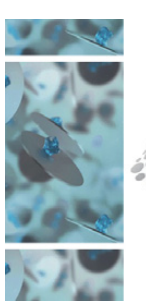
VOLUME 20, ISSUE 3 | FEBRUARY 6, 2024

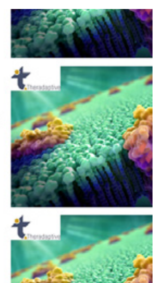
WEEK IN REVIEW

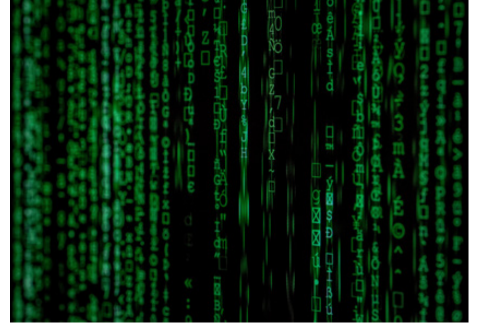
4 Arnold Caplan PhD Has Died, Age 82 >> Dr. Arnold Caplan, "Arnie" to his thousands of colleagues and friends around the world, left us on January 10, 2024. His unifying vision for living cell therapies and regenerative medicine has become a foundational part of musculoskeletal care. The passing of Arnie Caplan is a significant loss. Here is his story.

10 2023 Big Year for Ortho Data Breaches >> 2023 was a big year for data breaches with a whopping 578 breaches of unsecured protected health information affecting 500 or more individuals. More than 112 million individuals were affected.

12 The Interesting Turn BMP2 Bone Grafting Is Taking >> All BMP-2 bone grafting products require an FDA PMA for commercialization in the United States. Three young companies are working their ways through that gauntlet. If successful, and I think one or more will be, then Medtronic's Infuse, the market leader in advanced osteogenetic bone grafts will have its first direct BMP competitor.







BREAKING NEWS

16 Hospital and Ortho Group **Fight Back Against Cybercriminals**

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18 How Much **Skeletal Mass** Is **Lost After a Fragility Fracture?**

20 98% of Cervical Patients **Drive Within 16 Days Postop**

21 Can a Drug Reduce a **Smoker's Risk of Pseudoarthrosis?**

22 How **Price Sensitive** Are **Spine Patients?**

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: Inflation is down. Economic growth is strong, in fact #1 globally. And last week's jobs report, 352,000 new jobs in January, was historically strong—and blasted through consensus forecasts. Those three facts are fueling a bull market—which is good news for every company seeking growth capital. One pattern we're watching among the Ortho and Spine companies we're tracking is the 2024 class of new CEOs. A new CEO, particularly for a troubled company, often translates into 12-18 months of above average stock performance. OFIX, BVS and ZBH added new CEOs in 2023. Definitely worth noting.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	4	Zimmer Biomet	19.31%	4.86%	ZBH reports Q4 sales and provide 2024 guidance later this week. Given SYK and DePuy's numbers, we expect ZBH to beat Wall Street's 5.60% growth estimates on strong TJA sales.
2	5	Smith & Nephew	10.06	5.33	SNN reports Q4 and provides 2024 guidance in about three weeks and, again, the trends are pointing to a better-than-expected 5.30% Wall Street sales growth forecast.
3	3	Orthofix	(8.51)	8.87	New CEO at OFIX and the initial take is unbridled enthusiasm. After a tumultuous few months in 2023, OFIX is setting up to have a settled and growing 2024 under CEO Calafiore and new CFO Andrews.
4	6	Integra LifeSciences	17.32	(1.54)	IART remains grossly undervalued—literally the cheapest equity in all of Ortho and Spine right now. Has agreed to buy Acclarent to fold into the Codman franchise.
5	7	Medtronic	19.26	5.32	MDT is purely a value play these days. Key stats to keep in mind: 5th lowest P/E ratio. 4th lowest P/E to growth ratio. Forward dividend yield: 3.15%.
6	1	Pacira Biosciences	12.86	(5.39)	PCRX continues to struggle with Wall Street's instutional investor crowd. Preliminary 2023 sales were $675 million, up a mere 1.2% growth rate. Where's the sales growth?
7	2	Bioventus	(5.33)	(13.22)	Face it. Wall street is going to miss Tony Bihl. New CEO Claypoole is a blank slate in Ortho, Regen and Spine. Still more recovery work to do after Reali. Picture should be clearer in 6-9 months.
8	NR	Axogen	(9.75)	44.80	Big clinical study news. Statistical superiority vs standard of care neurectomy. Better pain reduction. 12-month follow-up. Innovative peripheral nerve healing and regeneration.
9	8	Globus Medical	17.73	(0.19)	GMED is the slumbering giant at the moment. 2024 could be it's wake-up year. Managememt aggressily buying back stock. Wall Street expects 15% 2023, 13% 2024 sales growth rates.
10	10	ConMed	7.42	(25.33)	CNMD was seriously crushed by Wall Street's bears. Down 25% in 30-days. Why? Missed Wall Street's sales and earnings forecasts for both 2023 and 2024 guidance. Oops!

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	AxoGen	AXGN	$9.60	$413	44.80%
2	Alphatec Holdings	ATEC	$16.62	$2,265	17.79%
3	Stryker	SYK	$342.05	$129,943	16.37%
4	Orthofix	OFIX	$14.11	$519	8.87%
5	Smith & Nephew	SNN	$27.84	$12,171	5.33%
6	Medtronic	MDT	$87.63	$116,518	5.32%
7	ZimVie	ZIMV	$17.96	$477	4.97%
8	Zimmer Biomet	ZBH	$126.32	$26,398	4.86%
9	Anika Therapeutics	ANIK	$23.10	$338	2.08%
10	Medacta	MOVE	$145.46	$2,909	0.07%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	SINTX Technologies	SINT	$0.16	$3	-60.79%
2	MicroPort Scientific	0853	$0.72	$1,314	-30.55%
3	ConMed	CNMD	$80.91	$2,488	-25.33%
4	Nevro Corp	NVRO	$16.26	$590	-15.05%
5	OrthoPediatrics Corp	KIDS	$26.23	$613	-14.59%
6	Bioventus	BVS	$4.53	$357	-13.22%
7	Dynatronics Corp	DYNT	$0.53	$2	-11.67%
8	Xtant Medical Hldgs	XTNT	$1.07	$139	-10.83%
9	Aurora Spine	ASG.V	$0.27	$19	-9.28%
10	Pacira Biosciences	PCRX	$30.34	$1,409	-5.39%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Integra LifeSciences	IART	$40.17	$3,140	17.39
2	Johnson & Johnson	JNJ	$156.61	$377,004	18.85
3	Medtronic	MDT	$87.63	$116,518	20.79
4	Zimmer Biomet	ZBH	$126.32	$26,398	26.21
5	Globus Medical	GMED	$51.83	$7,287	26.62

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medacta	MOVE	$145.46	$2,909	55.62
2	Smith & Nephew	SNN	$27.84	$12,171	54.58
3	Pacira Biosciences	PCRX	$30.34	$1,409	38.75
4	Stryker	SYK	$342.05	$129,943	36.81
5	ConMed	CNMD	$80.91	$2,488	36.01

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Smith & Nephew	SNN	$27.84	$12,171	-6.82
2	ConMed	CNMD	$80.91	$2,488	1.42
3	Integra LifeSciences	IART	$40.17	$3,140	1.95
4	Globus Medical	GMED	$51.83	$7,287	1.96
5	Medacta	MOVE	$145.46	$2,909	1.99

