital.

HIGHRIDGE H.I.G. CAPITAL ZimVie

Source: Highridge, H.I.G. Capital, ZimVie Inc.

The sale is for a total of $375 million. Under the terms of the agreement, H.I.G is paying $315 million in cash "subject to certain customary adjustments as set forth in the agreement" and a $60 mil-

lion promissory note. The promissory note "will accrue interest at a rate of 10% per annum, compounded semi-annually, payable in kind, subject to a maturity no later than five and a half years" from the date of closing.

Headquartered in Miami, Florida, H.I.G. Capital is a global alternative investment firm. It has $60 billion of capital under management. The acquired spine business will operate as an independent entity under the name of Highridge Medical.

ZimVie is a global life sciences company based in Westminster, Colorado. After the sale, its sole focus will be on the dental industry. This includes the development, manufacturing, and delivery of, according to the company, "comprehensive portfolio of products and solutions designed to support dental tooth replacement and restoration procedures."

ZimVie President and Chief Executive Officer Vafa Jamali commented, "The completion of the sale of our Spine business is the culmination of months of partnership with H.I.G. Capital and years of commitment from our global Spine team members; I would like to thank everyone for their immense contributions."

Jamali continued, "I could not be more excited for the future of our company as we continue to invest in differentiated solutions for Dental patients and providers in our most attractive end markets, while optimizing our structure to deliver value for our shareholders."

According to the press release, ZimVie plans to "immediately pay down $275 million of outstanding debt." This leaves "total debt of approximately $234 million, and estimated cash of approximately $66 million." Additionally, ZimVie expects to accomplish an "annualized financial profile of $455+ million in Net Sales, and a 15%+ adjusted EBITDA margin(1) one year following the close of the deal."

Highridge Medical

Highridge Medical's senior leadership are among the most experienced, successful, and active spine industry executives. Executive board chairman is Eric Major, co-founder and CEO of K2M, which Stryker purchased in 2018 for $1.4 billion. Chief Executive Officer is Glenn Kashuba, whose 30+ year career in orthopedics and spine included, most recently, the CEO position at Cerapedics where he led that company to become the second largest supplier of bone graft products, behind Medtronic, in spine.

Highridge Medical generated about $400 million in sales and approximately $30 million in operating profit in 2023. Under this management, we would expect the company to quickly establish its identity and set out a plan to invest in innovation and differentiation leading ultimately to accelerated sales and market share in the spine and neurosurgery market. — *KD*

LEGAL

Who Pays for a Data Breach?

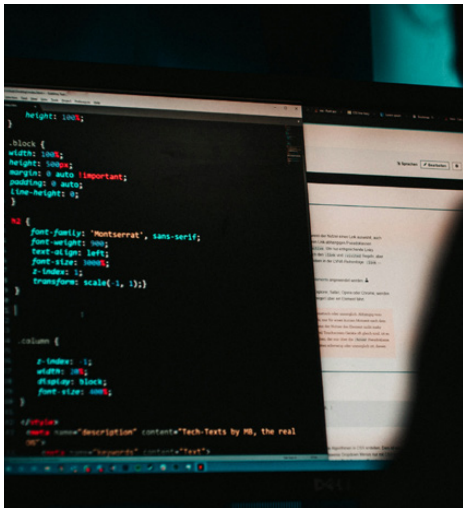
Do you know who pays for a data breach?

Your first response may of course be the individuals who have had their data exposed. Those individuals pay with the time, stress, and potential risks associated with their data being exposed as well as the costs to monitor their personal information.

However, orthopedic practices and hospitals may also have to pay. Especially if the organizations are sued by the individuals who had their data exposed.

Northeast Orthopedics and Sports Medicine, PLLC is facing such legal action. The proposed class action comes in response to the November 2023 cyberattack that exposed the personal data of approximately 177,276 individuals.

The lawsuit claims that Northeast Orthopedics failed to protect the personal data of the individuals who had their information exposed during the cyberattack. In the lawsuit, it is alleged that the orthopedic practice failed "to properly secure and safeguard the personally identifiable information that it collected and maintained as part of its regular business practices, including, but not limited to, names, Social Security numbers, driver's license information, payment information, and dates of birth ('personally identifying information' or 'PII') and medical and health insurance information…."



Source: Unsplash and Mika Baumeister

This is not the first class action to be filed against an organization after a data breach. *OTW* has covered a number of these lawsuits. For *OTW*'s previous coverage of organizations paying for data breaches, see "Bienville Orthopaedic Specialists Sued Over Data Breach," "The Price of a Data Breach," "Banner Health Agrees to Pay $6 Million for Data Breach," and "Victims Can Sue Ortho Clinics if Data Hacked."

