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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: The stock market continues to hit record highs and this week the small caps took center stage. We are in a bull market for stocks. How durable is this surge in buying? There is still a plenty of money on the sidelines. And this is the time of year (December to the end of January) when buying is typically strongest.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	11.52%	9.14%	De-risks with $1.4 billion litigation settlement. Rumors of bidding for SNN won't die. In fact, they're heating up.
2	3	Zimmer	29.12	10.26	Big jump for Big Blue. Zimmer spine had a great NASS. Showed up with an impressive, innovative line.
3	6	Medtronic	28.84	12.11	Wall Street broker Jefferies raising target price for MDT. Huge jump in price at MDT over last 30 days. And, oh yes, spine sales rose year-over-year.
4	4	NuVasive	8.01	22.70	Holy moly rocky! What a jump in valuation. Someone really wants to own a lot of this leader in spine.
5	5	Globus Medical	29.68	10.04	Normally, Globus's valuation would look toppy to us. But earning 30 cents on every sales dollar justifies a 25 P/E.
6	2	ConMed	10.51	6.61	Despite a nice run this past month, CNMD is still the 3rd least expensive equity in orthopedics. What does 2015 hold for CNMD? Should be very interesting.
7	7	Smith & Nephew	19.92	10.47	Bloomberg and Barron's are both reporting that Stryker is mulling a bid. For *OTW*, mergers are the gift that just keeps on giving. Go SYK go!
8	8	MicroPort	16.53	(8.64)	MicroPort's equity marches to a different drummer. Too bad. Investors are missing one of the great strategic values in orthopedics.
9	9	Integra LifeSciences	12.57	(2.78)	What is IART morphing into? Spine business spinning off. As the least expensive equity in ortho, there is plenty of upside available.
10	10	Symmetry Medical	6.55	(6.73)	Most investors are waiting for the dust to settle from the proposed OEM solutions divestiture.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	RTI Biologics Inc	RTIX	$4.87	$277	36.80%
2	K2M Group Holdings	KTWO	$17.97	$667	24.53%
3	NuVasive	853	$43.40	$2,042	22.70%
4	MiMedx Group	MDXG	$10.52	$1,125	17.81%
5	Aurora Spine	ASG	$1.63	$26	17.74%
6	Tornier N.V.	TRNX	$26.19	$1,281	14.22%
7	Medtronic	MDT	$72.49	$71,297	12.11%
8	Smith & Nephew	SNN	$34.62	$15,460	10.47%
9	Zimmer Holdings	ZMH	$110.48	$18,710	10.26%
10	Globus Medical	GMED	$22.57	$2,211	10.04%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc	BAXS	$0.02	$1	-80.59%
2	Bacterin Intl Holdings	BONE	$2.91	$19	-37.55%
3	Wright Medical	WMGI	$28.45	$1,453	-9.71%
4	MicroPort Scientific	853	$0.48	$678	-8.64%
5	Symmetry Medical	SMA	$9.14	$343	-6.73%
6	Alphatec Holdings	ATEC	$1.38	$136	-5.48%
7	CryoLife	CRY	$9.81	$274	-4.01%
8	Integra LifeSciences	IART	$47.50	$1,557	-2.78%
9	Orthofix	OFIX	$28.15	$519	-2.60%
10	TiGenix	TIG.BR	$0.66	$105	-1.81%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$107.86	$301,912	17.96
2	Medtronic	MDT	$72.49	$71,297	18.50
3	Zimmer Holdings	ZMH	$110.48	$18,710	19.05
4	Exactech	EXAC	$21.86	$302	19.18
5	Integra LifeSciences	IART	$47.50	$1,557	22.53

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MiMedx Group	MDXG	$10.52	$1,125	1048.96
2	RTI Biologics Inc	RTIX	$4.87	$277	291.20
3	Orthofix	OFIX	$28.15	$519	179.84
4	NuVasive	NUVA	$43.40	$2,042	112.02
5	Symmetry Medical	SMA	$9.14	$343	60.20

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	$9.81	$274	1.12
2	Exactech	EXAC	$21.86	$302	1.28
3	ConMed	CNMD	$41.91	$1,154	1.80
4	Globus Medical	GMED	$22.57	$2,211	1.83
5	Integra LifeSciences	IART	$47.50	$1,557	1.86

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MiMedx Group	MDXG	$10.52	$1,125	69.93
2	RTI Biologics Inc	RTIX	$4.87	$277	19.41
3	NuVasive	NUVA	$43.40	$2,042	9.80
4	Orthofix	OFIX	$28.15	$519	9.77
5	Symmetry Medical	SMA	$9.14	$343	5.02

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Baxano Surgical Inc	BAXS	$0.02	$1	0.06
2	Bacterin Intl Holdings	BONE	$2.91	$19	0.56
3	Alphatec Holdings	ATEC	$1.38	$136	0.66
4	Symmetry Medical	SMA	$9.14	$343	0.86
5	RTI Biologics Inc	RTIX	$4.87	$277	1.10

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.66	$105	18.41
2	MiMedx Group	MDXG	$10.52	$1,125	11.64
3	LDR Holding Corp.	LDRH	$33.35	$869	7.79
4	Wright Medical	WMGI	$28.45	$1,453	5.14
5	Globus Medical	GMED	$22.57	$2,211	4.80

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

The ELEVEN Best New Spine Technologies for 2014

BY ROBIN YOUNG

The companies that submitted winning technologies were: 109 Design; Aesculap, Inc.; Medacta International SA; Medtronic, Inc.; NLT SPINE; SafeRay Spine, LLC; SafeWire, LLC; Spinologics, Inc.; Vital 5, LLC; Whale Imaging, Inc. and ZipLine Medical, Inc.

This year's scores included a virtual tie so we have 11 wining companies and, we note, a healthy and welcome plurality of young innovative companies.

This annual award rewards inventors, engineering teams, surgeons and their companies who've created the most innovative, enduring and practical products in 2014 to treat back pain. To win the *Orthopedics This Week* Best New Technology Award for spine care, a new technology must meet the following criteria:

1. Be creative and innovative.
2. Have long term significance to the problem of treating the diseases of the spine. Does this technology have staying power?
3. Solve a clinical problem. To what extent does this technology solve a current clinical problem or problem that is inadequately solved today?
4. Does it have the potential to improve standard of care?
5. Is it cost effective?
6. I would use it.

Our panel of surgeons score every submission on a scale of 1 to 5 (5 being the highest score) for each of the above criteria.

We and our panel of surgeons were impressed that inventors—despite ever growing hurdles to innovation and entrepreneurism in spine—still managed to create a solid group of more than 40 new products to submit for the 2014 Orthopedics This Week Spine Technology Awards.

Photo creation by RRY Publications LLC

We offer our thanks and deep appreciation to the engineering teams, surgeon inventors and the following companies for submitting their best ideas this year: *(See table on page 5)*

The Judges

Our intrepid and detailed panel of surgeon judges included:

- Neel Anand, M.D.: Dr. Anand is the Director of Orthopaedic Spine Surgery at the Cedars-Sinai Institute for Spinal Disorders in Los Angeles and a frequent contributor to such peer-reviewed publications as the *Journal of Spinal Disorders*, *Journal of Orthopedic Trauma, Spine* and the *Journal of Bone and Joint Surgery.*
- Scott Blumenthal, M.D.: Dr. Blumenthal is a leader in spinal arthroplasty and currently serves as a clinical assistant professor of orthopedic surgery at the University of Texas Southwestern in Dallas and is an ongoing contributor

109 Design	Aesculap, Inc.	AlignMed	Amendia, Inc.
Benvenue Medical, Inc.	BioStructures, LLC	CareFusion Corporation	Centinel Spine, Inc.
Exactech, Inc.	Expanding Orthopedics, Inc.	Icoteg AC	K2M, Inc.
Mainstay Medical Ltd	Medacta International SA	Medtronic Spinal	MI4 Spine LLC
Mighty Oak Medical	NLT SPINE	NuVasive, Inc.	Orthobion Gmbh
Orthopedic Sciences, Inc.	Renovis Surgical Technologies, Inc.	SafeRay Spine, LLC	SafeWire, LLC
Shanghai Sanyou Medical	Spinal Simplicity, LLC	Spine Wave, Inc.	Spinologics, Inc.
Stryker Spine	Synergy Disc Replacement, Inc.	Trinity Orthopedics, Inc.	Vertebral Technologies, Inc.
Vital 5, LLC	Wenzel Spine, Inc.	Whale Imaging, Inc.	Zimmer Spine

to the first non-profit foundation created for arthroplasty patients. He also currently serves as a spine consultant for the Dallas Mavericks.

- Alan Hilibrand, M.D.: Dr. Hilibrand is a Professor of Orthopaedic Surgery and Neurosurgery, as well as the Director of Medical Education for the Department of Orthopaedic Surgery at the Rothman Institute and Jefferson Medical College.
- Daniel Riew, M.D.: Dr. Riew is the Mildred B. Simon Professor of Orthopedic Surgery; Dr. Riew is a professor of neurological surgery and Chief of the Surgical Spine Center and Director of the Cervical Spine Institute at the Washington University School of Medicine.
- Rick Sasso, M.D.: Dr. Sasso is a founding member, and the president of Indiana Spine Group. He is the co-medical director of the St. Vincent Spine Center, and a clinical associate professor and chief of spine surgery at the Indiana University School of Medicine, Department of Orthopaedic Surgery.

