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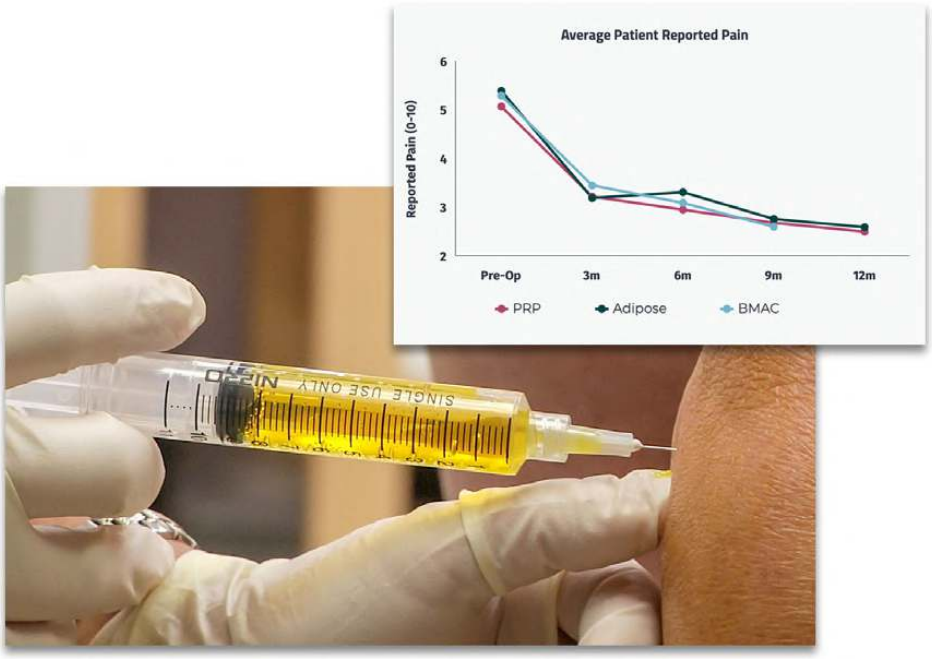
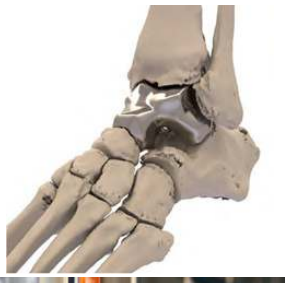
Orthopedics This Week

WEEK IN REVIEW





BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Institutional investors are betting that stimulus dollars plus an accelerating vaccine rollout will fuel a U.S. economic bounce between now and late summer/early fall. Then what? Smart money is on a return to value investing and inflation resistant stocks. To be sure, ortho has been in a deflationary cycle for the better part of 10 years. A little inflation would not hurt. Also, ortho demand is stable, long term, predictable and on an upward trajectory.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	NuVasive	4.78%	17.62%	NUVA hits a 52-week high. Among NUVA's latest developments—a 10-year study of MIS adult deformity surgery outcomes.
2	1	Zimmer	12.91	1.00	ZBH is never far from the top of our weekly Power Rankings mainly due to its low valuation. But, under the hood, ZBH is transforming.
3	3	BioVentus	9.08	1.15	BVS is the new public face of regenerative medicine innovation. The latest is a placental tissue based treatment for knee OA.
4	4	ConMed	7.71	3.84	CNMD is on the Power Rankings by virtue of its low price-to-sales and earnings. It's a value. But...return on equity is just 1.3%, which may explain why it's cheap.
5	5	Integra LifeSciences	16.78	(6.16)	No change in IART's ranking this week, despite a 6% sell off. At these prices, IART is the 3rd best PE ratio and 2nd best PE to growth ratio.
6	6	Johnson & Johnson	26.06	(3.39)	We just saw a headline "JNJ favorite stock of retirees." With a 2.49% dividend yield and odds that they have a DePuy hip or knee, why not?
7	10	Orthofix	(3.24)	7.88	OFIX is among the better performing equities in ortho. The effect of new products and acquisitions has been blunted by COVID. Rebound in 2nd half?
8	NR	Pacira	(31.82)	(5.63)	Just heard a presentation about using Exparel in spine surgery. Cuts time in the hospital and supports increased spine surgery in the ASC setting.
9	9	SeaSpine	(27.16)	5.70	So far, 2021 has a busy year for new product launches at SeaSpine. Which bodes particularly well for the 2nd half of this year.
10	NR	Medtronic	13.67	(1.30)	Recent Wall Street market share estimate for 2020 spine market had Medtronic GAINING share at the expense of Synthes, SYK and NUVA.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Aurora Spine	ASG.V	$0.60	$30	52.55%
2	Xtant Medical Hldgs	XTNT	$2.98	$232	30.13%
3	NuVasive	NUVA	$67.08	$3,447	17.62%
4	Alphatec Holdings	ATEC	$18.29	$1,740	11.32%
5	AxoGen	AXGN	$21.47	$875	10.50%
6	Lattice Biologics	LBL.V	$0.05	$5	10.17%
7	Orthofix	OFIX	$45.85	$895	7.88%
8	SeaSpine Hldgs Corp	SPNE	$19.11	$534	5.70%
9	MiMedx Group	MDXG	$10.15	$1,129	4.75%
10	ConMed	CNMD	$125.54	$3,633	3.84%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	SINTX Technologies	SINT	$2.08	$51	-25.45%
2	MicroPort Scientific	853	$5.55	$10,062	-22.60%
3	Nevro Corp	NVRO	$142.81	$4,945	-19.06%
4	Smith & Nephew	SNN	$37.90	$16,655	-13.80%
5	Dynatronics Corp	DYNT	$1.32	$20	-11.41%
6	Flexion Therapeutics	FLXN	$10.18	$508	-10.78%
7	Surgalign Holdings	SRGA	$2.48	$273	-10.47%
8	Globus Medical	GMED	$60.47	$6,030	-9.37%
9	Stryker	SYK	$230.00	$86,526	-6.72%
10	CryoLife	CRY	$23.25	$906	-6.63%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Pacira	PCRX	$70.06	$3,073	19.65
2	Johnson & Johnson	JNJ	$160.04	$421,338	23.93
3	Integra LifeSciences	IART	$66.77	$5,633	31.43
4	Stryker	SYK	$230.00	$86,526	35.76
5	Smith & Nephew	SNN	$37.90	$16,655	37.18

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MicroPort Scientific	853	$5.55	$10,062	217.41
2	Orthofix	OFIX	$45.85	$895	189.38
3	ConMed	CNMD	$125.54	$3,633	127.27
4	Medtronic	MDT	$116.62	$157,212	51.89
5	Zimmer Biomet	ZBH	$160.16	$33,352	47.83

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Pacira	PCRX	$70.06	$3,073	0.47
2	Integra LifeSciences	IART	$66.77	$5,633	2.47
3	Stryker	SYK	$230.00	$86,526	2.89
4	Globus Medical	GMED	$60.47	$6,030	3.53
5	MicroPort Scientific	853	$5.55	$10,062	4.07

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$45.85	$895	20.15
2	ConMed	CNMD	$125.54	$3,633	9.22
3	Smith & Nephew	SNN	$37.90	$16,655	8.08
4	Medtronic	MDT	$116.62	$157,212	5.71
5	Johnson & Johnson	JNJ	$160.04	$421,338	4.27

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Dynatronics Corp	DYNT	$1.32	$20	0.37
2	Lattice Biologics	LBL.V	$0.05	$5	1.64
3	Aurora Spine	ASG.V	$0.60	$30	2.03
4	Orthofix	OFIX	$45.85	$895	2.20
5	Surgalign Holdings	SRGA	$2.48	$273	2.69