Patients and other individuals have found that they can sue after their data is exposed and if the lawsuit is successful, the organizations have to pay. Do these continuing lawsuits indicate a growing trend? If this is a trend then it may indicate that orthopedic practices and hospitals not only need to be worried about cyberattacks but also about the threat of litigation after the cyberattack. — *KD*

LARGE JOINTS

$33 Million to Truly Regenerate Arthritic Joints

Duke School of Medicine, Boston Children's Hospital, and University of California Los Angeles (UCLA) have been awarded a contract of up to $33 million from the Advanced Research Projects Agency for Health to develop an osteoarthritis treatment that is not only disease modifying but will also regenerate joints.

Benjamin Alman, M.D., chair of the Department of Orthopaedic Surgery at Duke University School of Medicine and director of the project, stated, "We need a new approach to treat osteoarthritis, which is a leading cause of disability and represents a $128 billion cost

Source: Wikimedia Commons and Macklay63

burden on the U.S. health care system. Regenerating cartilage and bone would be an effective therapy, and we have the technology, resources, and expertise in hand to make this a reality."

Working from recent evidence that joint tissues can heal, the researchers say they will build on previous findings such as

"the identification of small molecules and proteins that improve the cartilage regeneration process; the development of methods to deliver agents and target them to relevant joint tissues; the restoration of joint and bone tissue to a more normal 'younger' state in animal studies; and an understanding of the genes and pathways needed to generate articular cartilage."

When *OTW* asked for details on these small molecules and proteins, Dr. Alman commented, "These agents were selected because there is evidence that they will help cells in arthritic joints regrow and will be safe to use in patients. This is a time release method that will allow each small molecule or protein to be delivered at just the right time. They are also selected to also be safe and cost effective."

"We will achieve our goal of delivering a regenerative treatment for osteoarthritis by capitalizing on the expertise of our multi-site team, which includes biologists with extensive experience in bone and cartilage regeneration, as well as chemists and bioengineers with expertise in cutting-edge technologies to deliver therapeutic agents to the right place at the right time," said Thomas Kremen, M.D., orthopedic surgeon at UCLA Health and lead investigator for the planned clinical trial.

The researchers propose three therapies.

1. The first would be an injection targeted into the joint to release regenerative factors in the bone supporting injured cartilage.
2. The second would be an injection into the joint to regenerate cartilage tissue.
3. A third therapy would be a systemic version of the injectable that could home in on diseased cartilage tissues in patients who have osteoarthritis in multiple joints.

The first of the three proposed therapies would be an injection targeted into the joint to release regenerative factors in the bone supporting injured cartilage. The second treatment involves an injection into the joint to regenerate cartilage tissue. "A third therapy would be a systemic version of the injectable that could home in on diseased cartilage tissues in patients who have osteoarthritis in multiple joints. By applying these therapies to specific cell populations over the appropriate time frame, the researchers hope to rebuild and rejuvenate a fully functional joint."

"Our team represents a collective and relentless effort to deliver a solution to

those that suffer from joint pain," said April Craft, Ph.D., assistant professor of orthopedic surgery at Boston Children's Hospital and Harvard Medical School and site director of the research project. "Our goal is to restore function to damaged joints by reactivating our own cells in a way that promotes healthy tissue regeneration."

"A unique aspect of the work is considering the diversity of patients who would benefit from the treatment from the start of the project," Dr. Alman said. "Osteoarthritis does not affect all populations equally, and the project will include an arm to identify populations that would benefit the most and to ensure that the proposed therapies are readily available to those patients."

"The program aims to develop treatments that can be tried in patients within five years," stated Dr. Alman to *OTW. — EH*

Mixed-Reality TKA Guidance System Announced

A mixed-reality total knee arthroplasty was announced by its manufacturer, Miami-based Polaris. "Mixed Reality" refers to systems—which, incidentally, came out of the gaming industry—that combine the real information (images, sounds, etc.) with digital sound, graphics, labels, or 3D models. By using a mixed reality system, surgeons can interact with both physical and virtual objects simultaneously.

Polaris's new mixed reality system, brand named the STELLAR Knee system, received FDA clearance in 2023 and has just recently been employed at

PolarisAR STELLAR knee/ Source: PolarisAR

New York-Presbyterian/Columbia University's Irving Medical Center.