So, without further delay, here are the 11 best new spine technologies for 2014 arranged in alphabetical order by category:

Continued on page 6 >>

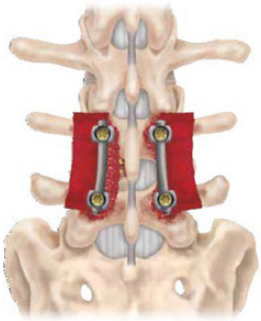
Catergory: Biomaterials and Biologics

Medtronic Spinal– MAGNIFUSE II

Inventors: Kerem Kalpakci, Ph.D., Daniel Shimko, Ph.D., Jason Rister and Bill McKay

Engineering Team: Kerem Kalpakci, Kelly Schlachter, Suneeth Mohan, Guobao Wei, Susan Drapeau, Daniel Shimko, Ph.D., Bill McKay

(From left): Susan Drapeau, Ph.D., Kelly Schlachter, Curtis Glass, Jeff Soucia, Daniel Shimko, Ph.D., Jason Rister, Kelly Anglin, Courtney Long, Kerem Kalpakci, Ph.D., not pictured: Bill McKay, Suneeth Mohan, Scott Barry, Guobao Wei, Ph.D., Matt Jenkins



MAGNIFUSE II DBM bone graft is assembled at the time of use by the clinician. The clinician is able to combine the provided demineralized allograft bone with recovered autograft, and then pack the combination of tissues into a unique, self-contained, resorbable mesh bag using the provided disposable funnel and plunger. The surgeon can then place the fully contained construct into bone voids. The ability to add autograft into the resorbable mesh is a significant advantage of the MAGIFUSE II DBM bone graft as it places patient autograft in direct contact with the highly inductive MAGNIFUSE DBM tissue fibers. The MAGIFUSE II DBM bone graft kit provides enough material to make and deliver bilateral constructs for either single or two level fusion cases.

To further improve on the MAGNIFUSE device, MAGNIFUSE II DBM bone graft was developed and launched. With the addition of MAGNIFUSE II DBM bone graft to the market place, clinicians can now extend robust containment to their autograft as well by use of the provided PGA mesh containment bag. The ability to co-locate autograft and allograft has always been desirable, but no commercial offering has achieved the level of containment and ease of placement made available by MAGNIFUSE II DBM bone graft.

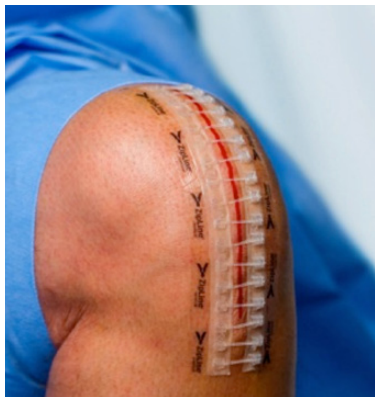
Category: Cervical Care

ZipLine Medical, Inc. – Zip Surgical Skin Closure

Inventors: Amir Belson, M.D., Eric Storne, Eric T. Johnson, Robert R. Ragland, Phillip C. Burke, Luke Clauson

Engineering Team: Kei Ichiryu, Zach Kimura, Alan Schaer, Daren Stewart, Melissa Guerrero, Jeremy Edinger, Emily Cullinan, Lori Munoz, Julie Ridgeway, John Tighe, Eric Storne

Tom Bishow and John Tighe



The Zip Surgical Skin Closure provides a non-invasive alternative to staples, sutures and glue for surgery and lacerations. It is used by surgeons (orthopedic, general, cardiac, ob/gyn, plastic/reconstructive, dermatology) and emergency department physicians, and because of the device's ease of use, no suturing skill is required so the closure task using the Zip device can be delegated to a physician's assistant or RN.

This Zip is applied to intact skin immediately surrounding a surgical incision, and is placed at the end of the procedure, when the skin layer is to be closed. It replaces conventional means of skin closure such as staples, sutures and glue. It utilizes a strong yet skin-friendly hydrocolloid adhesive that lasts for 14 days, and is easily removed. The incision is closed by sequentially tightening a series of ratcheting straps, similar to "zip-ties," to produce the desired incision closure and tension.

The Zip consists of biocompatible polymeric materials, including hydrocolloid adhesive, polyurethane monofilm, nylon injection-molded tensioning mechanism and polyester force-distributing plates. It is a single-use device and is provided sterile in a sealed pouch suitable for aseptic transfer to a sterile field.

Category: Diagnostics and Imaging

Three Winning Technologies

SafeRay Spine, LLC – Lessray

Inventor: Rob Isaacs, M.D.

Engineering Team: Randall Campbell, Samuel Johnson, Ph.D., David Skwerer, MEng.

Tom Bishow, Robert Isaacs, M.D. and Joshua Kazdan

Lessray is an image enhancement platform designed to take low quality, low radiation images and improve them to look like conventional full dose images. It uses proprietary image processing to post-process low dose/pulsed images, improving clarity and contrast to provide a clinically valuable image. Lessray interfaces directly with the fluoroscope. The captured low dose images created by the fluoroscope are transmitted to the Lessray computer where the images are enhanced and then displayed on the Lessray monitor in real time. Further, as a result of the way the software acts upon the image, new radio dense metal tools and implants added to the field can be rendered partially radiolucent or made to disappear and reappear, allowing the physician to better view their relationship to the underlying anatomy.

Fluoroscopic radiation has been identified for decades as a potential cause for a host of medical problems and is a well-established cause for cancer, cataracts, cardiovascular disease, and mental retardation in newborns, prenatal death, and more. It has been widely estimated that 2% of all the newly diagnosed cancers in the U.S. are as a result of medical imaging. While physicians are expected to use the lowest radiation setting possible, the image quality of ultra-low radiation imaging becomes too grainy for safe use during an X-ray dependent procedure. Lessray can make the lowest radiation images on a fluoroscope appear similar to a full dose, conventional X-ray. In fact, in many instances, more information about the underlying anatomy is given to the physician.

Spinologics, Inc. – Scolioscreen

Inventors: Mark Driscoll, P.Eng., Ph.D., Stefan Parent, M.D., Ph.D., Hubert Labelle, M.D., and Jean-Marc Mac-Thiong, M.D., Ph.D.

Engineering Team: Mark Driscoll, P.Eng., Ph.D.

The Scolioscreen was developed as a medical device to be used in combination with a smartphone for the early detection of spinal deformities such as scoliosis. The Scolioscreen is made from a medical grade thermoplastic rubber for comfortable and safe contact with patient skin. The Scolioscreen is also sized to effectively hold all smartphones, with or without a protective case. That is, the novel expandable walls of the Scolioscreen device enable it to securely hold and support any smartphone.

Mark Driscoll, P.Eng., Ph.D., Hubert Labelle, M.D., Jean-Marc Mac-Thiong, M.D., Ph.D., Stefan Parent, M.D., Ph.D.

Mobile smartphones are equipped with inclinometers enabling them to acquire angular clinical measures. The adoption of smartphone in the practices of medical professionals is quickly growing. The Scolioscreen has been developed in conjunction with a smartphone APP to enable the measure of the angle of trunk inclination (ATI) which is a clinical index used for the early detection of spinal deformities.

Whale Imaging – G-Arm Multi-Plane Surgical Imaging

Inventors: Sean Zhu, Shiyu Wei and Jun Zhang

Engineers: Feng Zhou, Yang Li, Liu Cao, Chunpeng Zhu, Xinghong Sun, Chunlei Tian, Yixiu Wang

What if you no longer have the challenge of shifting between AP/LT views? With the G-Arm's X-Beam advanced digital platform the surgeon can confidently perform procedures more accurately and in less time than ever before. The unique system platform provides bi-plane views and allows both AP/LT anatomy to be viewed live and simultaneously at up to 25fps on each plane. Right and left monitor views are real time, giving you unprecedented ability to carry out the procedure accurately, quickly and confidently.

Here are the key attributes of this innovative G-Arm:

- Lower dose: Fewer corrective exposures means cumulative radiation can be minimized for patient and staff
- Less infection risk: Eliminating the need to alternate the detector plane decreases disruption of the sterile field
- Reduced time: Faster placement due to live twin plane views decreases time lost moving the arm and repositioning between
- AP and lateral views
- Greater accuracy: X-Beam technology enables better precision. Better placement makes revision is less likely

(Left to right): Katelyn Dittmer, Melissa Brumley, Hannah Shi, Tom Bishow, Sean Zhu, Vincent Yang, Laurence Heron and Alex Qi

Category: Minimally Invasive Spine Care

Two Winning Technologies

109 Design – Smart Strap

Inventors: Sebastian Monzon, Ellen Su, Levi DeLuke

Engineering Team: Levi DeLuke, Ellen Su, Sebastian Monzon

Levi DeLuke, Ellen Su and Sebastian Monzon

The young inventors (see photo) that comprise 109 Design developed a system to improve adolescent scoliosis treatment. Their invention combines a medical device which gathers data on each patient's treatment using a software platform that sends that patient's data to doctors, the patients themselves, and parents. That feedback capability incentivizes these young patients to wear their brace and keep it tightened as prescribed by their physician.

Smart Strap

The hardware consists of a "smart" strap that replaces the existing straps of a scoliosis back brace. These straps can measure how long and how tightly the braces are being worn and then sends the real-time data to a smartphone application using Bluetooth Low Energy.

As most parents and physicians of adolescents with scoliosis can attest, compliance, defined as the brace wear time, is a big issue. That alone constitutes the most significant challenges for successful bracing treatment. Researchers who've studied this report that increased compliance leads to better outcomes, in other words lower curve progressions.

And that, of course, is the whole point behind Design 109's smart strap.

Here's how the system works. A smartphone application downloads the data collected by the smart strap to the Internet. From there, patients, parents, and doctors can access it. The system compares actual time and tightness that the brace is being worn with the doctor's prescriptions. Parents and patients can see a quick overview of brace wear. Parents can set incentives to encourage their children to wear the brace as prescribed. Doctors, of course, also see the data via a web application which they can use to fine tune the treatment prescriptions in real time.

Aesculap, Inc. – S4 Element MIS

Inventors: Peyman Pakzaban, M.D., Scott Webb, D.O.