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Medtronic	MDT	$87.63	$116,518	6.17
2	Johnson & Johnson	JNJ	$156.61	$377,004	4.01
3	Zimmer Biomet	ZBH	$126.32	$26,398	3.78
4	Pacira Biosciences	PCRX	$30.34	$1,409	3.37
5	Stryker	SYK	$342.05	$129,943	3.34

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Dynatronics Corp	DYNT	$0.53	$2	0.06
2	ZimVie	ZIMV	$17.96	$477	0.52
3	Bioventus	BVS	$4.53	$357	0.70
4	Aurora Spine	ASG.V	$0.27	$19	1.00
5	Orthofix	OFIX	$14.11	$519	1.13

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	SI-BONE, Inc	SIBN	$20.52	$831	7.81
2	Globus Medical	GMED	$51.83	$7,287	7.12
3	Medacta	MOVE	$145.46	$2,909	6.66
4	Alphatec Holdings	ATEC	$16.62	$2,265	6.46
5	Stryker	SYK	$342.05	$129,943	6.34

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

Arnold Caplan PhD Has Died, Age 82

BY ROBIN YOUNG

Arnold Caplan, Ph.D. / Courtesy of Case Western Reserve University

Dr. Arnold Caplan, "Arnie" to his thousands of colleagues and friends around the world, left us on January 10, 2024.

Dr. Caplan was professor of Biology and director of the Skeletal Research Center at Case Western Reserve University. He also was the lifetime achievement award winner from the Tissue Engineering and Regenerative Medicine International Society.

Titles, however, don't describe Arnold Caplan's life work—which became a foundational body of knowledge in the musculoskeletal field—expressed in more than 400 published papers—translated into multiple clinical therapies, brought to life as start-up companies and—above all—carried forward by the scientists he trained, entrepreneurs he inspired, and patients whose pain and disability his insights relieved.

Dr. Caplan's unifying vision of regenerative medicine lived within an exceptionally creative, warm. and generous mind. His legacy will drive musculoskeletal care for generations to come.

Too Soon

Last October, less than 90 days before he died, Arnie and his wife Bonnie Caplan were visiting their son, Aaron, who said, "Dad, you don't look so good, you look yellow." A couple days later, a doctor told Arnie and Bonnie that he had a blockage in one of his liver's biliary ducts.

The surgery went well. His doctors removed the blockage and inserted a stent to keep the duct open. Arnie recovered well. The yellow pall was gone. But when his doctors got the report back from pathology, they found that Arnie had a metastasizing liver cancer.

A week after Thanksgiving, December 5, Arnie had surgery to remove his cancerous lobe and then, hopefully, with chemo and other treatments, begin the healing process. It didn't work out that way.

The day before Arnold Caplan had the liver surgery, he had walked for two miles and felt ok.

The surgeons couldn't remove his lobe because the cancer was more extensive and in more locations than they'd expected. Over the next couple of weeks, doctors tried various strategies to attack the cancer. Nothing worked. Then Arnie said "stop."

On January 3, 2024, Bonnie, sent the following email to Arnie's global community of colleagues and friends:

> "Here is where we are: Arnold is stable, but he is 100% done with this entire process and does not see a positive outcome to further procedures and he is not willing to endure any further pain, indignity, and overall suffering. He has stated that he wants to take the path of hospice."

Arnold's birthday was two days after that email. The response to Bonnie's email from around the world was, in Bonnie's words, "overwhelming."

"People from all over the world responded," remembers Bonnie, "They passed my email on. The responses began to come, and Arnold loved reading them. He answered some of the emails. But the outpouring from around the world was quite an experience. It was the never-ending response of: 'I love you, Arnie'."

Arnold's friends started to stream into Cleveland for his birthday.

On Friday, January 5, to celebrate Arnold's 82nd year, more than 50 of his friends and colleagues were in a conference room at hospice.

Throughout Arnie's stay in the hospital, he was never alone. Bonnie, Aaron, and his daughter Rachel took shifts. A handful of young college students also joined the small group.

It had been five and a half weeks since Arnold entered the hospital. To Bonnie and the family, it felt more like an intense and brutal five months.

January 5, Arnold's birthday, arrived. He was looking forward to seeing everyone. Remembers Bonnie, "His birthday was on Friday. He was brought to the hospice place, which was quite lovely, actually, on Thursday afternoon. And I had arranged that we would have a gathering. We had a great big cake. It said love. It was pretty, it was cheery."

"But then that morning, he said to me, 'I can't do this'. The idea was to wheel his bed into this big room and then people would talk to him. And I told Arnie, 'I'll protect you. If it's too much, I'll protect you.'

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"So he agreed to go. Around 50 people came, was a great big room. He had what he called a fabulous time."

"He talked to everybody. He held hands. I didn't have to protect him. After an hour, it was enough. And he went back to his room."

Over the entire time, Arnold's family was with him constantly and had those essential conversations with Arnie, shed rivers of tears, expressed their love and…said goodbye.

On January 10, a Wednesday, with his son Aaron by his side, Arnold Caplan drew his final breath.

The Beginning

Arnold Caplan was born January 5, 1942, and grew up in a tough Chicago neighborhood. His father, David, whose formal education ended at 8th grade, worked a lot of different jobs including, for a while as bagman (the guy who collected the money) for a pool hustler. Arnold's mother, Lillian, the youngest of 10 children in her own family, graduated from high school and worked for a while as a secretary.

Arnie, David and Lilian's first-born child, had four sisters.

And he went to college—the Illinois Institute of Technology. Arnie was the first person in his immediate—plus his father's and mother's—family to go to college. Arnold Caplan was a kind of miracle kid.

Arnie's neighborhood was Italian with some Jewish, though not a lot. If somebody approached Arnie and said, "Are you Jewish?" He'd punch the guy. Arnie's dad taught him how to fight—if there's one person, you punch him. Two people, you punch them. Three or more, run.

"Nobody had any money,." remembers Bonnie. "Arnold had saved up, like, $600 bucks to go to the Illinois Institute of Technology. His parents gave him, I think, $7 a week for the bus to Illinois Tech."

The Illinois Institute of Technology, a private research university was, at the time Arnold enrolled, the largest engineering school in the United States. Among its many distinctions, was a stunning Mies-designed campus (Ludwig Van Mies De Rohe is considered to be

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one of the fathers of modern architecture).

Its alumni include three Nobel Prize Laureates, two Fulbright Scholarship recipients, one recipient of the National Medal of Technology and, in 1964, a young chemistry major, Arnold Caplan.

Arnold was a smart and curious student. His grades were excellent, he loved research, so he applied to graduate schools and managed to be accepted by Johns Hopkins University.

"Johns Hopkins opened a whole world of diverse students, people from all over the world," remembers Bonnie.

While Arnie was at Illinois Tech, Bonnie was at Roosevelt University. She had dated a couple of Arnie's fraternity brothers, which introduced her to Arnie. They stayed in touch after graduation (Bonnie went to graduate school at the University of Illinois and Arnold when to Johns Hopkins).

"At Christmas time 1964, Arnie came back to the city. He called me and said, 'You want to have coffee?'" remembers Bonnie. "We went out. I had a car. He did not. And I got home at two in the morning. My parents were not pleased."

They stayed in touch. "We wrote letters. We wrote about values, what we wanted to do, how our lives were," remembers Bonnie, "Arnie was funny. Interesting. I had dated a lot but Arnie just sort of checked all the boxes."

On July 4, 1965, they got married. Bonnie moved to Baltimore. With her master's degree she found a job at a home for unwed mothers and Arnold began his Ph.D. study in Albert Lehninger's lab at Johns Hopkins Medical School.