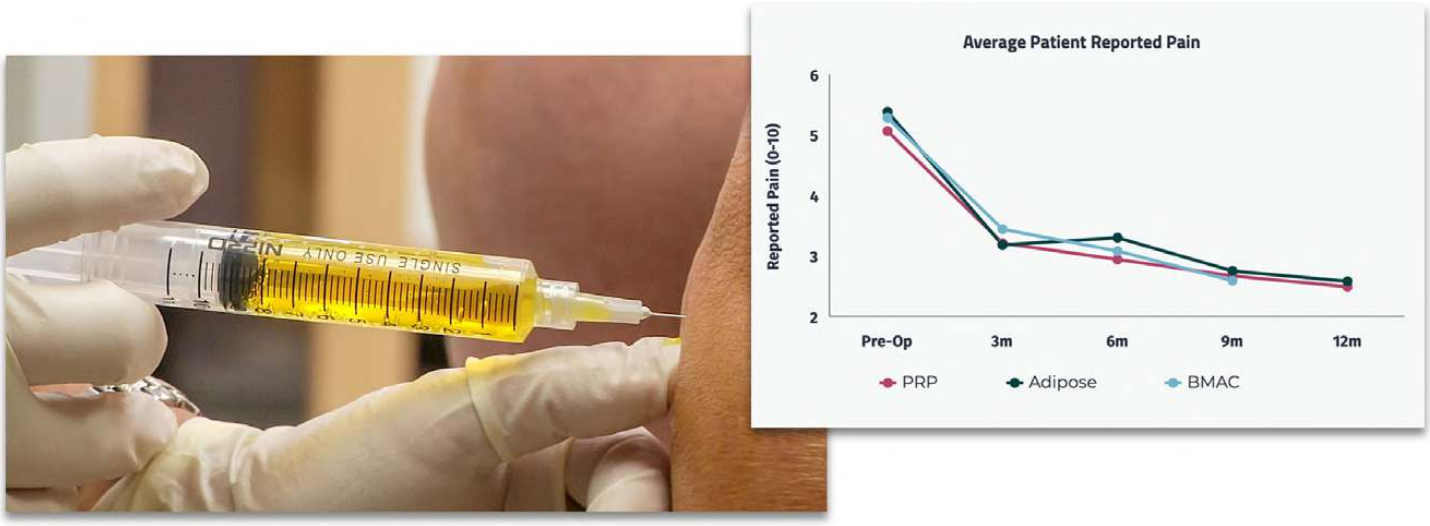
HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	SINTX Technologies	SINT	$2.08	$51	74.52
2	OrthoPediatrics Corp.	KIDS	$50.95	$1,002	14.09
3	Nevro Corp	NVRO	$142.81	$4,945	13.66
4	MicroPort Scientific	853	$5.55	$10,062	12.68
5	Alphatec Holdings	ATEC	$18.29	$1,740	12.01

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

Outcomes Registry Data for Regenerative Treatments

BY ROBIN YOUNG



Source: Wikimedia Commons, Alice Pien M.D. and DataBiologics Report

How consistently and effectively do any of these regenerative medicine treatments work? A new, impressive outcomes registry covering a broad array of regenerative medicine treatments has just been released and it comes with the most definitive, data-based answers yet to that basic question.

The 20-page report, "An Overview of Regenerative Treatments for Orthopedic Conditions 2021 Outcomes Report," presents real world, outcomes data collected from 65 physicians at 43 clinics in 25 states.

The patient outcome data covers the following 11 regenerative medicine treatments:

- Adipose (MFAT)
- Bone Marrow
- Hyaluronic Acid
- Perinatal Tissue
- Platelet Lysate
- Platelet Poor Plasma (A2M, PPC)
- Platelet Rich Plasma (PRP)
- Prolotherapy
- Shock Wave Therapy (ESWT/EPAT)
- Sonex
- Tenex

Author, Author!

There has been a paucity of real-world patient outcome data for the vast majority of regenerative medicine treatments. It's an exciting and innovative field of care, but it has often felt a bit like the wild, wild west.

This report is notable, if for nothing else, for avoiding hype and using accurate and precise nomenclature to refer to various treatments. For example, the words "stem cells" do not appear in this report. Instead, authors referred to living cells with therapeutic value as "regenerative cells" and usually in combination with the term "growth factors."

As we referred to earlier, 65 physicians from 43 clinics joined in this effort. The organizers, authors and whose signatures grace this report are:

Gerard Malanga, M.D.

Board certified physician specializing in Physical Medicine & Rehabilitation, Sports Medicine and Pain Medicine. Dr. Malanga is also the founder of the New Jersey Regenerative Institute and former President of the Interventional Orthobiologics Foundation (IOF).

Jay Bowen, D.O.

Board certified physician specializing in Physical Medicine & Rehabilitation, Sports Medicine and Pain Medicine. Dr. Bowen is Medical Director of the New Jersey Regenerative Institute.

Christopher Rogers, M.D.

Board certified physician specializing in Physical Medicine & Rehabilitation. Dr. Rogers is the founder of the San Diego Orthobiologics Medical Group and Medical Director of Personalized Stem Cells, Inc.

Courtesy of DataBiologics

Supporting them are the following members of a scientific advisory board:

- Steve Sampson, DO, founder of Orthohealing Method and The Orthobiologic Institute (TOBI)
- Ken Mautner, MD, Director of Sports Medicine at Emory Healthcare
- William Murrell, MD, Chief Medical Officer for Emirates Healthcare in Dubai

Vision and Mission

This is the inaugural orthobiologics registry report and, as such, the authors took care to articulate a mission, a vision and map out where this emerging practice specialty is heading.

"Our mission", wrote the authors, "is to empower an international network of physicians, researchers and patients with an outcomes data registry in order to pioneer innovative and effective treatments for patients with orthopedics conditions".

If successful, and we think this report will demonstrate that they are, the vision is to tether the growth of this dynamic and rapidly evolving orthobiologic practice specialty to real-world safety, efficacy and cost effectiveness data.

One of the ultimate goals of the DataBiologics organization is to help weed out "bad actors" by using real-world patient reported data to demonstrate safety and efficacy of quality physicians.

Background

As Malanga, Bowen, and Rogers wrote in their introduction to this registry report, regenerative medicine is a field notable for its innovative energy to develop alternative treatment options for both acute and chronic orthopedic conditions.

But, importantly, this field requires patient-centered data from a wide array of clinics about the real-world effectiveness, complication rates, and predictability of the different forms of orthobiologic therapies.

And, fundamentally, Malanga, Bowen, and Rogers hope that physicians who read this outcome registry report will "gain an understanding of the progress regenerative medicine has achieved, as well as recognize the dire need for more real-world evidence in order to shape a better orthopedic landscape. Most importantly, we hope this resource will demonstrate our efforts to provide a tool for physicians that improves the quality of patient care and outcomes."

Scope of the DataBiologic's Outcome Registry Report

The patient outcomes which are covered in this report include:

- Adverse Events
- FAAM
- HOOS Jr.
- KOOS Jr.
- Neck Disability Index
- Oswestry Disability Index
- Pain Scale (NPRS)
- PHQ-4
- QuickDASH
- VISA-A

And the clinical problems addressed cover spine, large joints, extremities and both acute and chronic conditions.

Data Summary

The report presents standardized reporting data from 9,450 assessments of 3,275 enrolled patients. The average patient age was 54 years, and the average body mass index (BMI) was 26.8.

Most of the patients were treated for knee pain (34%), followed by shoulder (14%), hip (14%), spine (11%) and foot/toes (8%). Also represented were elbow, ankle, wrist/hand and pelvis.

The most common orthobiologic treatment employed in the registry was platelet-rich plasma (PRP) (64%) followed by adipose (17%), bone marrow aspirate stem cell concentrate (BMAC) (12%) and other (7%).

The creators of the report are very clear in stating the data presented in the report is just an overview. More high-quality outcomes data needs to be collected in order to better understand the nuances of treatment effectiveness for specific conditions and patient populations.

PRP Outcomes Data

Seventy-three percent of the patients treated with (PRP) reported a meaningful reduction in pain within 12 months following treatment. Based off published literature, best results with high quality evidence for PRP came from patients treated for lateral epicondylitis or knee osteoarthritis.

There is also strong evidence for PRP in cases of patellar tendinopathy or plantar fasciosis.

Finally, for rotator cuff tendinopathy, osteoarthritis of the hip or high ankle sprains, the outcomes and quality of evidence was "emerging."