Engineering Team: Thomas Hur, Andrew Dauster

John Love, Peyman Pakzaban, Tom Bishow, Tommy Hur, Scott Webb, Jeff Cole and Marissa Varju

S4 Element MIS is all about direct visualization through an endoscope and allows the surgeon pure percutaneous posterior pedicle screw fixation. Here's how:

First, you can better see what you are doing and do so with much less radiation exposure. Why? The endoscope. Many surgeons rely heavily on C-arms to compensate for the lack of direct visualization, especially during screw insertion and rod passage. Because of this, they are exposed to radiation for considerably longer periods especially if they are new to MIS.

With S4 Element MIS the surgeon can visualize during rod passage, confirm rod delivery, position, and length, and, therefore, trouble shoot challenges and minimize guesswork (i.e., soft tissue impeding starting set screw, impeding rod delivery, confirmation of downtube proper reattachment, etc.) associated with MIS. And, of course, there's that reduction in radiation exposure.

Finally, the S4 Element MIS downtube has industry leading rescue instrumentation and technique that enable in-situ downtube reattachment to the screw in the simplest, possible way. This robust instrumentation and technique eliminates the concerns of open conversion, builds confidence, and provides a powerful arsenal in the surgeon's bag.

Category: Thoraculumbar Care

Four Winning Technologies

Medacta International SA – MySpine Patient Matched Technology

Inventors: Prof. Claudio Lamartina, M.D. I.R.C.C.S., Kai-Uwe Lewandrowski, M.D., Meinrad Fiechter, Francesco Siccardi

Engineering Team: Alberto Lipari

MySpine Patient Matched Technology utilizes patient CT scans and unique 3D planning tools to create patient-specific anatomical drill/screw placement guides to simplify pedicle screw placement during spine surgery. A low-dose protocol for collecting patient CT scans has been identified and validated. Adapted from the 3D reconstructed patient's vertebrae, a pre-surgical planning document is prepared, allowing the screw size, trajectory and position to be defined by the surgeon. The entire process is collaborative with the treating surgeon, as traditional CAD (computer aided design) software is utilized to demonstrate initial screw position, and then modified with surgeon input reflecting specific preferences designed to improve treatment outcomes. After surgeon approval of the pre-operative planning, the guides are designed and state-of-the-art 3D Laser Printing equipment is used to create an anatomic 3D model of each affected spinal vertebra and the corresponding guide. The drill guides are designed to accommodate all instruments necessary for intraoperative pedicle identification and screw insertion. The MySpine technology in most instances significantly reduces the need for intraoperative imaging and exposure to both surgeons and patients.

Claudio Lamartina, Tom Bishow and Meinrad Fiechter

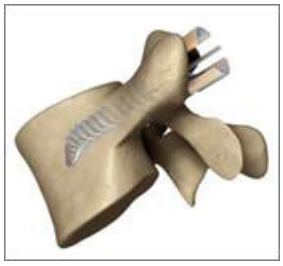
NLT SPINE – ARC Pedicle Screw System

Inventors: Tzony Siegal, M.D., D.M.D., Oded Loebl, Didier Toubia

Engineering Team: Oded Loebl, Moti Altarac

Tom Bishow and Didier Toubia. not pictured: Dr. Tzony Siegal and Oded Loebl

The ARC pedicle screw system is a pedicle screw and delivery instrument system intended for posterior fixation in the thoracolumbar spine. It is comprised of two subsets: the single-use ARC percutaneous pedicle screw, consisting of a full array of lengths and diameters, and a set of reusable instruments (the ARC pedicle screw delivery system) used for screw implantation. The screws are cannulated for over-the-wire, percutaneous insertion and made of titanium alloy. The screws have bendable tips for increasing the pullout strength of the screw from the bone. The tip bending is completely reversible for removal/revision of the screw, if necessary.



SafeWire, LLC – Tiger Express

Inventors: Wyatt Geist and Choll Kim, M.D.

Engineer: Wyatt Geist

The Tiger Express Pedicle Access Needle with Broach is designed to improve the surgeon's workflow, depth accuracy, and reduce the need for fluoroscopy when accessing the pedicle. First it is an extremely strong design, which will allow the surgeon to access the pedicle no matter how hard the cortical bone might be.

Wyatt Geist and Tom Bishow
Not pictured: Choll Kim, M.D., Pierce Nunley, M.D.

Second, it incorporates a broach that will prepare the first 15mm of the pedicle with a 4.4mm hole for easier insertion of MIS screws. The design rational was to leave the last 5mm of bone in the pedicle unbroached. The last 5mm is usually more cortical and should result in good fixation since it will be un-broached and untapped.

Third, a depth stop is incorporated to aid the surgeon to achieve a set depth. Lastly, it incorporates an atraumatic mechanical back-out feature. No longer will surgeon have to struggle removing access needles, it is removed simply and coaxially, while putting almost zero torque on the guidewire, reducing the chance of accidently removing the guidewire.

Vital 5, LLC – ReLeaf Anesthetic Delivery Catheter

Inventors: Frank M Phillips, M.D., Kern Singh, M.D., Thomas Wade Fallin, Jean-Sebastien Merette, Patrick Michel White

Engineering Team: Thomas Wade Fallin, Jean-Sebastien Merette, Patrick Michel White

Vital 5's invention is a dual function directional analgesic infusion catheter and wound drainage system. While continuous anesthetic infusion to the surgical site in the immediate post-operative period has been clinically proven to provide significant improvements to pain management, it is not compatible with the millions of surgical cases where a wound drain is prescribed.

(Left to right): Tony Recupero, Tom Bishow, Kern Singh, M.D. and Frank Phillips., M.D. Not pictured: Lisa Smith, Wade Fallin

Vital 5's innovation solves that problem. The system provides a continuous local anesthetic infusion while also providing an effective wound drain function. The name of the invention is the ReLeaf.

Because of the inherent conflict between infusing local anesthesia and allowing the wound to drain, most physicians avoid a "local" in spine with exposed dura because of concerns for inadvertent spinal nerve blockade. The ReLeaf solves this problem with a barrier technology to minimize local anaesthetic contact with exposed neural elements. The clinical applications for the Vital 5 ReLeaf include any invasive surgical procedure, including spine, orthopedic, cardiothoracic, plastic, general, obstetrics and gynecological procedures. ♦

Spinal Cap III: The Taming of the Pedicle Screw, Part 1

BY WALTER EISNER

The Shakespearean spine drama of private greed and public corruption in California termed "Spinal Cap" by the FBI has entered Act III. At the end of October the sealed whistleblower lawsuit that started it all was made public and patients began to sue surgeons, hospitals and others for allegedly putting counterfeit pedicle screws and rods into their backs.

Let's recap the first two acts of this drama.

Act I: Drobot's Fall

In Act I, Michael Drobot, the former owner and operator of Pacific Hospital of Long Beach, admitted to compensating physicians to refer patients to his hospital and bribing a state senator to keep a favorable workers' comp law on the books.

Drobot is waiting to be sentenced this coming December.

Act II: Crooked Doctors and Fake Screws

Then came Act II, as Arthur Golia, a spine patient, filed suit on June 13, 2014, accusing, Jack Akmakjian, M.D., a spine surgeon, a spine distributor and a mom-and-pop machine shop of putting seven non-FDA approved devices into his spine.

Act III: Taming of the Pedicle Screw

Act III begins as Drobot and his alleged accomplices are accused by the whistleblowers of building a web of interlocking companies to hide their ill-gotten gains and paying surgeons and chiropractors referral fees to send patients to their hospitals.

Photo creation by RRY Publications LLC / Sources: Wikimedia Commons and Kaudris

The plot thickens as Drobot and two of his alleged accomplices, Paul Randall and Roger Williams, are accused of establishing spinal hardware distributorships and manufacturing companies and paying unlawful kickbacks to surgeons to use their implants. They then sold the hardware to collaborating hospitals at grossly inflated prices.

The whistleblowers say the group of defendants overinflated the price of the "counterfeited" devices to hospitals, which in turn falsely billed the state workers comp program. A group of surgeons is also accused of knowingly utilizing the counterfeit screws and rods sold to the hospitals, with the hospital's knowledge and collaboration.

Like a Shakespearean drama this play requires a playbill of the list of actors.

The Whistleblowers

Mark Sersansie and William Reynold—Sersansie is a former employee of Platinum Medical Group. Reynolds is a former employer of two workers' comp carriers in California.

The Accused

Michael Drobot—Former owner of Pacifica Hospital, West Coast Surgery Center Management and International Implants, LLC.

Paul Randall and Christine Hernandez—Owners of Summit Medical Equipment, Inc. and Platinum Medical Group. Located in same complex as Tri-City Regional Medical Center. Randall,

Mark Sersansie/ nbclosangeles.com

a central character in this alleged conspiracy, was allegedly paid $100,000 per month by Drobot for marketing services.

Michael "Mic" McGrath—Owner of Comprehensive Intra-Operative Services (C.I.O.S). A spine device marketing company. Had contracts with Tri-City Regional Medical Center, Pacific Hospital, Riverside Hospital, Michael Drobot and Roger Williams.

Michael Drobot/nbclosangeles.com

Roger and Mary Williams—Owners of Spinal Solutions, LLC. Manufacturers and distributors of alleged counterfeit spine devices. The company had marketing arrangement with Randall and "Mic" McGrath.

William Crowder—Owner of Crowder Machine & Tool Shop, hired by Williams to make alleged counterfeit pedicle screws and rods.

Beryl Weiner and Arthur Gerrick—Weiner is Tri-City's former attorney and Gerrick is the hospital's former CEO. They established Willshire Boulevard-based South Bay Hospital Management Company LLC as a "management company" for Tri-City. According to the whistleblowers, the real purpose was to funnel and siphon-off unlawful profits from Tri-City arising from unlawful billings for spinal fusion surgeries and hardware.

The Defendant Hospitals

Tri-City Regional Medical Center—Managed by South Bay Hospital Management.

Pacific Hospital of Long Beach—Purchased by Drobot in 1997 and managed by West Coast Surgery Center Management, Inc., also owned by Drobot.