Challenging Both Dogma and Lehninger

In a 2020 published interview with Anthony Atala, M.D.[i], the G. Link Professor and founding director of the Wake Forest Institute for Regenerative Medicine a, Arnie recounted the following formative moment in his career:

"I was a graduate student in the laboratory of Albert Lehninger at Johns Hopkins Medical School."

Lehninger had, in 1948, discovered along with Eugene P. Kennedy that mitochondria are the site of oxidative phosphorylation in eukaryotes, which ushered in the modern study of energy transduction in cellular biology. It was, at the time, the cutting edge of biochemistry.

Arnold Caplan, a researcher in Lehninger's lab was drafting a manuscript—his first—and had sent it to Professor Lehninger for review. This was 1965.

In the discussion section of the draft, Arnie hypothesized that calcium ions might well be transported into the mitochondrial interstices passing inward from the outside media and eventually passing through the inner membrane and that it had nothing whatsoever to do with the oxidative phosphorylation chain—countering the dogma at the time.

Transporting calcium was, Arnold suggested, an indirect activity, not, as Lehninger taught, a direct connection. "This not only went against the dogma in Lehninger's laboratory but also was in opposition to his published interpretation," remembered the Dr. Caplan, "which stated that calcium transport into the interstices of the mitochondria happened through the functioning of the electron transport chain itself."

Unbeknownst to either Dr. Lehninger or Dr. Caplan at the time, at Glynn Research Laboratories, Bodmin, Cornwall, UK Professor Peter Mitchell was also thinking that the electron transport was an indirect activity. He postulated that there was no electron transport chain, per se, but rather an electrical potential differential between the inside and outside of the inner mitochondrial membrane that was controlled by hydrogen ion transport.

For that insight Mitchell received the Nobel Prize in 1978.

Dr. Lehninger compelled the young Dr. Caplan to edit his discussion section and bring it in line with the lab's traditional views.

"It not only hurt my pride but also, in the end, was a block that impeded innovative thought and potential progress in that field of study. The other takeaway from this experience is that it will require a huge amount of time and energy in order to change the standard, accepted explanation, the dogma of the day, within a scientific context," remembered Arnie in that interview with Dr. Atala.

Arnold Caplan was granted his Ph.D. in 1966 for studying the inner and outer mitochondrial membranes. For his postdoc, Arnold and Bonnie moved to Boston where Arnie joined Professor Nathan O. Kaplan, chairman of the Department of Biochemistry at Brandeis University.

Reparative Cells of the Mesenchymal Lineage

At Brandise, as Caplan told Atala in their interview, "Professor Kaplan had previously published the effects of nicotinamide and its analogs and the formation and functioning of NAD/NADH.

In the literature, I found other publications in which analogs of nicotinamide caused teratology in developing chick embryos: one group of molecules caused muscle defects and another group of molecules caused bone and cartilage defects."

"My naïve idea was to initially set up a culture of developing embryonic chick skeletal muscle cells as described in the 1960s by Irwin R. Konigsberg and coworkers and expose these cells to the teratogens and to unravel the biochemical mechanism of action in the myogenic developmental process in cell culture."

"To accomplish these experimental objectives, Nate Kaplan introduced me to a wonderful gentleman, Professor Edgar Zwilling in the Biology Department, who agreed that I could work in his laboratory to establish this culture system and run my experiments. I did not know Zwilling from a hole in the wall and I had never read any of his classic papers in the mid-1950s involving the development of embryonic chick limb buds."

It was in Zwilling's laboratory in 1967 that Arnold developed a way to isolate the undifferentiated mesodermal cells from the developing embryonic chick limb buds. This system allowed him to study the ways in which cartilage, bone, and muscle cells differentiate from embryonic limb bud cells in culture. Arnold's resulting paper was published in 1968 in the journal *Science*.

Arnold demonstrated that the external concentration of nicotinamide in cell culture controlled the cytoplasmic concentration of NAD, which eventually involved the PolyADP-ribosylation of histones as the cells were differentiating. That work established Dr. Arnold Caplan as an emerging thought leader and developmental biologist who, in 1969, was recruited by the Biology Department of Case Western Reserve University to teach their long-standing courses in Developmental Biology and Embryology.

Caplan Meets Urist…and Defines Mesenchymal Stem Cells

The official unveiling of the now ubiquitous concept of mesenchymal stem cells was in 1991 when Dr. Caplan's paper was published in the *Journal of Orthopedic Research*.

But the idea of mesenchymal stem cells took root about 15 years earlier when Dr. Arnold Caplan met the inimitable Professor Marshall Urist.

From that same Atala interview with Caplan, here is how Arnold remembers

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the moment. "In the late 1970s, I was mesmerized by a lecture given by Professor Marshall Urist, M.D., on the effects of demineralized bone and the formation of de novo new bone in the muscle pouch of adult mice. Marshall Urist was an orthopedic surgeon at UCLA with an innovative and inquisitive mind."

"He deduced that inductive molecules must have leached out of the demineralized bone and stimulated progenitor cells to form bone in this abnormal site. He named these factors bone morphogenetic proteins, or BMPs, and spent many years trying to purify these molecules from demineralized bone."

"I joined the race to purify these molecules and developed an assay for molecules found in a high-salt extract of demineralized bone. The extracted factors were placed into the medium that bathed cultures of undifferentiated embryonic limb bud cells; these extracts caused the cells to form cartilage under conditions where cartilage never usually formed (a study that we published in *Developmental Biology* in 1985). My laboratory then tried to purify these molecules and, indeed, we were competitors and in a race with my good friend Marshall Urist."

"I was intrigued by the original Urist observation and concept that there must have been a receptive cell in the adult mouse muscle that responded to the BMPs. Steven Haynesworth, Ph.D. (a postdoctoral fellow in my lab), and I started to purify culture adherent cells from fresh scopes of human bone marrow (known to have osteochondral progenitors) which could be expanded and induced into the cartilage and bone lineages in culture."

"The unique trick to this new technology was the use of the optimized culture medium (selected batches of fetal calf serum) which had been previously used with the embryonic chick limb bud cell cultures. Because of the mesodermal origin of the embryonic chick limb bud cells, I called these adherent human marrow cells *mesenchymal stem cells (MSCs)*, because we could cause them to differentiate into mesenchymal phenotypes in culture and coined the term in a publication in the *Journal of Orthopedic Research* in 1991."

END OF PART I:

PART II: "*Becoming the Father of Regenerative Medicine*" will appear in the next edition of Orthopedics This Week ♦