Adipose Tissue Therapy

Seventy percent of the patients treated with adipose tissue therapy reported a meaningful reduction in pain within 12 months following treatment. Based off published literature, best results with strong evidence (a lower bar than "high quality evidence" came from patients treated for knee osteoarthritis.

For rotator cuff and labral tears or osteoarthritis of the hip, the quality of evidence was "emerging."

Bone Marrow Aspirate

Sixty-one percent of the patients treated with bone marrow aspirate reported a meaningful reduction in pain within 12 months following treatment. Based off published literature, best results with strong evidence were for knee osteoarthritis and low back pain.

For degenerative meniscal tears, hip capsular injury, intervertebral disc repair and patellar tendinopathy, the quality of evidence was "emerging."

The Future of Regenerative Medicine

As the first outcomes data registry with a meaningful 'n' and with standardized data derived from a broad base of clinics around the United States, this is a very important and relevant report.

Our article only touches the surface of what is in this registry report. We urge ALL of our readers, physicians and companies alike, to get a copy of this report and support the efforts of these pioneering physicians.

Going forward, according to the authors, this new DataBiologics platform will allow physicians who employ these therapies to begin patient-reported outcome data collection and contribute to building this important registry. Malanga, Bowen, and Rogers and their registry group are developing the next generation of DataBiologics software which, they hope, will make it easier for physicians to collect and report their outcome data.

If you want to be part of the DataBiologics future, please contact: info@databiologics.com. ♦

New Hope From Innovation in Chronic Pain Management

BY ADAM SUHY, PH.D.

WaveWriter Alpha Portfolio / Courtesy of Boston Scientific Corporation

Marlborough, Massachusetts-based Boston Scientific Corporation has made great strides in recent months on their WaveWriter Alpha™ line of spinal cord stimulators (SCS). We reported in October 2020 on Boston Scientific's launch of the devices in the European market. Later in 2020, the same devices received FDA approval, enabling the company to launch the portfolio in the U.S., which it announced in mid-January 2021.

The WaveWriter Alpha portfolio includes four different implantable pulse generators (IPGs). Rechargeable and non-rechargeable versions are available with either 16 or 32 leads. Deciding between rechargeable and non-rechargeable IPGs depends on a few factors, including the frequency and intensity of the prescribed therapy. The lifespan of the rechargeable IPG is longer than the non-rechargeable, but comes with the inconvenience of regular charging sessions. Additionally, the entire portfolio is designed and approved for safe use of full-body MRI.

The regulatory success of the devices follows some nagging issues the company has faced in the last few years while trying to expand programming options for its SCS devices.

The company was blocked from adding high-frequency stimulation therapies to its offerings after successful attempts by Nevro Corp., maker of the Senza II spinal cord stimulator, to prove infringement of its high-frequency stimulation therapy patents. The remaining claims of the lawsuit were dropped in December 2020 after Boston Scientific agreed to forgo high-frequency therapy.

Without high-frequency options available, Boston Scientific developed new stimulation modalities to differentiate the WaveWriter Alpha from other traditional or more standard burst stimulation technologies. Through the company's research, it has created what it calls FAST™. Fast-Acting Sub-perception Therapy (FAST) taps into a new mechanism of action that, like some

other advanced stimulation modalities, does not produce paresthesia, and provides relief within minutes with no wash-in or wash-out period.

With fast relief, the need for stimulator trials is reduced, which equates to fewer office visits and insertion procedures. The success of the FAST mechanism is under continued investigation in the Paresthesia-Free Fast-Acting Sub-perception (FAST) Study with sites in South Carolina and Oregon.

Nevro, however, rejuvenated its legal battle with Boston Scientific and filed a new lawsuit claiming that Boston Scientific has infringed upon other patents held by Nevro with its paresthesia-free therapy. Regardless of the outcome of the legal battle, the technology developed by Boston Scientific is fascinating, and gives us a glimpse at the future of pain relief.

In addition to the new stimulation therapy options with the WaveWriter Alpha, new technology in the devices allows for more convenient patient care and continual research opportunities. Remote monitoring allows specialists to track their patients' use and quality-of-care.

New Pain Survey During COVID

A survey conducted in mid-2020, at the height of the COVID-19 pandemic, found that during the pandemic pain increased, on average, due in part to enforced postponements of elective procedures, the conception that doctor offices and healthcare facilities were unsafe, and feelings that the pain was bearable enough to wait out the threat of the pandemic.

Studies have also shown a connection between emotional pain and actual pain, which could explain that stress and the challenges of the pandemic actually increased perception of pain. The survey also uncovered a general lack of knowledge of non-opioid pain relief options, so patient that did seek help tended to not ask for spinal cord stimulation.

More Studies

OTW recently had the opportunity to speak with Nilesh Patel, M.D., who became the VP of Medical affairs at Boston Scientific in 2019. As a former specialist with over 25 years at the Cleveland Clinic, Patel has seen the progression made in spinal cord stimulation for pain relief over the last few decades. He has extensive experience providing pain relief with spinal cord stimulation and radiofrequency ablation techniques.

Patel has great expectations for the WaveWriter Alpha product line. Studies prior to launch showed significant pain reduction with 88% of patients achieving the typical endpoint of at least 50% pain reduction when treated with WaveWriter Alpha in the COMBO study.

Another study, the FAST PRO study, showed fast-acting sub-perception therapy (FAST) could reduce NRS pain scores from an average of 6.5 to 1.3 immediately after activating FAST during the programming session. Pain relief was maintained through 3- and 6-month follow-up visits with average NRS pain scores of 1.6 and 1.5 points, respectively. Results for both the survey and FAST study were presented at the North American Neuromodulation Society (NANS) 2021 meeting.

In addition to 3 level 1 randomized clinical trials, another 3 "real-world" studies investigated the WaveWriter Alpha system. The WaveWriter study reported that 61% of patients achieved an NRS of 2 or lower at the final follow up. The Halo study showed that effective pain relief (final NRS = 2.5) could be achieved using 88% less energy than 10kHz (high-frequency) therapy. Finally, the Lumina study showed clinically relevant pain relief (NRS <3) through 2 years of follow up.

Expanding on the interaction of the pandemic and pain, Patel explained that in the Envision study, which was conducted in partnership with IBM, found that patients responded differently to relief from the WaveWriter during the pandemic. Additionally, the new technology allowed the study investigators to compare pain and pain responses before and during the pandemic as well as intervene as pain changes.

Another exciting aspect of the ongoing studies is the investigation of biomarkers, such as data from wearables like sleep monitors, to develop artificial intelligence that will allow the WaveWriter Alpha to predict changes in pain, possibly even before they happen. As a simple example, the device may learn that a poor night's sleep leads to increased pain the following day, and therefore knows to increase the intensity of the therapy. With enough data, even more complex scenarios could be possible in the future.

With increasing pressure on physicians to reduce opioid prescriptions alternatives are crucial for meeting the increasing pain relief needs of patients. Further, pain is experienced in many different ways thereby requiring different methods for pain relief.

"Ultimately," says Patel, "the WaveWriter Alpha will usher in the next era of personalization in pain relief therapies." ♦

Humanitarian Approval for "First-Of-Its-Kind" Bone Replacement

BY WALTER EISNER

On February 17, 2021, the FDA announced the approval of "a first in the world and first-of-its-kind implant" to replace the talus for the treatment of avascular necrosis (AVN) of the ankle joint. The approval came through the humanitarian device exemption (HDE) process. AVN is a progressive condition that causes a lack of blood supply and leads to the death of bone tissue.

3D-Printed Talus Spacer

The 3D-printed Patient Specific Talus Spacer implant from New Jersey-based Additive Orthopaedics, LLC, can be used in talus replacement surgery. Using computed tomography (CT) imaging, the spacer is made individually for each patient. During the surgery, the patient's talus bone is removed and replaced with the cobalt chromium alloy implant. The procedure, according to the FDA, offers an alternative to joint fusion or below-the-knee amputation for the painful, progressive condition that causes a lack of blood supply and leads to the death of bone tissue.

Avascular Necrosis

The damage to the bones of a joint, such as in the case of the ankle, causes the cartilage that keeps the bones from rubbing together to deteriorate, causing arthritis and pain. Late-stage AVN of the ankle may result in the talus bone partially or fully collapsing.