Between 2001 and 2010, the hospital performed 5,138 fusion surgeries and billed $533 million, three times as much as any other California hospital over the same time period.

Riverside Community Hospital and St. Bernardine Medical Center—Other hospitals accused of participating in the billing scheme.

The Accused Doctors

Jack Akmakjian, M.D., G. Sunny Uppal, M.D., Joseph Vanderlinden, M.D., and Edward C. Kolpin, M.D.—All performed spine surgeries at defendant hospitals. They are accused of taking illegal kickbacks to perform surgeries at those hospitals and knowingly implanting the alleged counterfeit screws and rods into patients. They are also accused of taking kick-backs for using those implants.

Ismael Silva, M.D. and Jeffrey S. Catanzarite, D.C.—Were allegedly paid $1.8 million and $1.7 million, respectively, by Drobot and International Implants in exchange for referral of patients.

Drobot and Randall Go Into Business

According to the whistleblower suit, Paul Randall went into business with Drobot after getting out of federal prison following a 21-month term stemming from a 1993 conviction for buying wooden shipping pallets on credit and reselling them without paying the original vendors. He began steering spinal patients and surgeons to Drobot's Pacific Hospital.

Randall introduced surgeons to Drobot for which he was allegedly paid $25,000 a month. The two also co-owned a weekend retreat in Bullhead City, Arizona, along with a doctor.

After a business dispute with Drobot in 2008, Randall and his partner, Christine Hernandez, formed the Platinum Medical Group, a spinal distributorship that employed one of the whistleblowers, Mark Sersansie. They shifted their marketing business to Tri-City Regional Medical Center and began recruiting the same surgeons Randall had brought to Pacific Hospital. Randall allegedly paid the accused surgeons $15,000 and $20,000 for each referral.

Tri-City is a non-profit 107-bed facility near Long Beach. The hospital had marketing agreements with Randall and McGrath and others and allegedly paid them as much as $100,000 per month to steer patients to the hospital. They paid Randall, according to the whistleblowers, more than $3.2 million between 2008 and 2011.

In 2007, Tri-City billed $3 million to workers' comp for spinal fusions. In 2010 that jumped to $65 million.

Sersansie claims that Randall, through Summit Medical Equipment, purchased alleged counterfeit implants and resold them to the defendant hospitals.

Drobot and Randall got back together in August 2011 with another marketing contract that allegedly paid Randall $100,000 per month.

The Whistleblower Charges

Specifically the defendants are accused of violating the California Insurance frauds Prevention and False Claims Acts. Those violations include:

A. Employing, or as acting as, runners, cappers, steerers or other persons for the purpose of procuring patients;
B. Paying illegal kickbacks to chiropractors, doctors, lawyers and other persons for referring patients to Defendant Hospitals;
C. Inflating the cost of spinal implant hardware above that which is allowable under California law;
D. Paying illegal kickbacks to doctors and surgeons for choosing particular spinal implant hardware;
E. Manufacturing counterfeit, non-FDA approved spinal implant hardware and billing insurers as if they were approved; and
F. Performing non-medically necessary surgeries.

Spinal Solutions, McGrath and the Surgeons

Roger and Mary Williams, the owners of Spinal Solutions had marketing agreements with Randall and Michael "Mic" McGrath. They are accused of hiring Crowder Machine Shop to make the alleged counterfeit implants and selling them through Spinal Solutions. The whistleblowers say Williams flew surgeons who used their implants on his private plane to foreign countries and other vacation destinations. Two of those surgeons, Akmakjian and G. Sunny Uppal, along with McGrath, attended a conference in Montreal.

McGrath and his spine device marketing company, Comprehensive Intra-Operative Services [C.I.O.S.], had contracts with various hospitals, Drobot and Williams.

Sham "Consulting Agreements"

McGrath is accused of entering into sham "consulting agreements" with Drs. Uppal and Akmakjian to use his clients'

hospitals and choose Spinal Solutions' implants. In November 2002, McGrath allegedly paid Akmakjian $25,000 in three checks of $8,333 each.

In a note to Williams and Spinal Solutions, McGrath allegedly discussed the illegal kickback scheme. Attached to the note were two checks for $750, one for Uppal and one for Akmakjian. In the note, McGrath informs Williams: "Rog, these checks are....for Sunny and [j]ack. I had to pay to stop their crying. I'll take it out of Spine-Line at the end of the month."

According to the whistleblower complaint, on January 20, 2010, McGrath issued an invoice to Spinal Solutions seeking money for kickbacks to surgeons using Spinal Solutions' implants. The invoice indicates that Uppal and Akmakjian were paid $1,500 per spinal fusion surgery. The invoice even indicates the name of the patients and the hospital where the surgeries were performed.

The whistleblowers say they also have checks issued to Joseph Vanderlinden, M.D. and are signed by McGrath. Over a period of three months, McGrath allegedly paid Vanderlinden $24,000 in kickbacks for using his and Spinal Implants' implants.

There are apparently more surgeons involved and the whistleblowers say they will name them as they are "ascertained."

The Reckoning

In addition to the kickback charges and setting up the web of management companies and distributorships to hide their profits, the accused are also charged with manufacturing cheap counterfeit screws and rods to make even more money.

And that caught the attention of patients and lawyers.

On October 17, 2014, 28 former patients filed a lawsuit against most the group for placing non-FDA-cleared devices into their bodies. There are now 32 civil cases from patients pending in state courts.

In the last scene of Act III of this drama, Drobot claims his innocence of the counterfeiting charges and countersues the attorneys representing the patients. We'll take a look at the evidence and bring you the conclusion in next week's installment of the "Taming of the Pedicle Screw." ♦

New Harvard Study Could Change Orthopedics Forever // Which Spine Surgery LEAST Likely to Repeat? Riew and Hilibrand Tackle Question // Two Million Patients Studied…Blood Transfusion on the Rise

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

New Harvard Study Could Change Orthopedics Forever In what is likely the one of the first-ever attempt to map a cycle of care using an advanced economic model, researchers from Harvard have joined together with business gurus at the same institution. Jon J.P. Warner, M.D. is chief of the Shoulder Service at Massachusetts General Hospital and co-director of the Boston Shoulder Institute Fellowship worked in collaboration with Laurence D. Higgins, M.D. chief of the Sports Medicine and Shoulder Service at the Brigham and Women's Hospital. A former president of the American Shoulder and Elbow Society (ASES), Dr. Warner told *OTW*, "Dr. Higgins and I have worked with Robert Kaplan and his colleagues at the Harvard Business School, and have just completed a study where we looked at the actual cost of an episode of care for rotator cuff surgery. By mapping the entire cycle of care and carefully analyzing each step, we were able to reduce the price of the entire one year episode of care by 15%.

Image created by RRY Publications, LLC / Sources: James Heilman, M.D. and Wikimedia Commons

"The tool we used—Time-Driven Activity Based Costing (TDABC)—allowed us to map the cycle of care. This accounting methodology analyzes use of resources including individual caregiver's time for each step in the care cycle. A cost-capacity rate for an individual is their cost per minute for their time based on their salary and benefits and number of minutes worked per year. This is also combined with cost for using equipment and space. Such accounting is more accurate in representing true costs than allocation of historical costs. Moreover, this method allows us to analyze a care map looking for bottlenecks in the process and thus improve the efficiency of the entire care process. Applying this methodology allows us to bring healthcare delivery on par with other industries."

"The single most important factor in the cost of rotator cuff repair was personnel (73%). So if you take a look at the evidence based medicine you see that the patient does not need physical therapy (PT) in the first four weeks after rotator cuff repair and voilà…you just saved a substantial amount of money."

"We also found that in the entire year of care the day of surgery accounts for 53% of the total cost of care; PT is 22%. As a field we need to understand the value of taking apart what we are delivering. With this work we were able to

improve 15 different elements of the cycle of care. We started the episode of care on the day that the patient signed up for surgery. This involved: measuring how many places he or she went, how many stops they have to make (and the indirect and direct costs of those stops), how many people they see on the day of surgery, how much time they spent in preanesthesia, what sort of bottlenecks there are from an equipment standpoint. Two institutions—Massachusetts General and Brigham and Women's ambulatory center (Faulkner Hospital)—were studied. When all was said and done the cost difference between having rotator cuff surgery at one hospital versus another was inconsequential. These institutions used the same pathways of care and came up with the same cost of a cycle of care!"

"In addition to this study, we have established an outcomes registry for rotator cuff surgery; I believe that we are the first researchers to calculate the recovery curve for rotator cuff and shoulder replacement. The process is such that patients go online and input their feelings and information about pain levels. Then we calculate the mean recovery rate of patients' pain and functional improvement. The most amazing finding was that two different surgeons at two institutions achieved the exact same outcome! People who have shoulder replacement recover faster than rotator cuff and do not experience much pain as compared to those undergoing rotator cuff surgery. But if you look at the standard deviation it decreases as the patient gets further from the point of surgery. So five weeks after surgery we'll do risk modeling, but I think it's high likely that these numbers represent a serious complication. Cardiothoracic surgeons have done some of this work in the past. We need to catch up with them…and with industry."

Which Spine Surgery LEAST Likely to Repeat? Riew and Hilibrand Tackle Question Dan Riew, M.D. is the Mildred B. Simon Professor of Orthopedic Surgery, Professor of Neurological Surgery, and the Chief of the Cervical Spine Service for Washington University Orthopedics and Director of the Orthopedic Cervical Spine Institute. He and his co-authors Jae Chul Lee, Sang-Hun Lee and Colleen Peters have just published the lead study in the November 5, 2014 issue of the *Journal of Bone and Joint Surgery (JBJS)* looking at the incidence of reoperation for adjacent level pathology (ASP) follow-

ing a variety of spine operations. With nearly 1,400 consecutive patients, says Dr. Riew, it is the largest such series to date. He tells *OTW*, "All patients in this retrospective study had been diagnosed with radiculopathy, myelopathy, or myeloradiculopathy and underwent cervical spine surgery performed by a single surgeon. We looked at anterior and posterior surgery, both fusion and non-fusion operations, and calculated the annual incidence of ASP requiring surgery and found that the operation that is least likely to require repeat surgery was laminoplasty…this was pretty surprising. The surgery that was most likely to require an additional procedure was fusion done from back of the neck (a 7.5x greater risk of reoperation for ASP than laminoplasty)."