[i] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9216494/

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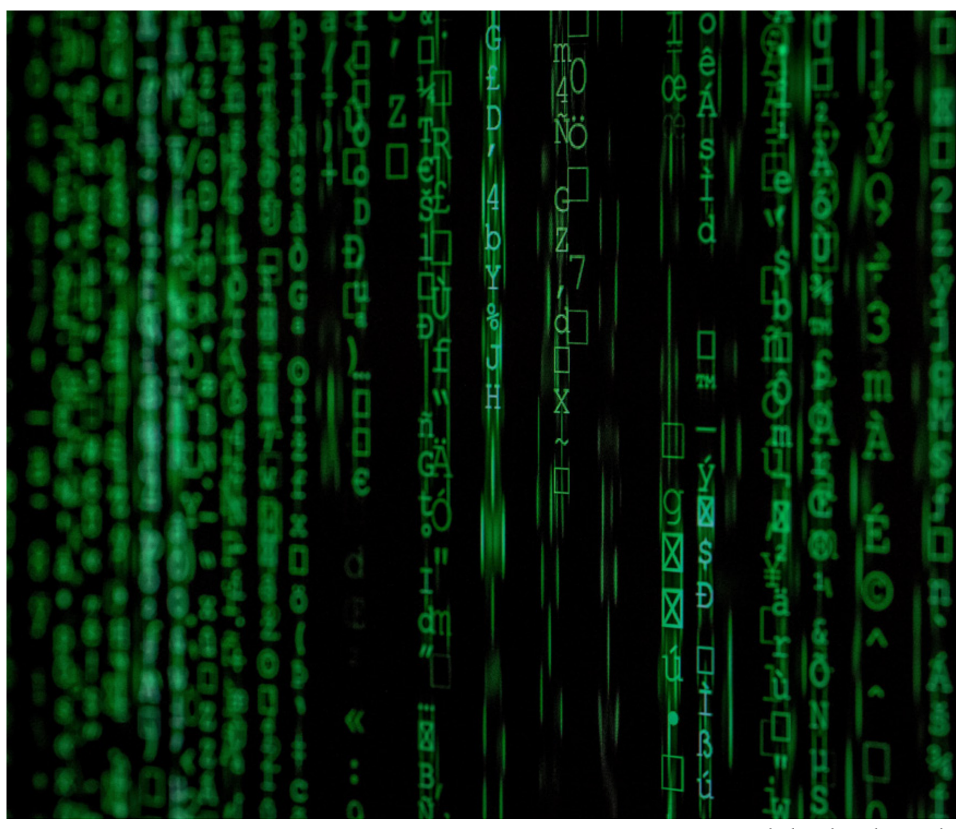
2023 Big Year for Ortho Data Breaches

BY KIM DELMONICO

Last year was a big year for data breaches. During the course of 2023, 578 breaches of unsecured protected health information affecting 500 or more individuals were reported. These breaches affected more than 112 million individuals according to the U.S. Department of Health and Human Services (HHS) Office for Civil Rights.

In 2023, over 20 data breaches were reported affecting more than one million individuals. Nashville, Tennessee-based HCA Healthcare notified its patients in August of last year of a breach that may have affected over 11 million people. This was the largest data breach of 2023.

Orthopedic and spine practices were not immune to data breaches and cyberattacks. Included with the nearly 600 reported breaches were a number of significant breaches impacting spine and orthopedic practices.



Source: Unsplash and Markus Spiske

In November 2023, Seattle, Washington-based Proliance Surgeons reported a breach that affected 437,392 individuals. The breach was a cyberattack in February 2023 that may have involved sensitive personal information, personally identifiable information, and protected health information.

Mississippi Gulf Coast-based Bienville Orthopaedic Specialists LLC reported a data breach in September 2023. The breach affected 242,986 individuals. Bienville Orthopaedic Specialists was sued after reporting the data breach and faces allegations of negligence, breach of implied contract, breach of fiduciary duty, invasion of privacy, and unjust enrichment. For *OTW*'s coverage of the litigation, see "Bienville Orthopaedic Specialists Sued Over Data Breach."

Bone & Joint Clinic, S.C. is an orthopedic and pain management clinical practice located in Northcentral Wisconsin. It reported a January 2023 data breach impacting 105,094 individuals including current and former employees as well as current and former patients.

Brooklyn Premier Orthopedics, a full-service orthopedic and pain management center based in Brooklyn, New York, reported a data breach in October 2023. The breach affected 48,459 individuals and may have included patient data such as names, addresses, dates of birth, Social Security numbers, and medical treatment information.

Southeastern Orthopaedic Specialists, PA, an organization made up of two North Carolina-based orthopedic practices, reported a data breach in December 2023. The breach impacted 35,533 individuals. According to its notice of data security incident, the following categories of information may have been exposed: name, demographic information, and reason for office visit.

It doesn't appear that the data breaches and cyberattacks are slowing down in 2024. Since the beginning of the year, there have already been 14 data breaches reported to the HHS Office for Civil Rights.♦

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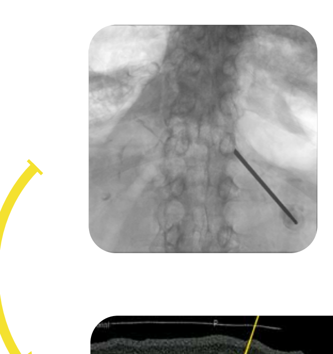
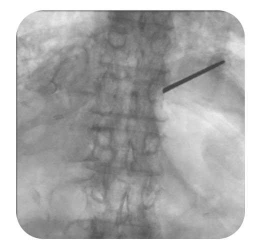
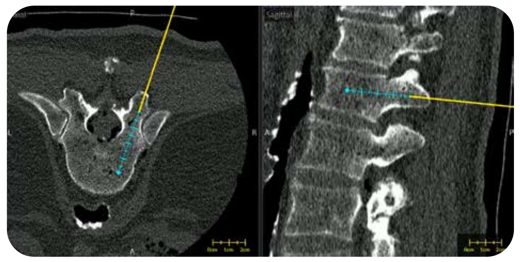

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The Interesting Turn BMP2 Bone Grafting Is Taking

BY ROBIN YOUNG

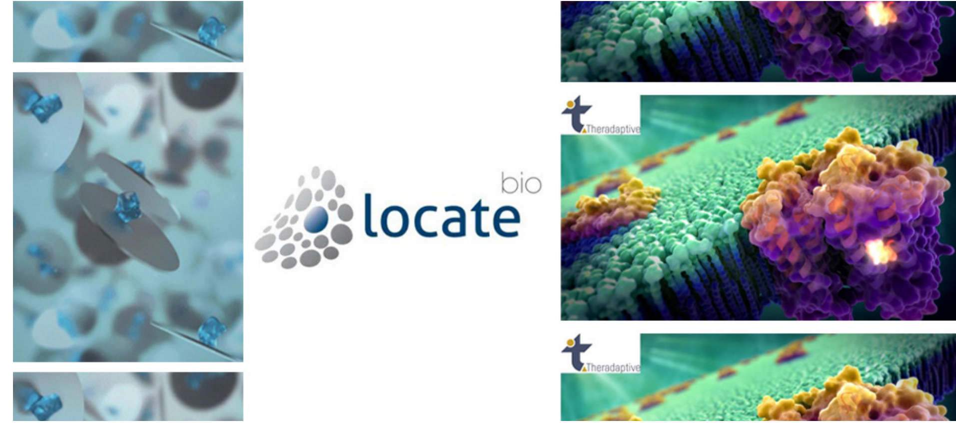
The recent announcement that Renovos Biologics Ltd. received FDA Breakthrough Device designation for its synthetic nanoclay bone fusion gel, RENOVITE® BMP-2, is the latest in a string of announcements regarding novel delivery scaffolds for BMP-2 (bone morphogenic protein 2) based bone grafts.

In April 2023, the Maryland Tech Council announced that Frederick, Maryland-based Theradaptive, Inc. won the Emerging Life Sciences Company of the Year award for its calcium based, BMP-2 delivery platform and for receiving THREE Breakthrough Device designations from the FDA in 2022.

Then, in May 2023, UK-based Locate Bio Limited announced that the U.S. Food and Drug Administration (FDA) had granted its BMP-2 based bone graft product, LDGraft, Breakthrough Device designation. LDGraft is a novel osteoconductive scaffold which provides controlled and extended release of recombinant human bone morphogenetic protein 2 (rhBMP-2).

Nearly a quarter century after BMP-2, in the form of Sofamor Danek's (later Medtronic Spine) Infuse, which used a collagen carrier from Integra LifeSciences Corporation, was approved for use in spine fusion surgery as a bone graft material, at least FIVE breakthrough device designations have been granted to three companies for their very novel BMP-2 delivery systems.