The FDA press announcement stated, "Current available treatments include fusing the joints in the foot and ankle together—a procedure which helps to alleviate pain caused by AVN but eliminates motion in the joint—or below-the-knee amputation."

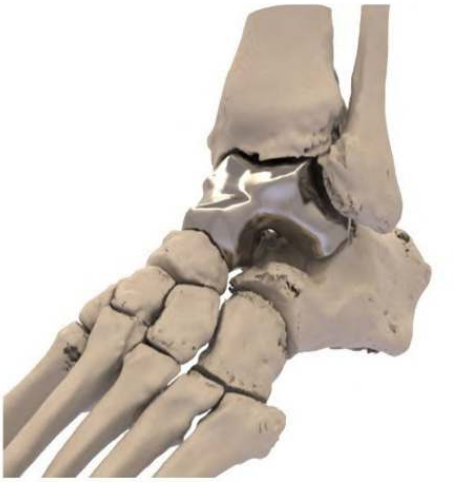
Fusion may still be necessary in the future, but the surgery is intended to be a joint-sparing procedure, as it allows the patient to retain motion in the ankle joint.

The Data

The FDA reviewed data for the device through the HDE process, which means that the device is intended to treat or diagnose a disease or condition that affects no more than 8,000 individuals in the U.S. per year.

The data included results from 31 patients and 32 talus replacement surgeries (one patient had operations on both ankles) with the implant. Three years after surgery, the average reported pain decreased from "moderate to severe" to "mild", and average range of motion in the ankle joint also improved. The measures were assessed using standard subjective scoring systems for pain and functionality.

After three years, out of 32 cases, there were 3 reported additional surgeries. The most common reported adverse events were pain and scar tissue at the surgery site.



Patient Specific Talus Spacer / Courtesy of Additive Orthopaedics, LLC

Humanitarian Device Exemption Process

Going through the HDE process means your device is exempt from the effectiveness requirements of the FDA Act and is subject to certain profit and use restrictions.

Additive Orthopaedics President Greg Kowalczyk said, the device "is another example of how 3D printed devices can improve the standard of care. This is a tremendous regulatory win which took significant effort from our team and I want to thank everyone, including the U.S. Food and Drug Administration, who assisted in making this technology commercially available in the domestic market for patients suffering from AVN."

The company plans an immediate launch of the spacer in the U.S. ♦

COMPANY

ReVivo Medical Moves Into Fund Raising Mode

Albany, New York-based ReVivo Medical, LLC, a medical device company focused on spinal products, is making the necessary moves to start raising funds….specifically, the company has decided to change its corporate status from limited liability corporation to a C-corp.

According to ReVivo Medical President and CEO Gary Mittleman, "Private Equity Funds, Venture Capital and Angel Investor Groups are known to prefer investments in C-Corporations rather than LLCs where they receive K-1s each year making for more complex accounting and reporting."

Mittleman continued, "We expect that by eliminating the accounting issues for potential investors, it will increase our likelihood of attaining the $1 million of funding we seek."

The company is in the initial stages of preparing for a FDA sanctioned clinical trial and has already raised $2.6 million. However, it still needs additional funding to complete the 50 patient clinical study. In the trial, participants will be given ReVivo Medical's "next generation design anterior cervical plate and interbody cages used in anterior cervical discectomy and fusion procedures."

OTW spoke with ReVivo Medical Co-Founder Eric Ledet, Ph.D., a biomedical engineer, about the upcoming year. Dr. Ledet told *OTW*, "ReVivo Medical is about to initiate a first in human use IDE [investigational device exemption] clinical trial for our anterior cervical plate and cage. After many years in development and very encouraging pre-clinical data, we are eager to work with the talented surgeons at the Cleveland Clinic and the Albany Medical Center Hospital to initiate the 50 patient clinical trial. Results from the IDE trial will support applications for clearance in the U.S. for both the plate and cage."

Dr. Ledet continued, "ReVivo Medical is currently fundraising for the clinical trial and to support the continued development [of] our product pipeline. ReVivo's Medical's devices are all investigational and none are currently cleared for use in the United States." — *KD*

ZygoFix Raises $2 Million

ZygoFix Ltd, 3-year old Israeli technology startup focused on a novel, screwless alternative to traditional spinal fusion and which was founded by serial spine industry entrepreneurs Yizhar Floman and Uri Arin, has just raised $2 million.

The funding round for Israel-based ZygoFix was led by Agriline and Trendlines Group Ltd. and involved additional private investors and the Israel Innovation Authority. ZygoFix will utilize the funds to undertake additional clinical studies, refine the system implant and tools, and to work toward regulatory clearance.

According to the company, "ZygoFix's zLOCK is a miniature screwless implant that provides spinal stability and fusion. zLOCK is the least invasive, simplest fusion option; it replaces complex screw stabilization, the current gold-standard used in such procedures. The ZygoFix zLOCK implant's patented bendable features enable adjustment to specific joints' shapes during insertion."

ZygoFix was founded in 2017 by Tel Aviv University Professor Yizhar Floman and Uri Arin, who had previously founded ApiFix, which was acquired by OrthoPediatrics Corporation in April 2020 in an earnout deal that could be worth up to $67 million.

Both ApiFix and ZygoFix were established in The Trendlines Group incubator and received funding from Trendlines and the Israel Innovation Authority. For *OTW's* coverage of that acquisition see "OrthoPediatrics Acquires ApiFix."

ZygoFix has been in clinical trials in Hungary in 2018 and has recently begun a clinical study in Israel.

Source: Wikimedia Commons and Flying Logos

ZygoFix CEO Ofer Levy commented, "Our technology rethinks spinal stability. We leverage the natural anatomical structure of the spine and insert the zLOCK implant which locks the motion in the joint."

He continued, "We are very satisfied with this first case in Israel as zLOCK adds a new treatment option to the surgeon's toolbox. Its unique ability to perform internal facet fixation with a minimally invasive procedure enables us to treat pathologies in a simple manner, that were too complex and invasive to treat otherwise." — *KD*

Spineway and Tsunami Medical Announce Partnership

Courtesy of Tsunami Medical + Spineway

Spineway and Tsunami Medical have announced a partnership to sell twin peaks interbody cages made with three-dimensional (3D) printers.

Based in Italy, Tsunami Medical SrL is an innovator in spinal technology, that provides 3D printed solutions for spine surgery and diagnostic invasive procedures.

France based Spineway "designs, produces, and markets innovative implant lines and ancillary surgical equipment" used to treat spinal pathologies. With this partnership, Spineway will "market a line of implants made of laser-sintered titanium using 3D printers."

OTW spoke with Tsunami Medical Chief Commercial Officer Peter Witke about the new partnership. Witke, a veteran in the international spine market, told *OTW*, "We are most excited about Spineway clearly recognizing Tsunami Medical as one of the pioneers and, after years of further development and experience, now one of the leaders in using 3D printing technology for the production of innovative and differentiating spinal surgical solutions."

Witke continued, "Also given Tsunami Medical's proven experience in product design we feel confident about contributing in a meaningful way to Spineway's future growth!"

The twin peaks products include the following interbody fusion cages: twin peaks PLIF, twin peaks OLIF, and twin peaks TLIF. Each system is "an internal spinal fixation system intended to provide stabilization of the spine while biologic fusion occurs."

Tsunami Medical CEO Stefano Caselli emphasized the unique benefits of the interbody cages. Caselli commented in part, "Particularly innovative, the new devices marketed by Spineway stand out from existing solutions because their cavity grids participates in the bone growth and fusion sought by surgeons. Moreover, it provides for easy viewing during medical imaging."

In the future, surgeons should look forward to additional products arising from this partnership. Spineway Chairman and CEO Stéphane Le Roux commented, "We are working on several projects with Tsunami Medical and plan to launch several surgical devices in the short and medium term in order to meet the needs of surgeons in terms of the performance and efficiency of the surgical procedure." — *KD*

Larry Chen: New Managing Director at Bioventus

Armed with more than 20 years of experience in sales and marketing, Larry Chen, formerly director, Asia Pacific at Zipline Medical, Inc., has been named Managing Director, China and Asia Pacific for Bioventus Inc. Chen, whose prior roles were at health care companies with a presence in the region, will be based in Shenzhen, China.