"This was the first study to look at reoperation rates following all types of cervical operations in large numbers, using Kaplan-Meyer survivorship analysis. My good friend Alan Hilibrand of the Rothman Institute did a study years ago where he defined ASP, not by reoperation rates, but by when a patient came back to see Henry Bohlman on two consecutive occasions complaining of problems at the adjacent level. Most surgeons misquote his paper, thinking that he looked at reoperation rates. He argues in this article that his is more objective in that it is patient and not surgeon-controlled. While that may be true, the surgeon can still minimize patient reported symptoms, or worse, not even diagnose them properly. We both trained with Dr. Bohlman, and we both saw that if a patient complained of neck pain after a myelopathy or radiculopathy operation, he would minimize it by saying, 'don't sweat the small stuff' and usually not even mention it in his notes."

"Also, if a patient complained of ulnar forearm and hand symptoms, he would diagnose a cubital tunnel syndrome instead of a C8-T1 radiculopathy. Despite all the C4,5,6 corpectomies that he did, I never saw him do a C7-T1 or T1-T2 level operation once during my year with him. Nor did he ever diagnose a C8-T1 radiculopathy in that year. So, looking at the office notes for patient reported symptoms and surgeon diagnoses can also be inaccurate. But reoperation is very objective. More importantly, in order to compare apples to apples, we all have to have a uniform criterion by which we determine ASP rates. Every arthroplasty study defines ASP as reoperation. In fact, other than his paper, I don't know of a single paper in the literature that defines ASP as 'two consecutive office visits to the surgeon with complaints related to the next level.' Also, while I agree with him that patients and surgeons are reluctant to have surgery again, there is no reason that this reluctance should be lower with one type of surgery as compared to another. So when we compare ASP rates amongst different operations, the same reluctance should hold for all of them."

Dr. Riew: "The surgeon also has control over the first operation. I agree that surgeons look better if they don't have to reoperate. But if someone complains about the next level and you ignore it, they will go elsewhere. Also, if you are a surgeon that ignores complaints and doesn't operate, you are also less likely to put it in the chart, and that is 100% under the surgeon's control. We published a study in *JBJS* several years ago that showed that office notes are a poor reflection of the patient's complaints about adverse events ("Accurate identification of adverse outcomes after cervical spine surgery," *J Bone Joint Surg Am* 2004;86(2):251-6). So we know office notes often aren't objective or accurate. Also, if you ignore the complaints, the patient may go to another doctor…and then you have no follow up. Finally, regardless of whatever conflicts the surgeon may have with implants and studies that may discourage reoperation, possibly the largest financial conflict that the surgeon has that we never seem to talk about is the one where the surgeon gets paid to reoperate."

Alan Hilibrand, M.D. is The Joseph and Marie Field Professor of Spinal Surgery and professor of Orthopaedic Surgery and Neurological surgery at Jefferson Medical College and the Rothman Institute. Dr. Hilibrand tells *OTW*, "Patients are often reluctant to have a second operation; sometimes the surgeon is reluctant as well because they may view it as their own 'failure,' although in my opinion it should never be viewed as such. If a patient is failing nonoperative treatment and comes in a second time with persistent complaints, then he or she is probably appropriate for surgery…yet there are many patients who just won't go through with it. Almost half of Dr. Bohlman's patients who developed adjacent segment disease didn't undergo surgery. For this reason, we ran the analysis on the basis of people coming in with symptoms, since nearly half of Dr. Bohlman's patients—developed symptoms and decided to just live with them."

"There are situations where the surgeon who did the first surgery is reluctant to do another one and puts the patient off, and it's not until they see a different surgeon that they are told that they need an operation. For example, in the 1990s when we gathered the data for our study, there were a number of arthroplasty studies where the design surgeon performed the index operation and then decided whether the patient later needed a revision. Obviously, if they did not reoperate then their procedure would look like it had greater durability. So when I did my study, I did not want to ignore the possibility that a reviewer might criticize the study

by asking whether Dr. Bohlman might have had that unconscious bias."

"I think that the most remarkable and noteworthy aspect of Dr. Riew's new paper is the comparison of the rates of adjacent level issues among the different surgeries, and I agree that basing this comparison upon reoperation rates is very appropriate and valid. And although I agree that the arthroplasty trials used reoperation rate rather than recurrent symptom rate as their determinant of adjacent level pathology, this does not mean that it's the best way to evaluate for adjacent segment disease. It all depends on the question asked: If a patient wants to know what are the chances that they will develop 'the same type of problem at another level,' I would quote them our data from Dr. Bohlman's patients (about 3% per year). On the other hand, if they asked, 'What are the chances that I will need another operation because of a problem at another level?,' then I will now quote them the data from Dan Riew's study, which can answer that question for both ACDF [anterior cervical discectomy and fusion] as well as posterior procedures."

Blood Transfusions (and Related Concerns) Are Up Using a database with two million patients, researchers have found that there has been an increase in allogenic blood transfusion among total hip arthroplasty (THA) patients. This is concerning, says Anas Saleh, M.D., an orthopedic surgeon at Cleveland Clinic, because transfusions are not without risk. Dr. Saleh tells *OTW*, "Blood transfusion is common in total joint replacement (and more common in total hips than in total knees). Despite blood conservation efforts and the advent of commercial products aimed at reducing the perioperative bleeding and blood transfusions, the rate of allogenic blood transfusion is increasing and the patient is still running the risk of pulmonary complications, infection, and a prolonged hospital stay."

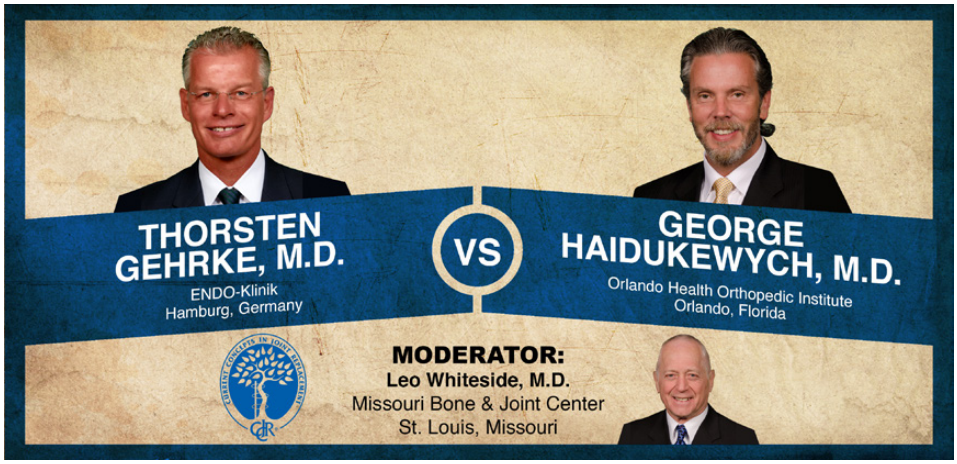
"We used the National Inpatient Sample (NIS) database, which collects information on about 20% of all hospital discharges; it is weighted so that it can be extrapolated to the U.S. population. Along with our statistician colleagues at Case Western Reserve University, we designed the study to look only at primary total hip replacement. They performed sophisticated analyses and controlled for patients' comorbidities, socioeconomic status, location, race, and insurance. While allogenic and autologous blood transfusions were noted, the focus was on allogenic because it is now more common than autologous."

"We found that the rate of allograft transfusion has increased over the study period, and that this is associated with an increase in complications (especially deep vein thrombosis, infection, and pulmonary embolism). There is currently a push for preop and perioperative methods of preserving blood. Clinical pathways exist that are aimed at optimizing the patient's blood counts preoperatively, which include providing iron and/or erythropoiten, to help ensure that their blood levels don't drop to a level where a transfusion is required. There are also intraoperative tools such as hemostatic agents which can stabilize clots in the surgical wounds. These hemostatic agents are expensive, however, and we need to decide whether these agents are cost-effective, or if they're effective at all. At Cleveland Clinic most primary hips and knee patients get intravenous or local tranexamic acid, as it has proved to be the most cost-effective option." ♦

Gehrke Debates Haidukewych: Mega Prostheses

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

This week's Orthopaedic Crossfire® debate was part of a landmark event, the first Brazilian CCJR meeting. The event, which took place in September 2014, was held in Iguassu Falls. The topic was, "Mega Prostheses for Well Fixed TKA Femoral Fx's." For the proposition is Thorsten Gehrke, M.D. from ENDO-Klinik in Hamburg, Germany; against the proposition is George Haidukewych, M.D. of Orlando Health Orthopedic Institute. Moderating is Leo Whiteside, M.D. from Missouri Bone & Joint Center.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Gehrke: "In our practice we see a lot of failures, including periprosthetic fractures. Recently, Clive Duncan and Fares Haddad published the unified classification system, which is great because it includes almost everything. For periprosthetic fractures they divided it into good bone, no implant loosening (B1), good bone with implant loosening (B2), and poor bone with implant loosening (B3). They forgot to include B4, which means poor bone, but well-fixed implant."

"Of course we have many options, including retrograde nailing, intramedullary nailing, less invasive stabilization systems, non-contact bridging plates with polyaxial locking screws. These are all good options and they can work well. But if we look at a recent paper from India we see that the locking plates in 25% were in need of revisions. The major problem with locking plates is nonunion. In this paper they compared intramedullary nailing with the periarticular locking plates. They found that the locking plate group had nonunion or delayed union in 19%; it was 9% in the intramedullary nailing group."