What are those systems and why should we care?



Left: RENOVITE® BMP-2; Right: AMP2, plus ReBOSSIS / Courtesy of Renovos Biologics Ltd., Locate Bio Limited and Theradaptive, Inc.

Nanoclay Gel rhBMP-2 Carrier

Starting with the most recent first, Renovos Biologics is working on a nanoclay bone fusion gel, brand named RENOVITE® BMP-2 which has the potential to deliver an improved (safer, more effective, lower dose) bone morphogenic graft implant.

To be clear, it is difficult, to put it mildly, to use rhBMP-2 as a bone graft without a carrier. First, rhBMP-2 has a short half-life. To be effective without a carrier, it's entirely possible that surgeons would have to administer high dosages (easily hundreds of times higher than naturally occurring BMP-2) repeatedly in order to achieve fusion. Second, rhBMP-2 has been shown in the literature to cause uncontrollable bone regeneration.

Also, rhBMP-2 is instable under thermal or fluctuant pH conditions. So, without a carrier, rhBMP-2 would not meet the exacting requirements of spine fusion surgery. More than that, the right carrier can significantly improve both the efficacy and safety of rhBMP-2.

UK-based Renovos Biologics is using a very innovative material, nanoclay, to hold and release its rhBMP-2. Nanoclay is a 2D nanomaterial for bone tissue engineering which is a highly versatile material with multiple possible functions including osteoinductivity and controlled drug release capabilities.

A mouse study ("Nanoclay Promotes Mouse Cranial Bone Regeneration Mainly through Modulating Drug Binding and Sustained Release") published in the December 2020 issue of *Applied Materials Today,* found that binding rhBMP-2 directly to a nanoclay scaffold provided protection from BMP-2 and delivered a sustained release. The study was conducted at the Iowa Institute for Oral Health Research, University of Iowa College of Dentistry.

Quoting directly from the published study: "To determine the role of NS [nanosilicates] in osteoblastic differentiation and bone formation, we used the mouse calvarial-derived pre-osteoblasts

(MC3T3-E1) and a clinically-relevant mouse cranial bone defect model. Instead of a hydrogel, we prepared biomimetic 3D gelatin nanofibrous scaffolds (GF) and NS-blended composite scaffolds (GF/NS) to determine the essential role of NS in critical low-dose (0.5 µg per scaffold) of BMP-2-induced cranial bone regeneration."

"In contrast to 'osteoinductivity', our data indicated that NS could enable single-dose of BMP-2, promoting significant osteoblastic differentiation while multiple-dose of BMP-2 (without NS) was required to achieve similar efficacy."

"Consistently, our *in vivo* data indicated that only BMP-2/NS direct binding treatment was able to repair the large mouse cranial bone defects after 6 weeks of transplantation while neither BMP-2, NS alone, nor BMP-2 released from GF/NS scaffolds was sufficient to induce significant cranial bone defect repair."

According to Renovos Biologics, "RENOVITE® BMP-2, based on a proprietary synthetic nanoclay gel, is in development as a safer and more effective alternative to currently available bone graft materials. The easy-to-use, injectable gel allows precise, localised bone formation at the target site. It contains BMP-2, a growth factor which promotes in-growth of bone forming cells. The nanoclay gel enables safe, highly targeted bone fusion, as it does not leach BMP-2, with the gel biodegrading as new bone forms."

LDGraft®

Locate Bio, a spin-out from the University of Nottingham and backed by Mercia Asset Management PLC and BGF, has created a novel osteoconductive scaffold which controls and extends the release of rhBMP-2. The carrier does not contain any liquid phase or surface attached rhBMP-2. Instead, Locate Bio encapsulates rhBMP-2 within a proprietary polymer scaffold system which degrades over several weeks, continuously releasing the rhBMP-2 as it does so.

John von Benecke, Locate Bio CEO, said: "According to the World Health Organisation, chronic low back pain is already the leading cause of disability worldwide, with 570 million prevalent cases worldwide. With a rapidly ageing global population, there is now an urgent need for next-generation products to relieve suffering and improve the quality of life for millions of patients."

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"We are delighted therefore to have been granted a Breakthrough Device designation from the FDA for LDGraft, our exciting controlled and extended-release rhBMP-2 scaffold for spinal fusion."

"Having recently completed our final preclinical work, we are looking forward to progressing LDGraft into human clinical trials later this year [2023] and ultimately, regulatory approval."

OsteoAdapt SP (AMP2 + ReBOSSIS Calcium Fibers)

Frederick, Maryland-based Theradaptive uses a calcium fiber-based scaffolding upon which it is binding its own form of BMP-2, which it has brand named AMP2. Early in 2023, the company's researchers presented an abstract which provided evidence of AMP2's efficacy and safety in rabbit posterior lumbar fusion (PLF) and sheep interbody fusion models.

The abstract was presented at the Orthopaedic Research Society's annual meeting in Dallas in early 2023. The abstract showed how coating an implant with its proprietary material-binding osteoinductive AMP2 protein resulted in precise localization of bone formation and consistent spinal fusion without off-target effects.

Researchers observed 100% fusion compared to the 60% associated with current autograft technologies in PLF.

By re-engineering rhBMP-2 to create a material-binding protein variant AMP2, Theradaptive has created a protein that induces bone-growth more potently and in a more precisely localized way than rhBMP-2, thus vastly reducing off-target effects. The Theradaptive process binds AMP2 to ReBOSSIS, a 510K-approved implant material, to create its OsteoAdapt SP Spinal Fusion implant, a safer alternative to commercially available rhBMP-2.

In this study, scientists from Theradaptive and the University of Iowa assessed the ability of OsteoAdapt SP to induce spinal fusion in rabbit posterolateral and sheep interbody models. Twelve rabbits underwent single level posterolateral fusion, using OsteoAdapt SP rather than autograft.

Three sheep underwent two-level lumbar interbody fusion using high or low dose OsteoAdapt SP.

In the rabbit PLF model, OsteoAdapt SP demonstrated an impressive 100% fusion, compared to the 60% associated

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with iliac crest bone grafts, the current best practice.

In the pilot sheep interbody model, CTs showed an increase in density of new bone formation over time with evidence of bridging bone by 4-8 weeks at the high dose and 8-12 weeks at the low dose.

Theradaptive CEO and Founder Dr. Luis Alvarez, Ph.D. sees these results as an encouraging step towards human clinical trials: "Current autograft treatments are painful, they risk adverse events, and they only work around 60% of the time."