"We are glad to welcome Larry to Bioventus and look forward to leveraging his experience and relationships in both China, as we explore our expansion opportunities there, and throughout the Asia Pacific region," said John Nosenzo, Chief Commercial Officer, Bioventus. "We believe patients and clinicians will benefit greatly from our solutions in osteoarthritic joint pain, minimally invasive trauma and bone graft substitutes."

Chen spent four years at Zipline Medical as director, Asia Pacific, until the company was acquired by Stryker Corporation. Previously, Chen was sales director, and later marketing director, Greater China, for Smith & Nephew; he also spent time at ArthoCare Corporation where he served in regional sales and marketing roles.

Larry Chen / Courtesy of Bioventus Inc.

His work experience also includes Asia Pacific regional commercial leadership roles at Johnson & Johnson Medical/Ethicon, Mentor Corp. and Stryker. Chen's initial work experience was

as an export sales manager at China Qing 'An International Trading in Beijing.

Chen earned an MBA from the University of Leuven and a Bachelor of Science in Economics from the University of International Business and Economics in Beijing.

Chen told *OTW*, "It is exciting to be a part of Bioventus as the company puts more focus on Asia, especially China, and to have the opportunity to plan and actively relaunch our products in markets within Asia where we have a presence. In addition, I look forward to identifying new market for our products."

As for how will proceed initially, Chen commented to *OTW*, "I will assess current coverage, representation and engagement of our distribution partners, visit markets to speak with customers and look to identify best practices across regions and segments, both in and outside of the company." — *EH*

Schivo Acquires Supreme Screw Products Inc.

Schivo

SSP
SUPREME SCREW PRODUCTS INC.
SINCE 1963

Schivo Medical's nano-Litre Dispense Module / Courtesy of Schivo Medical and Supreme Screw Products Inc.

Waterford, Ireland-based Schivo Medical, an original equipment manufacturer (OEM) contract manufacturing partner, has acquired Plainview, New York-based Supreme Screw Products Inc. (SSP).

OTW spoke with a company representative about the acquisition and what initially led Schivo to SSP. Schivo told *OTW* that SSP "represents the perfect partner for Schivo. Since their founding in 1963, SSP has earned a reputation as a leading supplier of precision machining, laser processing, and assembly services for the medical device market. This has been achieved through a culture of customer service and innate focus on providing innovative manufacturing solutions to complex engineering challenges."

During the past decade SSP has been focused on expansion, adding new machines and computer measuring

equipment. Additionally, SSP recently invested in a state of the art 30,000 square foot facility. SSP's expanded capabilities will complement Schivo.

Schivo explained to *OTW*, "SSP will complement Schivo's capabilities for minimally invasive surgery and life sciences markets through the addition of micro-machining, laser processing and assembly technologies."

Schivo continued, "The addition of SSP's two manufacturing facilities in Plainview, New York, significantly strengthens Schivo's manufacturing and development footprint in the U.S. With SSP joining the Schivo portfolio, our customers will benefit from working with a single proven partner, offering a wider set of solutions, capable of serving their needs both globally and locally."

Schivo engaged Kinsella Group to execute the acquisition. Kinsella Group provides MedTech expertise with "significant focused experience representing contract manufacturers, OEMs and investors in acquisition, sale and recapitalization transactions." While SSP was not actively for sale, Kinsella Group pursued SSP because SSP "complemented and enhanced" Schivo's global position.

Schivo acquired 100% of SSP and paid cash at closing. Its valuation was not disclosed. According to Kinsella Group, "SSP's management team will remain to continue executing SSP's growth strategy." This includes SSP President and CEO Misha Migdal.

Migdal commented in part, "The SSP team and I look forward to joining Schivo. This union expands our ability to provide sophisticated precision components and assemblies to innovative medical OEMs around the world." — *KD*

New Partnership for Remote Surgeon Training Launched

Mark Gittins, DO, FAOAO, an orthopedic surgeon with OrthoNeuro in Columbus, Ohio, has formed a partnership with Avail Medsystems, Inc. for remote physician surgical training. Avail, based in Palo Alto, California, is known for its Procedural Telemedicine™ solution that helps remove physical, economic and logistical barriers to "whenever, wherever" collaboration.

This partnership will enable Dr. Gittins to use the Avail system to teach robotic hip and knee reconstruction worldwide, performing the remote procedures at New Albany Surgery Center. Also part of the arrangement is Smith+Nephew, which has teamed up with Avail Medsystems to provide remote, real-time collaboration services in the operation room. Smith+Nephew is the first orthopedic company to use the Avail System and is bringing this remote collaboration to facilities across its customer base.

Mark Gittins, DO, FAOAO / Source: OrthoNeuro

"The Avail technology gives us the worldwide ability to educate and exchange ideas in the real time surgical arena," said Dr. Gittins. "We see a huge opportunity to advance patient care in arthritis surgery. This is an exciting time for all of the parties involved."

Per the company press release, "Avail's Procedural Telemedicine System facilitates medical expertise sharing and collaboration during live procedures by connecting physicians in the operating room to remote medical industry professionals and healthcare providers, enabling physicians to deliver the right knowledge, at the right time, regardless of location. The System was built by a team with deep expertise in medical technology and healthcare who understand the day-to-day needs of medical experts."

According to Avail, its Procedural Telemedicine System is "comprised of a portable Console that is placed in New Albany Surgery Center, the Avail Portal which enables a network of connectivity, and the Avail Remote App that allows a remote healthcare expert to control the Console's two high-definition pan-tilt-zoom cameras, plug-ins for surgical imaging and large display monitor in New Albany Surgery Center's operating room. A healthcare professional accesses the software platform remotely from an iPad or laptop to instantly join a procedure, control the console's cameras and surgical imaging views and speak directly with the treating physician. It's intuitive and easy to use."

"We created Avail with surgeons like Dr. Gittens in mind," said Avail CEO Daniel Hawkins. "We're thrilled to partner with OrthoNeuro and enable Dr. Gittens to broadcast procedures worldwide. Our mission is to use technology to eliminate physical boundaries to collaboration, infor-

mation sharing and education, and ultimately accelerate training, new product adoption, and healthcare innovation as well as to universalize access to medical expertise."

Dr. Gittins told *OTW*, "This is a collaboration with Smith+Nephew, Avail, and the New Albany Surgery Center. All parties played a role in building the program, which will assist in education for professionals and patients in the new era of limited direct contact."

When *OTW* asked why Avail was the right choice, Dr. Gittins commented, "Avail is the best partner due to their advanced technology in the field. They have a cost effective nimble footprint that functions great with educating and demonstrating surgical techniques. This concept is very important with today's educational environment and the robotic orthopedic world." — *EH*

Florida's Ascension Opens "Boutique" Ortho and Spine Clinic

Orthopedic patients in Northeast Florida looking for a specialty hospital now have one with the opening of the Performance Orthopedics and Spine Specialty Hospital at Ascension St. Vincent's. This facility is part of a broader partnership between Ascension Florida and Gulf Coast and Healthcare Outcomes Performance Company (HOPCo), in conjunction with Southeast Orthopedic Specialists.

The new specialty hospital seeks to provide a "boutique" experience, which includes a separate check-in area, as well as "…dedicated clinical and nonclinical staff, operating rooms, pre-op and recovery areas, inpatient hospital rooms, a rehabilitation unit and family waiting area."

Courtesy of Performance Orthopedics and Spine Specialty Hospital at Ascension St. Vincent's

"Patients should have the best, most personalized musculoskeletal care possible in the best setting possible, and that's why we've partnered to create the new Performance Orthopedics and Spine brand and specialty hospital," said orthopedic surgeon Gavan Duffy, M.D. "When all aspects of care are aligned and streamlined, it makes it more convenient for patients and can also help them get better, faster."

The Ascension HOPCo partnership has led to "…a new Performance Orthope-

dics and Spine brand that will manage a comprehensive musculoskeletal service line and foster a clinically-integrated network of musculoskeletal physician practices." This will also mean the co-development of ambulatory surgery centers in Northeast Florida.