"Theoretically, nails are good in all kinds of fractures, but they have limited use it you like to use them in combination with total knee arthroplasty (TKA). If you have a closed box you have no chance of putting a retrograde nail in to treat the periprosthetic fracture. Mega prostheses can be an option."

"Some of the distal femur replacements have too short of an anchoring distance, so they fail. You can only solve this by switching to a total femur replacement. In a paper comparing allograft with a revision system vs distal femur replacement and found that the operative time and blood loss were significantly less in distal femur replacement. A study by Antonia Chen showed that there were significantly more surgical procedures for open reduction and internal fixation (ORIF) to distal femur replacement compared to primary distal femur replacement that may be preferred in osteopenic patients."

"In another study they used mega prostheses in cases of periprosthetic fracture around the knee arthroplasty. They did 11 patients without the need for reoperation. Mega prosthesis can also be a good solution in elderly and osteopenic patients because they provide immediate stability and allow early mobilization."

"If you have a very old patient with an internal prosthetic fracture, you can use this device we developed—an interposition device which allows you a very quick salvage of the situation. And a recent experimental approach that we did involved something I call the 'coffin lid.' If you have two well-fixed implants in an interprosthetic fracture then we use a strut graft to solve this problem."

Dr. Haidukewych: "I'll concede that mega prostheses do have a role in the treatment of fractures above a well fixed total knee, but a very limited role…less than 10% in my practice. Perhaps in those very distal fractures with osteolysis where internal fixation is likely to fail. ORIF does remain the gold standard for these fractures. There are no published prospective randomized studies comparing modern ORIF to mega prostheses to substantiate any benefit of one choice over another in

regards to outcomes, cost, disposition, or hospital stay."

"Periprosthetic fractures are becoming more common. They are usually due to low energy falls and they always occur right at the flange of a very well fixed femoral component. The most common scenario we see in the U.S. is that the knee is functioning well, it's well fixed, and the fracture is a supracondylar femur fracture. The goals of treatment are to maximize distal fixation, get the fracture to heal in the correct alignment. The challenges include: osteopenic bone, short distal fragments that offer limited opportunity for internal fixation, and obstacles to distal fixation by parts of the femoral component."

"Two general trends exist in the U.S., namely, some form of submuscular locked plating and some form of retrograde nailing with multiplanar angle stable locking screws. Nails are tissue-friendly and mechanically sound, but you do need good notch access and it's hard to avoid malalignment. Most modern total knees have good notch access for retrograde nailing. I do these through an arthrotomy so that I don't damage the arthroplasty. I allow full weight bearing and early range of motion (ROM) on these constructs. Do not use short retrograde nails; most manufacturers are abandoning these for good reason."

"As for plating, lock plates offer coronal plane stability and can be used in any fracture…regardless of notch access. The advantage of an angled stable lock plate versus a single point of fixation with older implants is that you can get extremely distal—even fractures that go distal to the femoral flange. We no longer use any form of allograft struts or cerclage anywhere near the metaphysis because that's a good way to get a non-union."

"Every manufacturer now offers some way to angle and lock a screw, which is particularly advantageous in a periprosthetic fracture. Again, this lets you get good fixation very, very distally. And if you leave it alone it will heal biologically. The technique is the same whether you nail or plate. I like to prep the well leg and keep it out of the way. Not only is that a good control for alignment, leg length and rotation, but you can lift it over the C arm and not have to lift a fractured limb when you place your fixation. Avoid hyperextension by carefully positioning your bump; place your plate or nail, bridge the fracture, leaving the metaphyseal area alone… and this will heal predictably."

"Most systems offer all sorts of gizmos to help you get good reductions; they

can be helpful in doing a nice minimally invasive job on these fractures. Multiple series worldwide show that we can expect a union rate of well over 90%, with nails trending a bit better than locked plates."

"So why not perform a mega prosthesis for these fractures? Proponents will say that you can allow full weight bearing, there's no fracture to heal, and early ROM. The disadvantages are that they are extremely expensive—at least 10-15 times more expensive than a nail. The complication rates are in the double digits, it requires expertise, and they almost all have some sort of extensor mechanism problem. If ORIF fails I can put in a mega prosthesis. What do you do if a mega prosthesis fails? Just keeping adding segments until we get up to the hip, apparently."

"If you look at the complications with mega prostheses, Schwab showed that more than half had some sort of patella problem. The other complications are not insignificant, but in fact are well into the double digits. Many series have summarized this. Distal femoral replacements have a high rate of complication; the procedure should be reserved for patients for whom alternative treatments are not possible. I do a mega prosthesis as a last resort, with a very distal fracture, with severe osteolysis, non-unions, and those who have had multiple operations."

Moderator Whiteside: "Thorsten?"

Dr. Gehrke: "I agree that if you have very good bone stock and you can't solve the problem with a nail or plate I would do the same as you. The mega prosthesis is a very limited solution, but think about it as a solution in old patients and osteopenic patients with poor bone stock who need a quick procedure and fast mobilization."

Moderator Whiteside: "What about the patellar issues?"

Dr. Gehrke: "You have to find out the right rotation, which is the most important part of the tibial and femoral component. Then we don't see many complications with patellar tracking."

Moderator Whiteside: "That's what I see the most, i.e., patellar complications. I'm concerned that the patellar groove is not adequate and that the patellar tracking mechanism has been resected. You haven't seen that as a significant issue?"

Dr. Gehrke: "No. If you respect all the rules about the joint line and rotation of the components then you don't see if often."

Moderator Whiteside: "George, do you get referred patients with patellofemoral issues after a mega prosthesis?"

Dr. Haidukewych: "This occurs not only in referred patients, but in my own. They're too small and the trochlea isn't friendly for an unresurfaced patella or one that's been resurfaced. You basically resect all the distal soft tissue, so they never track well. They almost always need a lateral release."

Moderator Whiteside: "What do you do when you have persistent patellar dislocation with this prosthesis?"

Dr. Haidukewych: "I do a proximal realignment."

Dr. Gehrke: "In 2005 we published 100 consecutive cases with total femur replacements. We found patella problems only in 5% of patients; I don't think that this is the main issue here."

Moderator Whiteside: "Is this a cemented stem?"

Dr. Gehrke: "Until two years ago we used cemented stems almost exclusively, but we have now switched to cementless in some patients. I think the cementless stems are working better than the cemented stems."

Moderator Whiteside: "George, what do you do about rotational alignment of the distal femur when you have a highly comminuted fracture and you're plating it?

Dr. Haidukewych: "Whether plating or nailing it's the same issue…you need to have some comparisons. I'll have the other leg prepped in. When I pass my fixation device I will place the screw above or below then flex the knee and check rotation compared to the other side. And check your tracking, like you do with any other TKA. When you're done fixing it you compare it to the other leg and take the knee through a range of motion and hopefully you would pick up if you missed a little bit or internally rotated something."

Moderator Whiteside: "What companies make these plates available?"

Dr. Haidukewych: "All companies have multi-angled locking stable screws."

Moderator Whiteside: "Thank you both." ♦

Please visit www.CCJR.com to register for the 2014 CCJR Winter Meeting, December 10 – 13 in Orlando, Florida.

COMPANY

Baxano Files for Bankruptcy – Assets to be Actioned

Photo creation by RRY Publications LLC

Baxano Surgical, Inc. has filed for Chapter 11 Bankruptcy and its assets are going up for auction, according to a company announcement on November 13, 2014.

The company was unable to secure ongoing financing, so a decision was made to facilitate a going concern sale of the company's minimally invasive products under Section 363 of the U.S. Bankruptcy Code.

Company's president and CEO Ken Reali said, "We believe this is the best course of action for the company at this point in time and is in the best interests of all of our stakeholders. As we move through this transaction process we will continue to focus on supporting our commercial business and the surgeons and hospitals that use our products."

In conjunction with the bankruptcy filing, Hercules Technology Growth Capital, Inc., Baxano's pre-petition secured lender, has agreed to "debtor in possession" (DIP) financing. That means that anyone purchasing any of Baxano's assets gets them unencumbered from claims by Hercules. Any sale will be subject to Bankruptcy Court approval to support Baxano's continued operations during the pendency of the sale process.

Company Assets

The company's major assets include over 100 patents:

- AxiaLIF family of products for single and two level lower lumbar fusion,
- VEO lateral access and interbody fusion system featuring the REVEAL retractor
- iO-Flex system, a proprietary set of flexible instruments used by surgeons during spinal decompression procedures
- iO-Tome instrument, which rapidly and precisely removes bone, specifically the facet joints, which is commonly performed in spinal fusion procedures
- Avance, an MIS pedicle screw system used in lumbar fusion procedures.

AxiaLIF, VEO, REVEAL, iO-Tome and iO-Flex are all registered trademarks of Baxano Surgical.

End of TranS1/Baxano Experiment

This brings to an end the effort to join Baxano with TranS1, Inc. Raleigh, North Carolina-based TranS1 acquired Baxano in 2013 in a stock transaction valued at about $23.6 million.

TranS1's, primary revenue driver was its AxiaLIF device, which received FDA clearance in 2004 and was launched in 2005. Revenue reached $29.8 million in 2009, but has steadily declined each year since. Company executives attributed the sales slide to declines in surgeries because physicians had problems getting insurance reimbursements.

Reimbursement Challenges

AxiaLIF is a unique presacral lumbar interbody fusion procedure which was difficult to fit into existing CPT (Current Procedural Terminology) codes. On March 5, 2012, TranS1 announced that the American Medical Association's CPT Editorial Panel voted to approve an application for a new Category I CPT code, 225XX1, for L5-S1 spinal fusion. The CPT Panel also voted to establish a new Category III CPT code and elected to adopt minor revisions to the company's two current Category III codes. The new CPT codes, and the revisions to the existing CPT codes, became effective on January 1, 2013.

But that wasn't sufficient to convince enough payers to cover the procedure.

After combining the companies, second quarter 2014 revenue was $4.6 million, up 20% compared to the same period the previous year. The company's net

loss in the quarter was $5.6 million, a 31% improvement compared to a year ago. But the company was running out of cash and had just $3.8 million in cash and equivalents as of June 30, 2014.