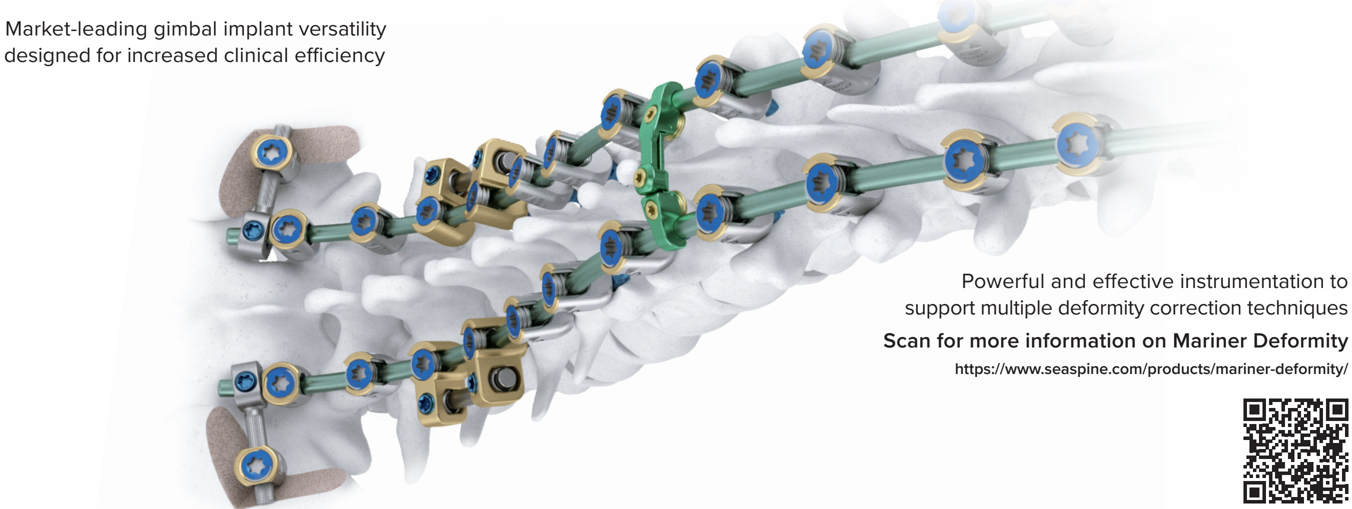
"Seeing OsteoAdapt SP beat the current standard of care in these well accepted models so convincingly in preclinical trials gives us optimism that targeted regenerative technology like AMP2 will improve outcomes for patients who currently have few options. We expect to start first in human trials later this year [2023]."

Douglas Fredericks, Director of the University of Iowa Bone Healing Research Laboratory, said "AMP2 promises a breakthrough to the problem of integrating spinal fusion implants with living tissues. Targeted delivery of biologics harnesses the excellent bone-forming capabilities of current biologics, while limiting off-target responses. Implants like OsteoAdapt SP simplify product preparation and, crucially, deliver an extremely high fusion rate as this study shows."

The Future

Clearly, BMP-based bone grafting is taking a big turn—led by three small technology companies—two in the UK and one in the U.S.

All BMP-2 bone grafting products require an FDA PMA (premarket approval) for commercialization in the United States. All three young companies are working their ways through that gauntlet. If successful, and I think one or more will be, then Medtronic's Infuse, the market leader in advanced osteogenetic bone grafts will have its first direct BMP competitor. As to when, my guess is within three years. Stay tuned, for sure. ♦



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LEGAL

Hospital and Ortho Group Fight Back Against Cybercriminals

Source: Pexels and Tima Miroshnichenko

It's no secret that medical practices and patients have been hit with data breaches over the past years. What may come as a surprise is the recent action by a hospital and orthopedic group in fighting back against the alleged cyber criminals and alleged associated parties.

Claxton-Hepburn Medical Center, Inc., Carthage Area Hospital, and North Country Orthopaedic Group, P.C. (collectively the "hospital group") have filed a lawsuit against John Doe and Jane Doe (collectively "Does") in the St. Lawrence County Court in New York.

The hospital group claims, per the complaint, that the identity of the Does "is currently unknown, as they have perpetrated the subject scheme in secrecy and utilizing the Worldwide Web." Additionally, the hospital group alleges that the Does "conspired to carry out the complex cybercrime and movement of stolen assets."

According to the hospital group, sensitive personal information was com-

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promised in the data breach. That information purportedly includes "names, addresses, dates of birth, financial information, social security numbers, health insurance information, and other personally identifying and protected health information, as defined by the Health Insurance Portability and Accountability Act of 1996." The sensitive personal information is supposedly still in the possession of the cybercriminals and their servers.

The hospital group claims that the data breach occurred on or about August 31, 2023. It further asserts that the Does "were able to gain access to the IT infrastructure of the Hospital Group and to transfer the stolen data to a cloud server owned and operated by Wasabi Technologies, Inc." Wasabi is a cloud storage company based in Boston, Massachusetts.

The hospital group believes that "Wasabi has already provided copies of the stolen data to the FBI." It is requesting injunctive relief against the Does and other entities to prevent the "access, transfer or duplication of the Stolen Data." It is also requesting that "after the Stolen Data is returned to the Hospital Group, all other copies of the Stolen Data be destroyed."

Will this case impact how hospital groups respond to cyberattacks in the future? It does raise some interesting considerations, the first being the actual filing of the lawsuit. In the past, medical groups have not typically responded to data breaches by filing lawsuits against the unnamed cybercriminals. Additionally, the lawsuit also raises interesting considerations for other entities associated with the data breaches including technology firms. — *KD*

REIMBURSEMENT

Do You Know How Much YOU Cost in Your State?

It's no surprise that the cost to visit an orthopedic surgeon varies by state. But do you know the average cost for an orthopedic surgeon visit in your state?

Sidecar Health, a health insurance company based in El Segundo, California, appears to have an answer.

Source: Pexels and John Guccione

On its website it has a list of estimated costs based on "cash prices that providers have historically charged on average for an orthopedic surgeon visit." This

Average Cash Price of an Orthopedic Surgeon Visit by State				
State	Cost		State	Cost
Alabama	$88 - $123		Montana	$92 - $129
Alaska	$119 - $167		Nebraska	$90 - $126
Arizona	$99 - $140		Nevada	$95 - $133
Arkansas	$87 - $122		New Hampshire	$95 - $134
California	$109 - $153		New Jersey	$115 - $162
Colorado	$96 - $135		New Mexico	$88 - $123
Connecticut	$105 - $147		New York	$108 - $152
Delaware	$102 - $143		North Carolina	$87 - $122
District of Columbia	$101 - $142		North Dakota	$97 - $136
Florida	$96 - $135		Ohio	$90 - $127
Georgia	$90 - $127		Oklahoma	$97 - $136
Hawaii	$91 - $128		Oregon	$99 - $139
Idaho	$89 - $125		Pennsylvania	$102 - $143
Illinois	$101 - $142		Rhode Island	$109 - $153
Indiana	$92 - $129		South Carolina	$93 - $130
Iowa	$84 - $117		South Dakota	$86 - $121
Kansas	$87 - $122		Tennessee	$87 - $122
Kentucky	$89 - $124		Texas	$94 - $132
Louisiana	$98 - $138		Utah	$98 - $138
Maine	$89 - $125		Vermont	$96 - $135
Maryland	$105 - $147		Virginia	$94 - $132
Massachusetts	$108 - $151		Washington	$105 - $147
Michigan	$99 - $139		West Virginia	$94 - $132
Minnesota	$112 - $157		Wisconsin	$99 - $139
Mississippi	$89 - $125		Wyoming	$96 - $135
Missouri	$88 - $124			

Courtesy of sidecarhealth.com

list includes all 50 states and the District of Columbia.

Sidecar Health does note on the list that the estimated costs "will vary depending on where the service is done." The estimated costs are not inclusive of other services and fees that may accompany a visit to the orthopedic surgeon such as anesthesia, imaging, and other doctor visit fees.

The most expensive state for an orthopedic surgeon visit based on the list is Alaska with an average cash price ranging from $119 to $167. The least expensive state for an orthopedic surgeon visit according to the list is Iowa with an average cash price ranging from $84 to $117.

Below is the list from the Sidecar Health website of the average cash price of an orthopedic surgeon visit by state. —*KD*

TRAUMA

How Much Skeletal Mass Is Lost After a Fragility Fracture?

Fragility fractures are bad enough, but to what extent do they trigger additional skeletal muscle loss?