"We are thrilled to see our plans to improve the level of orthopedic and spine care in Northeast Florida come to life," said James Machado, regional president of Ascension St. Vincent's Southside and Ascension St. Vincent's St. Johns County, which is currently under construction. "We've done the research and know that our community has long needed something like Performance Orthopedics and Spine that is dedicated to bringing musculoskeletal providers together into a top-notch, comprehensive network. This ultimately improves care and convenience for those we are blessed to serve."

The location of the new center, said Dr. Duffy, was selected based on "Convenience and community need. Ascension St. Vincent's Southside is centrally located in Jacksonville and northeast Florida, which does not otherwise have a specialty hospital dedicated solely to orthopedic and spine care."

When *OTW* asked what makes the treatment so personalized, Dr. Duffy stated, "We have a multidisciplinary team that is subspecialized and offers a full spectrum of non-surgical and surgical options. Additionally, everyone on our staff, from registration to post-op care, is specialty trained for orthopedics. This means that from the moment the patient walks through our doors to the time they are discharged, their entire care team is specialized for their needs.

DeLyle Manwaring, EVP of Marketing Transformation at HOPCo added, "HOPCo's most vital role was bringing in a management team with decades of experience in market transformation. This team implements HOPCo's suite of market and service line optimization tools that include our evidence-based protocols, clinical care pathways, outcomes reporting and IT [information technology] tools." — *EH*

Large Joints

Fascia Iliaca Block Not Advised for Pain Control After Hip Surgery

Fascia iliaca block should not be used as a routine form of pain control for hip arthroscopy, according to a new study.

In the study, "Fascia Iliaca Block for Postoperative Pain Control After Hip Arthroscopy: A Systematic Review of Randomized Controlled Trials," published March 12, 2021 in *The American Journal of Sports Medicine*, researchers conducted a systematic review on the efficacy of fascia iliaca block compared with other analgesic modalities after hip arthroscopy.

The research team collected data on postoperative pain scores and analgesic consumption. Only randomized controlled trials up to April 2020 were included.

Overall, five studies met the inclusion criteria for the systematic review. Together they included 157 patients undergoing hip arthroscopy with fascia iliaca block (mean age, 38.3 years; 44.6% men) and 159 patients in the following comparison groups: lumbar plexus block, intra-articular ropivacaine, local anesthesia infiltration, saline placebo, and a no-block control group (overall mean age, 36.2 years; 36.5% men).

The researchers found no significant differences in pain scores in the post anesthesia care unit between the fascia iliaca block and lumbar plexus block (34. vs. 2.9; p = .054), intra-articular ropivacaine (7.7 vs. 7.9; p = .72), control group (no fascia iliaca block: 4.1 vs. 3.8; p = .76); or saline placebo (difference, -0.2 [95% CI, -1.1 to 0.7]).

One study reported significantly higher pain scores at 1 hour post operation in the fascia iliaca block group compared with the local anesthetic infiltration group (5.5 vs. 3.4; p = .02). Another study found that the fascia iliaca block group consumed more pain medicine than the lumbar plexus group (20.8 vs. 17.0; p = .02).

Source: Unsplash and Ibrahim Boran

Overall, there were no significant differences in total post anesthesia care unit analgesic consumption between fascia iliaca block and other analgesic modalities.

"In patients undergoing hip arthroscopy, the fascia iliaca block does not appear to demonstrate superiority to other forms of analgesics in the immediate postoperative period. Therefore, it is not recommended as a routine form of pain control for these procedures," the researchers wrote. — *TR*

Is Mask Wearing Affecting Surgeon-Patient Relationships?

A new study from researchers at the University of North Carolina suggests that patients are having trouble communicating and building trust with their surgeons when they cannot see their entire face due to COVID-19 masking requirements.

This disconnect is affecting, not only how surgeons are viewed and rates by their patients, but also how well the patient does during and after surgery, they explained.

"At beginning of pandemic I had a patient say, 'Dr. Kapadia, it's odd you've taken out a big part of my colon and I don't even know what you look like," Muneera Kapadia, M.D., senior study author and associate professor of surgery in the University of North Carolina School of Medicine, said.

"It made me realize we don't have much information on how masks are affecting surgeon-patient communication and relationships."

Normal Mask vs. Clear Mask Demonstrated by Ian Kratzke, M.D. / Courtesy of University of North Carolina School of Medicine

In the study of 200 patients at 15 clinics, Kapadia and his colleagues investigated how the new masking protocols are affecting a patient's perception and trust of their surgeon during pre-operative meetings.

Surgeons were randomized to either wear clear or covered masks for each new patient clinic visit. After the meeting, patients were asked to complete a verbal survey which included validated Clinician and Group Consumer Assessment of Healthcare Providers and Systems questions as well as additional questions about surgeon empathy and trust and the patient's impression of the surgeon's mask.

Overall, patients said communication was better when surgeons wore a clear mask. This suggests, the researchers say, that not being able to see the surgeon's face could be negatively impacting the surgeon-patient relationship.

"When surgeons wore clear masks as opposed to traditional masks, patients rated their surgeon significantly higher in how well they provided an understandable explanation, knew the patient's history, demonstrated empathy, and built trust," said first author Ian Kratzke, M.D., a resident in the department of surgery at the University of North Carolina School of Medicine.

"Our face is how we connect with other people," Kapadia added. "We react to people with facial cues, which are being covered by the masks, and that's having a big impact on communication."

"We need to be cognizant that patients are having more difficulty connecting with us as providers. I think knowing that before interacting with them will help mitigate the issue by reminding us to spend more time getting to know our patients and making sure they understand what we are trying to convey."

The study, "Effect of Clear vs. Standard Covered Masks on Communication With Patients During Surgical Clinic Encounters," was published online in *JAMA Surgery* on March 11, 2021. — *TR*

LEGAL & REGULATORY

Ohio Surgeon Sentenced to 40 Months for Overprescribing Pain Pills

Source: Pixabay and lchigo121212

March 2021, George Griffin, M.D. of Cincinnati, Ohio, was sentenced to 40 months in prison for illegally distributing controlled substances.

Late last year, Dr. Griffin pled guilty to one count of unlawful distribution of controlled substances. As part of his sentence, he is required to surrender his medical license and never seek reinstatement of the license.

Dr. Griffin owned and operated Greater Cincinnati Orthopedic Physicians, LLC. As a physician, Dr. Griffin prescribed controlled substances including opioids. He was registered with federal and state authorities to prescribe controlled substances.

Dr. Griffin was initially charged in a 2019 indictment that listed 20 counts of unlawful distribution and dispensing of controlled substances. The indictment listed 20 prescriptions dated from 2014 through 2019, each of which constituted a separate count.

Under the law, valid prescriptions for controlled substances must be issued "…for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Individuals failing to follow that law are subject "to the penalties provided for violations of the provisions of law relating to controlled substances."

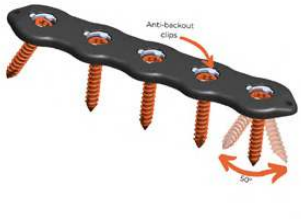
In sentencing documents, the government claimed that Dr. Griffin prescribed "powerful and addictive pain medications to his patients outside the usual course of professional medical practice and without a legitimate medical purpose." The government also referenced past issues involving Dr. Griffin prescribing "extremely high quantity and dosage of dangerously potent opioid substances."

Conversely, Dr. Griffin denied the claims that this was a case about a "pill mill" physician. Instead, he claimed that this was a case about a "hard-working, overworked solo practitioner who was doing his best to alleviate the suffering of patients who were struggling with disabling pain during a period when the standards of care for addiction and pain therapy were rapidly changing."

The case was investigated by the Drug Enforcement Administration (DEA), Federal Bureau of Investigation (FBI), U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG), Ohio Attorney General's Office; Ohio Bureau of Worker's Compensation; and Ohio Board of Pharmacy. — *KD*

One Screw, One System, One Step Forward

Austin, Texas-based Leith Medical, LLC, a medical device startup, has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its One Screw, One Step™ foot and ankle plating system with anti-backout technology.