The company reported that an independent auditor concluded that the company's recurring losses and negative cash flow raised doubts about the company's ability to continue operating. In its last quarterly report, management said that if it was unable to raise additional financing, it would "need to implement further expense reduction measures, including workforce reductions, the consolidation of operations and/or the delay or cancellation of certain operational programs, pursue a plan to license or sell our assets, or to cease operations."

Reali told us the auction will likely take place before the end of the year and will be government controlled. — *WE*

Infuse Sales Leading Medtronic Spine to Health

Medtronic Inc.'s spine's most recent quarter's sales beat Wall Street expectations. Most surprisingly, Infuse is credited with causing the surprise.

Yes, you read that right. Biologic sales for Medtronic's second quarter rose 9% on a reported basis while Core Spine and Interventional Spine, which consists of the company's balloon kyphoplasty product line slipped 1% and 6%, respectively. Management said the company's kyphoplasty sales were affected by a product supply issue related to the cement delivery system.

Underlying Stable BMP Demand

BMP (bone morphogenetic protein—Infuse) sales of a $120 million, according to Medtronic's CFO Gary Ellis, grew with stable underlying demand. "While sales of BMP bounced round a bit, we do believe we have turned the corner and would expect BMP sales growth to be slightly positive going forward."

After Carragee, after *The Spine Journal* and NASS (North American Spine Society), surgeons have decided their patients need the product. Omar Ishrak, the company's chairman and CEO, and his spine team never flinched. They just shrugged off NASS and let the evidence speak for itself.

Spine Revenue Flat

Overall spine revenue of $746 million grew 1%. Core Spine's flat year-over-year result was a "modest improvement" from last quarter, said Ellis. "We are encouraged that both the global and U.S. Core Spine markets continue to stabilize and are beginning to show bias towards low-single-digit growth."

Ellis added that the Core Spine business is launching a number of new products this fiscal year, which he expects will return the company's overall spine business to modest growth in fiscal 2015. "In addition to working with surgeons to develop the leading technology in spine, our business continues to focus on procedural innovation and our surgical synergy program, which integrates enabling technologies, surgical tools, spinal implants and our expertise."

Medtronic Spine 2Q15	Sales $ in million	% Change
Total Reported Sales	**$746.0**	**Flat**
Core Spinal	$551.0	Down 1%
Biologics	$120.0	9.00%
Interventional Spine	$75.0	down 6%

Source: Medtronic Inc.

The company generated $951 million in free cash flow during the quarter and is committed to returning 50% of that to shareholders in the form of dividends.

Medtronic

Spine Market Growing

Now that Medtronic has reported its results, all the spine players have reported quarterly sales figures.

RBC Capital Markets' Glenn Novarro said worldwide spine market growth during the quarter appears to be in the 3.5%-4.5% range on a constant currency basis.

He believes the underlying health of the worldwide spinal market improved

sequentially, owing to better U.S. growth. He estimates that the U.S. spine market was up 3%-3.5% and international growth was up 6.5%-7.0% on a constant currency basis.

Smaller Players Gaining Market Share

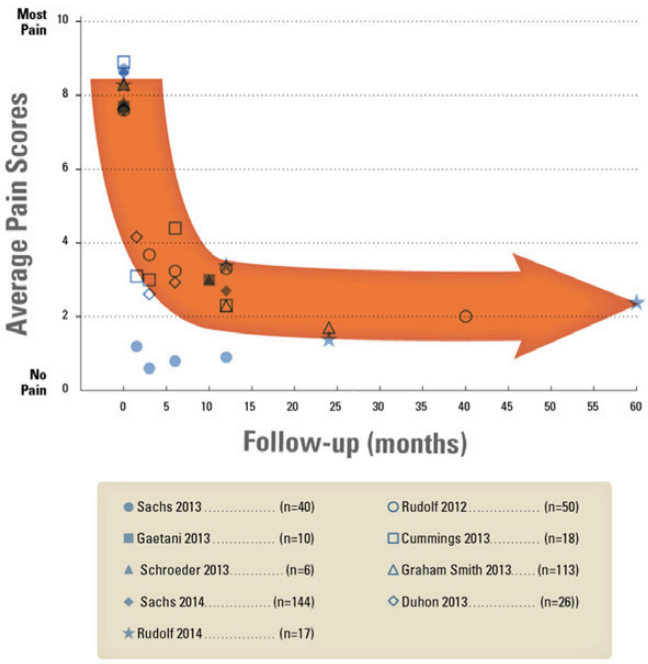
Smaller spinal manufacturers continue to gain market share. Novarro says NuVasive, Inc. which gained approximately 60 basis points of worldwide market share in the quarter while LDR Holding Corporation gained about 30 basis points of share. Other large share gainers included K2M, Inc. and Globus Medical, Inc.. He expects continued market share gains from the smaller spinal manufacturers for the remainder of 2014 and into 2015.

"Given the better than expected [third quarter] spine results, we now believe the worldwide spine market will grow in the 3%-3.5% constant currency range for 2014," concluded Novarro. — *WE*

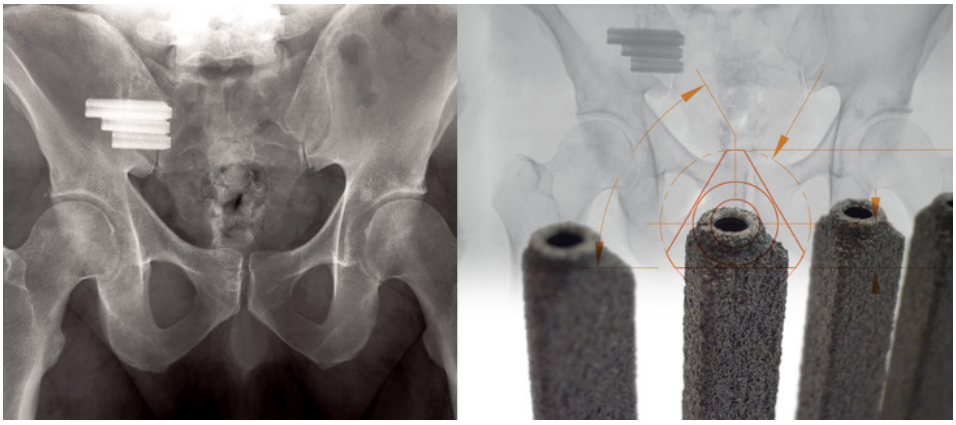
SI-BONE Hits Home Run With 5-Year iFuse Implant Data

It's good news for those suffering from degenerative sacroiliitis and/or sacroiliac (SI) joint disruptions. SI-BONE, Inc. is reporting 5-year results indicating that patients treated with its iFuse procedure experienced low back pain relief and patient satisfaction. In this single center study, the minimally invasive SI joint fusion involved a series of triangular TPS coated implants. These findings, reported in *The Open Orthopaedics Journal*, are consistent with multiple clinical case series previously published and a recently published multicenter prospective study.

The company reported that of the initial 21 consecutive patients, 17 provided clinical information and 15 patients underwent X-ray and CT imaging at 5 years. Clinical improvements observed at 12 months postoperatively were maintained or improved at the 5-year time point, including patient satisfaction (82% at both). Level of pain was assessed via the visual analog scale (VAS); pain improved from 8.3 at baseline to 3.4 at 12 months and further improved to 2.4 at 5 years. Functional improvement was assessed via survey, and evaluated the ability to perform light, moderate and vigorous activities as well as sleep disturbance, overall happiness and effect of pain on social life. The ability to perform light, moderate and vigorous activities showed continual improvement. Mean Oswestry Disability Index score was 21.5, indicating minimal to moderate disability.



There were no complications reported and no evidence of device migration. Qualitative review of X-ray and CT imaging, obtained at both 1 and 5 years following surgery, showed increased bone density immediately adjacent to all implants, which the company says is suggestive of biological fixation.



SI-Bone, Inc.

Dr. Gunnar Andersson, president of the International Society for the Advancement of Spine Surgery (ISASS) commented in the October 27, 2014 news release, "There are well over a dozen peer-reviewed publications now that demonstrate safety and effectiveness of the iFuse Implant

System. This most recent publication reporting 5-year results provides further clinical evidence that this minimally invasive surgical technique is safe and effective and provides lasting relief for patients who suffer from certain SI joint disorders."

SI-BONE recently submitted for publication six month results for all patients enrolled in their SIFI study. By the end of 2014 the company plans to submit their INSITE study for publication; INSITE is a prospective, multi center, randomized trial of iFuse vs non-operative care.

The graph below summarizes results for nine of the current publications that measured VAS pain scores and illustrates consistent rapid and sustained reduction in VAS pain scores among patients treated with iFuse. — *EH*

LEGAL

A First With Zimmer Cervical Plate Clearance

Zimmer Spine is on a roll.

After a 6% rise in sales for the third quarter, the company announced on November 10, 2014, the FDA 510(k) clearance of its Optio-C Anterior Cervical Plate for use with structural allograft/autograft as a stand-alone cervical system for cervical fusion procedures.

Structural Allograft/Autograft or PEEK

Steve Healy, the president of Zimmer Spine, said this is the industry's first no profile stand-alone device with structural allograft/autograft in one modular system. "In follow up to the PEEK option we launched earlier this year, we have expanded the Optio-C System to include multiple materials. Surgeons now have a choice to use structural allograft/autograft or PEEK in their stand-alone ACDF (anterior cervical discectomy and fusion) procedures."

Top: Optio-C Anterior Cervical Plate with PEEK, Bottom: Optio-C Anterior Cervical Plate with Structural Allograft/Zimmer Spine

The Optio-C system is comprised of one anterior cervical plate, three bone screws and either a PEEK IBFD or structural allograft/autograft. The device is secured by an anti-migration system that is designed to maintain no profile. The system is also designed to maximize fusion with a unique load-sharing interface and multiple implant footprints.