"This initial case represents a transition from a development stage to a commercial stage company," said Polaris[AR] CEO Paul Mikus. "We hired brilliant engineers from a variety of backgrounds so that there would be a divergence of thought. Our goal was to move away from the thinking in the orthopedic space and really create from a place of no limits. We are not just overlaying holographics, but also using mixed reality as the tracking and guidance device."

"We are using mixed reality to spatially map the clinical field and then precisely capture digital measurement," explained Mikus to *OTW*. "Using mixed reality visualization surgeons can see through to the site and accurately plan, place and confirm the location of instruments in the scene. The image of the real-time intraoperative plan is dynamically developed and displayed on the actual knee—without the need for CT or X-ray."

"Surgeons have long been stuck with technology that doesn't allow them to make important intraoperative adjustments. The STELLAR Knee, however, gives surgeons enhanced decision making capabilities as they can easily make real-time changes to the surgical plan."

"Approximately 30% of TKA cases have access to robotics. Thus, if you have 10 surgeons on staff and only 2 robots, then some people won't have that access. A hospital is not going to buy eight more robots. Also, while you can't take a robotic system to an ASC, with our technology, you just need a small headset. In addition, we're agnostic to implants so there is none of the 'Oh, it's a Stryker robot so you have to use a Stryker implant.'"

Particularly interesting, said Mikus to *OTW*, is that the STELLAR Knee creates a continuous data exchange between the surgeon and the software. "I think our system actually facilitates an intimacy between the surgeon and the technology. For the first step, taking measurements, information is coming from the surgical field into the headset, so there is a flow. In stage two—planning—the surgeon is interacting with the information and making adjustments where necessary. Then the surgeon uses that information to guide the instruments, so information is going out of the headset."

Not only does their technology create a flow, explained Mikus, but it relieves surgeons of the need to do calculations in their heads. "With the STELLAR Knee, we do the data gathering, focusing on optimization of lower limb alignment, soft tissue balance, joint line maintenance and component positioning. That way, surgeons can give 100% of their focus to the patient and procedure."

"I think there is a growing sense that robotics is reaching a flattening point. The reception from investors, doctors, and potential partners has been fantastic…they are saying, 'This mixed reality technology is the future!'"

"Democratization of vital technologies is a key objective for our company," Mikus told *OTW*. "Indeed, the STELLAR Knee's small intraoperative footprint opens robotics up to more widespread adoption." — *EH*

EXTREMITIES

What do Referring Doctors Want From Orthopedic Surgeons?

So much of each orthopedic and spine surgeon's business relies on referrals from primary care physicians—who, it should be mentioned, are overworked and may not understand how best to communicate with orthopedic and spine surgeons.

A new study from Harvard's Brigham and Women's Hospital studied the primary care physician and orthopedic surgeon link and uncovered fascinating insights and suggestions. Their

Primary care physician passing stethoscope to surgeon / Source: Shutterstock

work, "Primary Care Physician Preferences Regarding Communication from Orthopaedic Surgeons," was published in the December 23, 2023 edition of *Foot & Ankle Orthopaedics*.

"My appreciation for my colleagues in primary care and their administrative burden led me to this work," explained co-author Christopher Chiodo, M.D., section chief, Foot and Ankle Surgery Service, Brigham and Women's Faulkner Hospital. "In addition, I saw wide variation in my department when it comes to reaching out to primary care physicians regarding shared patients. Some colleagues sent every note to the patient's primary care physician while others sent nothing. I felt that some guidance was needed."

The Brigham and Women's team surveyed 107 primary care physicians, the researchers collected information on years in practice, panel size, typical number of electronic clinical messages received each day, time spent in the electronic medical record (EMR) after normal clinical hours, and burnout level.

The team found that PCPs were most likely to rate communication from orthopedists as highly important when the orthopedist needed information from the primary care physician. In these instances, primary care physicians preferred to receive an Epic Staff Message. Primary care physicians also told researchers that the following scenarios were important:

- the decision for surgery,
- hospitalization, and
- a major clinical change.

In these scenarios, a cc'd Chart rather than Staff Message was preferred.