One Screw, One Step™ foot and ankle plating system / Courtesy of Leith Medical, LLC

Advertisement

Founded by husband and wife duo Tim and Candace Leak, Leith Medical is "dedicated to changing the way orthopedic surgeries are performed with simple, common sense solutions." Its flagship product, the One Screw, One Step foot and ankle plating system with anti-backout technology utilizes its One Screw, One Step technology.

The One Screw, One Step system allows "micro-motion to stimulate physiologic bone healing" while simultaneously "prohibiting any screw back-out and fixation failure." The system boasts a "low profile design" which allows "the screws to sit flush with the bone without prominence regardless of angulation."

The patented system has made its way into the operating room. Earlier this month Arush Angirasa, DPM, FACFAS, a partner with Southwest Orthopaedic Group, performed the first patient surgery using the system.

Leith Medical CEO Tim Leak told *OTW,* "There is nothing like our system on the market. Surgeons are blown away at the angles that can be captured and how easily it compresses to the bone without the concern of screw back out."

Leak continued, "We really are changing the way foot and ankle surgeries are performed, and the greatest part is that it is a simple, common sense solution."

The initial product launch includes four plate systems. Surgeons will use the first tarsometatarsal, lesser tarsometatarsal, and first metatarsophalangeal joint systems in the forefoot and midfoot. The lateral malleolar fracture plate system is designed for "fixation of a variety of distal fibular fracture patterns."

The 510(k) clearance also allows the company to launch "additional tibial and fibular plating systems." Leak commented in the press release, "This is the first of many products we are developing with our One Screw, One Step technology, but for now our primary focus is getting the foot and ankle system into the operating room." — *KD*

FDA Rules to Expire in 2026

All FDA rules and regulations will expire in 2026.

That is the directive of a rule finalized by the Trump Administration the day before the Biden Administration was sworn in. The Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) rule requires the Department of Health and Human Services (HHS), including the FDA, to review 18,000 existing agency regulations or they will expire in 2026.

Source: https://publicdomainvectors.org/

Lawsuit: "Ticking Time Bomb"

On March 9, 2021, a group of plaintiffs went to the U.S. District Court in Northern California to argue that the rule is a "ticking time bomb" and will tie the current administration into bureaucratic knots.

The initial notice of the proposed rule came on November 4, the day after the 2020 election, with a public comment period of 30 days. The complaint alleges that the Trump administration rushed the rule through and did not follow legal requirements for the public to be able to weigh in.

Samara Spence, senior counsel at the Democracy Forward Foundation and lawyer for the plaintiffs told National Public Radio, "The promise made in the SUNSET rule is that the [Health and Human Services] department will go through and, one at a time, review all of those regulations. The lawsuit claims the five-year review window for most regulations would require staffers to do this work twenty times faster than has ever been done before."

"In other words, the outgoing administration planted a ticking time bomb set to go off in five years unless HHS, beginning right now, devotes an enormous amount of resources to an unprecedented and infeasible task."

The lawsuit states that plaintiffs have no guarantee that HHS will complete retrospective review on such a mass scale "and must assume that any, or all, of the regulations that affect them will disappear...All plaintiffs will have to divert significant resources to monitor the progress of each regulation that affects them and to attempt to stem the effects of potential automatic expiration."

18,000 Regulations and One-Fifth of the U.S. Economy

Since its inception in 1953, HHS has put approximately 18,000 regulations on the books.

The regulations covered by the SUNSET rule encompass the governance, safety, legality, and effectiveness of:

- health insurance
- hospitals and clinics
- pharmaceuticals and vaccines
- medical devices

- biologics
- mental health treatment
- Medicare and Medicaid
- public health emergency prevention and preparedness
- food safety
- protections for children and the elderly, and much more.

According to the lawsuit, the affected healthcare sector alone accounts for nearly one-fifth of the U.S. economy.

The plaintiffs want the Court to declare that the SUNSET Rule violates the Administrative Procedures Act because it was issued without procedures or consultation required by law, is contrary to law, and is arbitrary and capricious.

Plaintiffs include Santa Clara County, the California Tribal Families Coalition, the National Association of Pediatric Nurse Practitioners, the American Lung Association, the Center for Science in the Public Interest, and the Natural Resources Defense Council.

What happens next? Congress could eliminate the rule through the Congressional Review Act, or HHS could decide to hold off on implementing the rule while the litigation is pending.

If nothing happens, healthcare providers, patients and all the companies that supply them will be spending a lot of money trying to figure out where they stand. — *WE*

Mizzou BioJoint Lawsuits Settle for $16.2 Million

The University of Missouri has settled a number of personal injury and false advertising lawsuits over knee surgeries for $16.2 million.

University of Missouri / Courtesy of University of Missouri

Created in 2015, the Mizzou BioJoint® Center is part of the Missouri Orthopaedic Institute which is part of the

University of Missouri Health System. The Mizzou BioJoint Center was formed to develop, test, and market proprietary products and services on patients. According to its website, the surgeries performed at the Mizzou BioJoint Center include "restorative cartilage, bone, meniscus, ligament and tendon procedures designed to safely improve your joint health and function."

Mizzou BioJoint surgery involves the transplantation of human tissue called an osteochondral allograft into the knee joint. The procedure was marketed as a viable alternative to traditional partial or total knee replacement. Pioneers of the procedure include James Stannard, M.D. and James Cook, DVM, Ph.D., OTSC.

From 2018 to 2020, 22 plaintiffs filed lawsuits over the BioJoint surgeries. A number of these individuals claimed that after numerous unsuccessful BioJoint surgeries they had to have total knee replacement surgery. Plaintiffs alleged that the experimental nature of the surgery was not disclosed, and that Dr. Cook was falsely represented as an orthopedic surgeon and physician.

The defendants denied all allegations. In February 2021, the University of Missouri settled the lawsuits without admitting liability or negligence. All other claims were dismissed.

In a statement, University of Missouri Health Care CEO Jonathan Curtright remarked, "We are pleased to resolve this litigation. Providing safe, quality care is always our top priority, and we remain committed to excellence in restoring joint health and function for eligible patients."

Curtright continued, "We are confident in the expertise and dedication of our staff and the innovative, science-based services offered by the Missouri Orthopaedic Institute and the Mizzou BioJoint program."

OTW has been following the lawsuits against the Mizzou's BioJoint Center since they began in 2018. For its coverage of the lawsuits see "Mizzou BioJoint Lawsuits Continue to Grow," "Number of Mizzou Living Cell Lawsuits is Growing," and "Third Lawsuit Hits Mizzou Regenerative Medicine Center." — *KD*

SPINE

Screwless Spine Fusion Implant Focus of New Study

An Israel-based study of a novel, screwless spinal fusion implant

ZygoFix's zLOCK vs. screw and rod / Courtesy of ZygoFix Ltd

has just been started by the senior spine surgeon at Rambam Health Care Campus and principal investigator, Dr. Lior Merom. The first clinical case was a laminotomy and facet stabilization using two of the novel implants to achieve relief of back pain due to facet arthritis and spinal nerve compression (foraminal stenosis).

The implant is a miniature screwless implant that is able to delivery spinal stability and fusion by bending and adjusting to specific joint shapes during insertion. The manufacturer, ZygoFix Ltd, which has brand named the new implant 'zLOCK', says that it is a least invasive and simplist fusion option that could, potentially, replace complex screw stabilization.

The new clinical study will be used to measure how effective and safe zLOCK is. According to ZygoFix CEO Ofer Levy, "The first patient to undergo the procedure in Israel, was admitted to surgery due to facet degeneration in L4/5 and reported VAS [Visual Analog Score] pain levels of 10 Back, 6 Leg. Today, three weeks post-op, she reports a reduction in VAS to 2 Back, 2 Leg. Placement of the zLOCK took less than 30 minutes (bi-lateral)."

Furthermore, says Levy, "The study in Israel is following the EU pilot study that is ongoing since April 2018. The principal investigator of the study in the EU, Professor Attila Schwarcz stated: 'zLOCK is a no-risk surgery: the procedure is performed far from the nerve roots, the neurological complication rate is expected to be close to zero.' The first patients that completed the study (24 months follow up) report an average reduction of 70% in VAS and 62% in ODI [Oswestry Disability Index]."