A multicenter team set out to answer that question as well as to better understand the relationship of fragility fractures with malnutrition and physical function.

Finally, the team hoped to identify key risk factors for skeletal muscle loss in patients who had been treated with operative fixation of an isolated femoral fragility fracture.

Their multicenter, prospective observational study, "Substantial Loss of Skeletal Muscle Mass Occurs After Femoral Fragility Fracture," appears in the November 15, 2023, edition of *The Journal of Bone and Joint Surgery.*

Source: Shutterstock

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"Loss of function and independence are problems after hip fracture in older adults," co-author Michael Willey, M.D., clinical associate professor of orthopedics and rehabilitation at the University of Iowa, told *OTW*. "Additionally, malnutrition is extremely common and associated with low muscle mass."

"Our group believes that malnutrition and subsequent loss of muscle mass after fracture leads to this loss of function and independence. Our goal is to identify nutrition interventions to prevent loss of muscle mass after injury. Our goal was to document the amount of muscle that is lost after hip fracture and how that correlates with malnutrition and loss of function."

The researchers assessed skeletal muscle mass within 72 hours of admission and then again at 6 weeks, 3 months, and 6 months. At the time of injury, 30 patients (33%) were sarcopenic and 44 (49%) were at risk for malnutrition or had malnutrition.

From the time of injury to 6 weeks:

- participants lost an average of 2.4 kg (9%) of skeletal muscle mass.
- This early loss did not recover by 6 months (1.8 kg persistent loss compared with baseline)
- participants with normal nutritional status lost more skeletal muscle mass from baseline to 6 weeks after injury compared with those with malnutrition (1.3 kg more loss).
- A 1 kg decrease in skeletal muscle mass was associated with an 8-point decrease in the Patient-Reported Outcomes Measurement Information System Physical Function score.

According to co-author Dr. Willey, "Substantial loss of skeletal muscle mass occurs after hip fracture. Loss of function correlated with loss of skeletal muscle mass. Older adults with adequate baseline nutrition and higher muscle mass loss the greatest volume of muscle mass after injury."

"We hypothesized that these patients lost more muscle and function after injury because of a higher baseline health status, indicating that these patients would also be a population that would benefit from nutrition interventions after injury."

"High-quality randomized clinical trials are needed to define the impact of nutrition interventions on muscle mass, function, and independence after hip fracture in older adults." — *EH*

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SPINE

98% of Cervical Patients Drive Within 16 days Postop

Cervical spine patients do well after surgery and in terms of outcomes that are most relevant to the patients themselves. Indeed, this new study raised an important question: Do non-patient reported outcome measures have a role in post-op evaluation systems? If so, which ones can deliver relevant data and how valid, based on objective study, can they be?

A team from New York City-based Hospital for Special Surgery and Weill Cornell Medicine tackled this intriguing question in a new study, "Recovery Kinetics After Cervical Spine Surgery," which appeared in the December 15, 2023 edition of *Spine*.

First author Tejas Subramanian, B.E., a third-year medical student at Weill Cornell Medical, explained the team's rationale and hypothesis for the study to *OTW*, "Currently most of the counseling and pre-operative expectations are based on individual practitioners' experience and a 'best guess' as to how patients are going to do. This is, of course, useful and helpful to patients in most instances but it can be difficult to answer these questions in a data-driven way."

"Because there was surprisingly little data on this topic in the literature, we wanted to introduce our experience to help frame the conversation for providers across the country. Of course, there will be some variability between doctors (for example, based on their comfort level with immobilization after surgery or patients-specific factors like bone quality, etc.) but we are hoping that the data we presented can help bring consistency to the pre-operative counseling for patients undergoing cervical surgery."

Source: Shutterstock

The study enrolled 140 patients, of whom 70 were being treated with either anterior cervical discectomy and fusion (ACDF) and 70 were treated with cervical disk replacement (CDR). To measure outcomes, the team collected data on days to return to driving, return to work and days of opioid use after surgery.

Here is what the researchers documented:

- 98.2% of ACDF patients and 98% of CDR patients returned to driving in 16 and 12 days, respectively;
- 85.7% of ACDF patients and 90.9% of CDR patients returned to work in 16 and 14 days; and
- 98.3% of ACDF patients and 98.3% of CDR patients discontinued opioids in a median of 7 and 6 days.

"As a field, we have focused on patient-reported outcomes and disability for the past several years," stated Subramanian to *OTW*. "This is critical, of course, and has helped advance our field and has established the value of spine procedures. While this remains important to our patients, *ability* is as important as *disability*, and I think that is something we are now starting to realize."

"We are just more familiar with the language of complications and pain scores, but patients care deeply about their recovery from surgery and return to specific activities like driving, work, etc."

"I think discussing a return to these activities is something we have not focused on enough as a field and I hope this paper and others published by our group serve as a framework for some of those discussions."

"I think the most interesting finding was just how quickly patients are able to get back to most activities after these procedures; 98% of patients were driving and almost 90% were working by

16 days. Additionally, we found that patients recover in a similar fashion after ACDF and CDR."

"We need to continue to work on defining return to activities to help our patients get a sense for what they need to do to prepare for surgery and when they can return to specific activities. Our next focus is to look at cervical and lumbar patients and how they return to more athletic pursuits (sports, etc.). I would also love to see similar manuscripts or data from other institutions so that we could have more generalizable data for providers to access." — *EH*

Can a Drug Reduce a Smoker's Risk of Pseudoarthrosis?

Could using the drug varenicline cut the risk of pseudarthrosis for those patients who smoke?

New work, a mouse model, from Rothman Institute and Thomas Jefferson University delivered promising data. The study, "Varenicline mitigates the increased risk of pseudarthrosis associated with nicotine," was published in the September 2023 edition of *The Spine Journal*.

Lead author Brian Karamian, M.D. told *OTW*, "One of the most significant concerns for smokers undergoing spinal fusion is the increased risk of pseudarthrosis. In clinic, we do everything we can to help patients quit smoking. Despite counseling, long-term abstinence remains difficult for patients increasing the risk profile for patients requiring non-elective spine surgery who are unable to abstain from nicotine."

"One of the most successful pharmaceutical adjuncts for smoking cessation is varenicline, a partial agonist that outcompetes nicotine at the $\alpha4\beta2$ nicotinic acetylcholine receptor within the central nervous system. The $\alpha4\beta2$ receptor is the primary receptor targeted by nicotine inhaled from smoke. With a greater binding affinity than nicotine, varenicline decreases dopaminergic tone in the mesolimbic pathway, reducing habit reinforcing symptoms helping patients abstain from smoking."

Using a rodent model (n=60), the researchers set up four groups: control, nicotine, varenicline, and nicotine combined with varenicline.

They found that the fusion rate in the control (93.3%) and combined (93.3%) groups were significantly greater than that of the nicotine group (33.3%). They documented greater bone volume fraction and bone mineral density in the control and combined groups compared to the nicotine group; there was also a greater mineral apposition rate in the combined group compared to the nicotine group.

"The role of the central nervous system as a regulator of bone mass has recently come to light with the discovery that all components of the cholinergic system are present in mammalian non-neuronal cells," stated Dr. Karamian, to *OTW*.

"This means all necessary enzymes, transporters, and receptors for acetylcholine synthesis and recycling are in mesenchymal cells. As a partial agonist of the same receptors activated during smoking, it begs the question if varenicline is able to mitigate the harmful effects of nicotine on bone metabolism by out-competing nicotine and limiting the downstream activation of nicotinic pathways known to decrease trabecular bone volume, thickness, formation, and mineralizing rate."