Increased EMR use after-hours was associated with diminished odds of having high interest in communication from orthopedists. Furthermore,

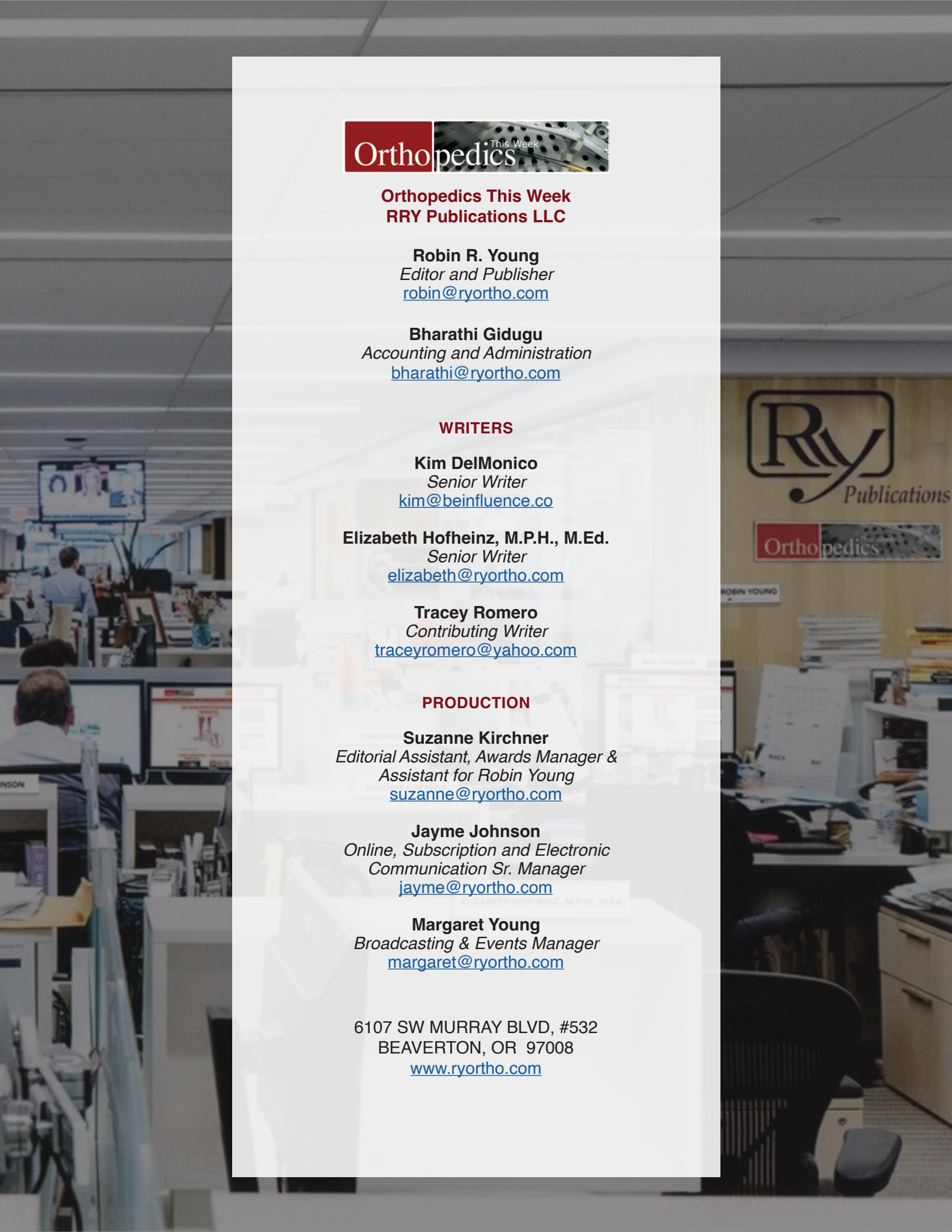
- Ninety-three primary care physicians (86.9%) reported spending at least one hour a day in Epic after clinical hours.
- Twenty-seven (25.2%) spent more than three hours.
- Forty-six PCPs (42.9%) reported experiencing at least one symptom of burnout.

"Several primary physicians have noted that the cc'd chart section of their in-basket has many more items when compared to the Staff Message section," Dr. Chiodo explained to *OTW*. "In addition, some have commented that cc'd chart messages are considered more of an 'FYI'. Staff Messages, however, is more akin to 'you need to know this' or 'your attention is needed here.'"

"I think the takeaway is that, unless you need the primary care physician to take action in some way, the information can be sent as a cc'd chart. I wouldn't say that primary care physicians prefer cc'd charts in critical situations, so much as that unless you need something from them, they prefer the message be sent as a 'lower priority' cc'd chart."

"Of course, they care if their patient is in a critical situation and do want to know. However, my interpretation is that they want to streamline what goes into the more 'high priority' inbox and with this streamline and prioritize workflow."

When *OTW* asked what remains unclear about communication between orthopedic surgeons and primary care physicians, Dr. Chiodo stated, "How to identify and possibly log the preferences of individual primary care physicians remains unclear. With this information, you could more fully customize communications at the institutional level. Perhaps artificial intelligence could play a role here." — *EH*



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