In Levy's view, the technology could rethink spinal stability. "We leverage the natural anatomical structure of the spine and insert the zLOCK implant which locks the motion in the joint."

And, says Levy, it is more simple than traditional pedicle screw based systems. "This customization doesn't require any effort from the surgeon as it is performed automatically while inserting the implant into the joint."

The current study, according to Levy, will continue to expand. "Following the opening of the Israel site and starting to recruit patients, we are looking into opening a wider pivotal study in the EU. The Israeli study will include an additional site in Assuta Medical Center and in total with the EU study will enroll 40 patients."

Concerning future system and tools enhancements, Levy told *OTW*, "We are enhancing the implant and tools for an easier implantation process, further improvement in primary stability and better visualization of bone growth." — *EH*

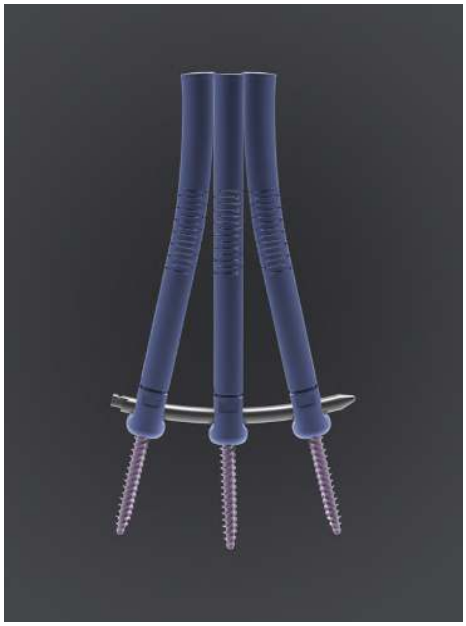
First-in-Man for Minimally Invasive Flex Tower

Orthopedic surgeon Dalip Pelinkovic, M.D., with Great River Medical Center in West Burlington, Iowa, performed the first-in-man implant of CTL Amedica's Minimally Invasive Flex Tower during a lumbar back surgery.

The detachable, Minimally Invasive Flex Tower, which is currently in beta launch, is "designed with a proprietary, mid-tower, accordion hinge that allows the tower to bend and contour in crowded surgical sites, mitigating tab interference while still maintaining construct integrity throughout the procedure. This flexibility enables the surgeon to navigate MIS [minimally invasive spine] lumbar procedures more freely."

"For this case, I utilized the flex tower at the lower lumbar levels because it provided greater flexibility. Uniquely, it accommodates the trajectory of pedicle screws in challenging anatomy without interference. It's compatible with the easy-to-load screw bodies, has better functionality with MIS retractors, and gives surgeons the option to attach tabs pre-op or in situ," noted Dr. Pelinkovic.

OTW asked for details on the development of the Minimally Invasive Flex Tower and Daniel Chon, CTL Amedica president and CEO, explained. "During multiple surgeon visits to our home base in Addison, Texas, we continued to



Minimally Invasive Flex Tower / Courtesy of CTL Amedica

hear stories about tower interference during minimally invasive surgery, from minimally invasive screw systems across the industry. We thought, 'Although this might not seem like a huge issue in all minimally invasive surgeries, sometimes solving the small frustrations can make such a big difference for our surgeons.'"

"And so our team got to work on a comprehensive solution. Our PICASSO II Minimally Invasive Pedicle Fixation Platform functioned as the starting point for this new design, and we were able to incorporate the proprietary hinge design into the screw tower, while still holding on to the many benefits the original tower design offered. In this way, we were able to offer the best of both worlds, while solving a frustration many surgeons experience on a daily basis during their minimally invasive cases."

Listening to Surgeons

Daniel Chon: "The flex towers were specifically engineered to solve the problem of tower interference. Through surgeon feedback, we found that this was a common issue during MIS surgery, particularly on lower lumbar levels. We also came across instances in which tower interference had the potential to prevent a set screw to fully seat to the rod, which would give a sense of 'false locking.' Our R&D department was able to develop a solution to this problem through the proprietary mid-tower accordion hinge design, which allows the tower to maneuver in situ, inevitably solving the interference issue during MIS cases.

Revamping the Surgical Experience

"Problem solving is our business," said Chon to *OTW*. "It's at the core of what we do as an organization. We continually strive to provide efficient solutions for surgeons, and ultimately their patients. The flex towers were designed to mitigate several issues consistent with lumbar MIS surgery, reducing surgeon frustration and allowing for a more streamlined experience in the operating room. At the end of the day, it's about creating an improved surgical experience for both surgeon and patient, and we are thrilled to add the flex towers to our portfolio." — *EH*

ROBIN YOUNG
Ortho Recruiters

THIS WEEK IN JOBS AND PEOPLE

MARCH 23, 2021

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- Currently engaged in a Business Development Role with an imaging company focused on the market adoption and development of a novel orthopedic imaging and surgical planning technology for both Hospital, ASC and Practice environments.
- Excels in building lasting customer relationships, provides clear communication to both internal and external stakeholders to achieve growth objectives.
- Proven ability to recruit highly talented sales representatives and groups in order to enhance an existing or develop an entirely new sales organization.
- Exceptional communication, presentation, and listening skills to mentor teams, key stakeholders and C-Suite decision makers
- Strong and consistent history of achieving revenue, profit, and market share growth objectives.

Founder and CEO of a $79million Orthopedic Implant distributor

- Grew organization from $300 thousand in annual sales in 1992 with one employee, to $79 million annually and 81 employees in 2020.
- Became the highest market share business unit for the distributor's major supplier, nationally, in 2014, maintaining that position through 2020
- Initiated a tailored motivational incentive program based on local market dynamics.
- Created a compensation program based on objective sales effort, as well as objective sales results, utilizing and training highly scrutinized sales talent.
- Author of "Selling Tool Box", a menu of categorized sales strategies that have been used successfully by several top sales performers over the distributor's history, resulting in collaboration and execution for both existing and future appropriate conversion prospects.

Award winning Hospital CEO & Medical Device Executive accomplished in both sales and hospital administration seeking a role in the Medical Device Space.

- Over 10 years of marketing and selling medical devices for diverse specialties, including orthopedics, plastics, ENT, neurosurgery, etc.
- Uniquely also managed hospitals for over 7 years, developing an understanding of OR, hospital and surgical challenges, and financial constraints.
- Known for developing trusting relationships with hospital administrators, surgeons, and physicians that consistently accomplish growth and innovation while consistently increasing market share.
- Natural skillset in building a culture of purpose, teamwork, leadership, continual growth, self-improvement, and out of the box thinking.
- Exhibits a unique prowess in building relationships in multiple capacities, in negotiating contracts, and in providing clear communication to both internal and external groups to achieve win-win objectives.
- Strong understanding of operations, KPI, financial performance, capital appropriation, pricing, and margins.
- Business Development executive with a unique differentiated background and know-how of medical devices and hospital administration, essentially being ambidextrous in both.
- Exceptional ability to create an entirely new practice and fulfill a vision, by applying teamwork and creativity to effect positive change.

CONTACT

NEAL HIGHTOWER
nhightower@sanfordrose.com
985-789-0490

TIM SCHMIDT
tim.schmidt@sanfordrose.com
985-789-0490

ROBIN YOUNG
robin@ryortho.com
917-887-7376

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Robin R. Young, CFA
Editor and Publisher

100 West Main Street Suite 350 • Lansdale, PA 19446
TOLL FREE: 1-888-352-1952
www.ryortho.com

RY Publications

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

Walter Eisner
Contributing Writer
walter@ryortho.com

Tracey Romero
Contributing Writer
traceyromero@yahoo.com

Kim DelMonico
Contributing Writer
kim@beinfluence.co

COMPANY
Bonnie Brault
VP of Operations, Manager Digital Product Launch Program
bonnie@ryortho.com

ADVERTISING
April Bruffy
Vice President of Sales
april@ryortho.com

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

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

Dana Bader
Production, Graphics, Design & Ad Manager
dana@ryortho.com