"This is the first validation of a noninstrumented nicotine-nonunion model using the rodent lumbar spine, providing a novel addition to the basic science approach to studying the clinically important topic of nicotine and pseudarthrosis after spine surgery."

"Additionally, this is the first investigation to evaluate pharmaceutical smok-

Source: Shutterstock

ing cessations agents and their role in fusion biology, both alone and in the presence of nicotine."

"There is a dearth of literature investigating the role of these drugs in musculoskeletal tissue, despite evidence that the target receptors for these drugs are also responsible in regulating bone metabolism. We used a novel approach to established research methodology to quantify changes in fusion morphology. Histomorphometry via fluorochrome labeling has previously been used to study bone mineralization in many different settings. However, to our knowledge, this is the first application of fluorochrome labeling in the setting of bone fusion."

When *OTW* asked for details about the research methodology, Dr. Karamian said, "We delivered pharmaceuticals through subcutaneous osmotic pumps to achieve more consistent delivery and maintain target serum concentrations."

"Targeted concentrations were selected based on the serum concentrations of a heavy smoker and recommended dosing of varenicline. Serum concentrations were then validated using ELISA and liquid chromatography/mass spectrometry testing. The subcutaneous osmotic pumps were exchanged at four weeks to ensure no drop off in the concentration of drug delivery based on our validation data."

"Pumps were implanted two weeks prior to surgery as pre-treatment to mimic the real-life scenario of current smokers undergoing surgery, obtaining the desired steady state concentrations in the serum prior to fusion surgery."

"Vaping has resulted in a nicotine resurgence with the advent of electronic cigarettes. More often we will be seeing chronic nicotine users in our clinic again."

"Surgeons should be apprehensive about performing spinal fusion in nicotine users given the well-documented increased rates of pseudarthrosis and instrumentation failure, alongside worse long-term clinical outcomes. However, our findings have the potential to significantly impact clinical practice guidelines and the use of pharmacotherapy for active nicotine users undergoing fusion surgery." — *EH*

How Price Sensitive Are Spine Patients?

When patients present for spine surgery, they have typically endured weeks if not months of serious pain, tingling and/or numbness. The decision to have surgery is not entered into lightly.

What role, large or small, does the cost of surgery play in their decision to have surgery?

Researchers from Brown University have completed the first large study which attempts to tease out answers to that interesting question. For the study, Brown's research team asked patients how much they might be willing to pay for various procedures at various price points.

Their work, "How much are patients willing to pay for spine surgery? An evaluation of attitudes toward out-of-pocket expenses and cost-reducing measures," appears in the December 2023 edition of *The Spine Journal*.

The survey, which generated 979 responses, asked patients about the costs of anterior cervical discectomy and fusion (ACDF), degenerative lumbar spinal fusions (LF), and adult spine deformity (ASD) surgery.

Co-author Alan Daniels, M.D., associate professor of orthopedics and spine surgery at Brown, told *OTW*, "This survey was inspired by an excellent paper by Wahl EP et al that appeared in *The Journal of Bone and Joint Surgery:* 'Patient Perspectives on the Cost of Hand Sur-

Source: Shutterstock

gery'. We were curious how spine surgery patients would match up with patient perspectives regarding the cost of hand surgery. We chose three very different spinal procedures to see how patient perspectives differ based on surgical invasiveness and risk."

The average age of respondents was 36.2 years, with 44% of participants reporting a household income of $50,000 to 100,000. A total of 63% had Medicare and 13% had Medicaid; 40% stated they had high levels of financial stress.

Patients were asked, if they had to pay $3,000, would they still be willing to undergo a spine surgery? The survey found that 30.1% of participants were willing to undergo an ACDF, 30.3% were willing to undergo a degenerative LF, and 29.6% were willing to undergo ASD.

Interestingly, the researchers found that for ACDF, a $100 increase in price resulted in a 2.1% decrease in willingness to pay; for degenerative LF surgery it was a 1.8% decrease, while for ASD surgery it was 2%.

Cost Savings Data

When patients were asked which measures they were least comfortable with for ACDF:

- 60% stated "Use of the older generation implants/devices" (LF: 51%, ASD: 60%),
- 61% stated "Having the surgery performed at a community hospital instead of at a major academic center" (LF: 49%, ASD: 56%), and
- 55% stated "Administration of anesthesia by a nurse anesthetist" (LF: 48.01%, ASD: 55%).

Conversely, 36% of ACDF patients were uncomfortable with a "Video/telephone postoperative visit" to cut costs (LF: 51%, ASD: 39%).

Patients Want the Latest Technologies, Regardless…

"Patients were not comfortable forfeiting the latest implants—even though spinal implants from the last decade work exceptionally well!" stated Dr. Daniels.

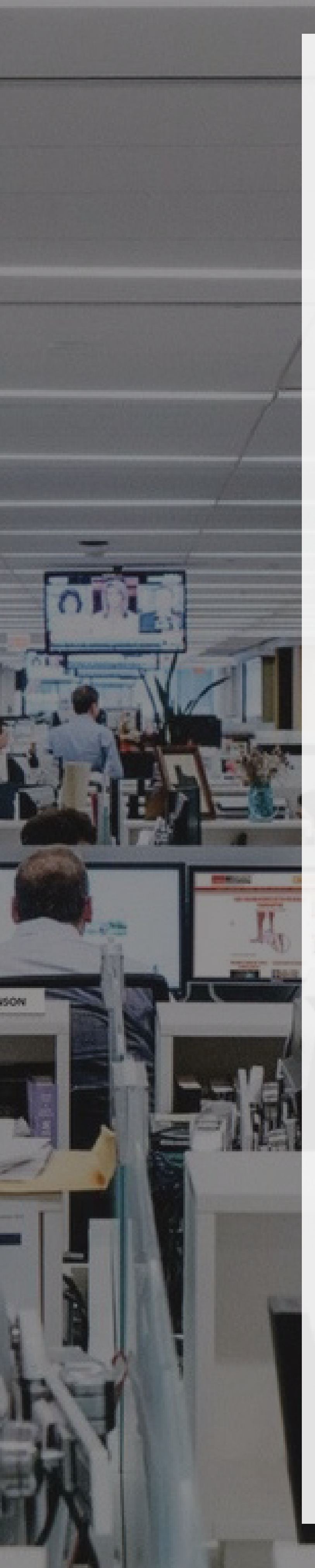
"Patients may not understand that the most modern implants may actually have higher risk of failure as they are not tried and true tested with long term safety. There have been products lauded as the latest and greatest implants which were launched and failed such as ACDF plates with failing locking mechanisms and expandable cages which collapse over time. The latest implants are not always the greatest!"

And Think Community Hospitals Don't Have the Latest Technologies…

"Furthermore, patients were not comfortable undergoing surgery in community hospitals and receiving care by physician extenders. Patients should be educated that community hospitals, especially ones with spine centers, can provide excellent care in spine surgery and may actually be better places to go for routine spinal surgery compared to major academic centers. Physician extenders are an essential part of almost all surgical teams, and often are able to spend more time with patients compared to busy surgeons."

"Finally, patients wishing to save money felt that they were willing to convert postoperative visits to telehealth and forgo neuromonitoring. Spinal deformity patients must get X-rays postoperatively to monitor for devastating complications which can lead to paralysis such as proximal junctional failure, and neuromonitoring is essential for patient safety in many spinal surgery types. Forgoing these essential steps places them at risk of catastrophic complications."

"Spine surgery patients have a poor understanding of which cost saving measures may impact their safety and surgical outcome. We need education, education, and more education. Patients must be educated regarding spine surgical risks and which components of care are essential for an optimal outcome." — *EH*



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