Benefits

Because it has no profile, the company says soft tissue irritation is reduced for less invasive ACDF procedures, and it eliminates the need for additional plating when addressing adjacent level disease. "With plate strength equivalent to a traditional cervical plate with no profile, stability through a three-screw fixation design, the Optio-C System takes cervical stand-alone devices to the next level," said the company statement.

12 New Products in 2014

The company says it has launched 12 new products since January including the Virage OCT Spinal Fixation System, a posterior system intended for the Occipital-Cervical-Thoracic spine (Occiput-T3), and the Optio-C Anterior Cervical System, a next generation modular stand-alone cervical device. Other new products include six new biologics lines, the TriCor Sacroiliac Joint Fusion System, the Ancora Lateral Interbody System, the UniLink and UniLink 5/1 Interspinous Fusion System, the Zimmer Facet Screw System and the Zimmer Anterior Buttress Plate System.

Healy said the new products are a combination of internal development and external licensing and distribution programs. "Over the next 12 to 24 months, we will continue to launch products we believe will advance spine surgery and provide surgeons with solutions for each patient's unique and ongoing needs."

Gaining Confidence

BMO Capital Market analyst Joanne Wuensch said the third quarter spine sales exceeded expectations with the second quarter launch of the company's Virage system, helping to penetrate customer accounts. "The Zimmer spine team has been working for several years to get a deformity and posterior fixation system to market, and management is gaining confidence in their execution."

With Medtronic, Inc. once again absent from the annual NASS (North American Spine Society) meeting, Zimmer Spine may get some extra looks from surgeons. — *WE*

FDA Clears First Patient-Specific Spinal Rod

The French-based Medicrea Group says it has received FDA 510(k) clearance for its UNiD spinal device, which according to the company, is the world's first patient-specific spinal osteosynthesis rod to treat degenerative spine conditions including scoliosis.

The technology was introduced at the 2014 North American Spine Society (NASS) Annual Meeting on November 12, 2014 in San Francisco, California. The first U.S. patient underwent surgery to have personalized UNiD rods implanted on November 10, 2014 in New York. The surgery was performed by Frank J. Schwab, M.D. The system has been implanted in over 100 patients in Europe.

UNiD Features

The system, according to the company, features a "user-friendly software tool to help surgeons pre-operatively plan their surgery and order customized, industrially-produced rods to fit the specific spinal alignment needed for each individual patient." The company says the device reduces the amount of time a patient spends in the operating room because there is no need to manually contour a rod during surgery. The surgeon is provided with a "precisely aligned" rod prior to surgery. Less time in the operating room impacts infections rates and quality of recovery.

Until now, surgeons have had to use a bending device, known as a French bender, supplied in all instrument kits to bend the rods manually. This manual rod-contouring process involves estimating the curve in a very empirical manner using pre-operative X-rays displayed on a wall in the operating room.

"Improved" Economic Outcomes

"UNiD rods provide surgeons a very precise surgical method, supporting

UNiD Patient Specific Rod/Medicrea Group

better patient care and improved economic outcomes," said Denys Sournac, founder, CEO and chairman of the company. He added that FDA clearance of UNiD is a major milestone for the company. "We started working closely with the FDA nearly two years ago on that strategic approval and this newly obtained clearance marks the culmination of years of research and surgery planning to bring a patient-specific spine implant to market as well as the beginning of a new exciting era in spine surgery."

UNiD Lab

In addition to the device itself, the system offers the UNiD Lab, which, according to the company, "provides a seamless process by which surgeons preoperatively analyze, design and order the patient-specific rod." The UNiD plug is proprietary to Medicrea and is embedded into the Surgimap software, and provides surgeons a quick and efficient option for ordering patient-specific rods. "After the planning process is complete, the order is transferred to the UNiD Lab, which processes the request and industrially produces and labels the rod specifically for the patient."

As soon as the surgeon validates the rod's design in the UNiD application, the company manufactures the rod and delivers it within five working days.

The company said its "groundbreaking" rods include the "most current clinical data and software development along with the latest in personalized production and industrialization to revolutionize how spine surgery is performed. UNiD rods provide surgeons a very precise surgical method, supporting better patient care and improved economic outcomes."

Large and Growing Market

The rods address a large market.

According to the National Scoliosis Foundation, an estimated six million people in the U.S. have scoliosis. The company said scoliosis patients make more than 600,000 visits to private physician offices each year, and an estimated 38,000 patients undergo spinal fusion surgery.

According to the press release: "Adult spinal deformity surgery is likely to increase in frequency with as much as 32% of the adult population suffering from scoliosis and a prevalence of 60% among the elderly. Hospital costs of adult spinal deformity surgery can exceed $100,000 per patient. Revisions and reoperations place a large financial burden on the health care system—increasing the average cost of adult spinal deformity surgery by more than 70%. The market for revision surgeries is growing at a significant rate because of the number of corrections performed with approximation errors and misalignment over the past 20 years." — *WE*

Biomet Settles Bone-Stim False Claims Charges for $6 Million

The federal bone growth stimulation investigations notched another settlement marker on October 29, 2014.

While not admitting any liability, Biomet Inc.'s EBI LLC agreed to pay $6.07 million to resolve allegations that EBI violated the False Claims Act (FCA) by paying kickbacks to induce use of its OsteoGen bone growth stimulators and billing federal healthcare programs for refurbished stimulators

Anti-Kickback Act

Between 2001 and 2008, the feds alleged that EBI paid staff at doctors' offices to influence doctors to order its bone growth stimulators. According to a U.S. Department of Justice announcement, these payments were allegedly provided pursuant to personal service agreements with staff members. The government concluded that these payments violated the Anti-Kickback Act and resulted in false billings to various federal healthcare programs, including Medicare. The settlement also resolves EBI's disclosure that it received federal reimbursements for bone growth stimulators that had been refurbished.

Whistleblower

The settlement resolves in part an allegation made by Yu Yue, a former EBI products manager, named in a lawsuit filed in federal court in New Jersey. The lawsuit was filed under the qui tam, or whistleblower, provisions of the FCA,

U.S. Department of Justice

which permit private individuals to sue on behalf of the government for false claims and to share in any recovery. Yue's share has not yet been determined, according to the government.

Medical Product Outsourcing (MPO) reported on November 10 that Biomet is still dealing with another FCA case initiated in 2005 that charges the company with defrauding Medicare by getting patients to buy its products rather than renting them. That case, which targets several other device makers, resulted in a $42 million judgment against Orthofix International NV two years ago.

August Flentje, acting deputy assistant attorney general for the Justice Department's Civil Division, said the Biomet settlement shows the department's commitment to protecting patients. "Medical device companies must not use improper financial incentives to influence the decision to use their products," he said in a statement.

Carmen Ortiz, U.S. Attorney of the District of Massachusetts, said, "This settlement demonstrates our resolve in ensuring that patients receive, and the government pays for, health care that is based on sound medical judgment, not compromised by kickbacks."

The Ft. Wayne *Journal Gazette* reported that a Biomet official didn't return a request for comment.

The Justice Department says it has recovered more than $23 billion in False Claims Act cases since January 2009, including almost $15 billion in settlements related to alleged fraud against federal health care programs. — *WE*

LARGE JOINTS

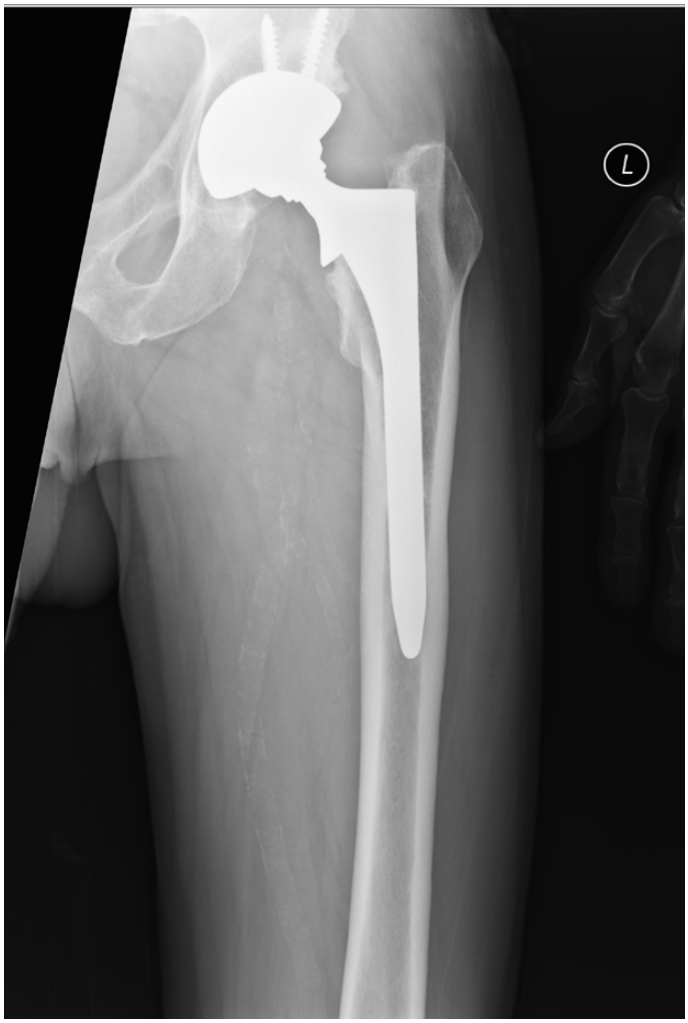
HSS: THR "Excellent for" Patients Under 35

How do young people with juvenile idiopathic arthritis (JIA) who undergo total hip replacement (THR) fare 15 to 20 years out? Researchers from Hospital for Special Surgery (HSS) are enlightening people on this little-researched topic. First of all, they say, THR is an "excellent option" for patients under age 35 when conservative treatments don't solve the problem. And, in 85% of patients, hip replacement lasted at least 10 years JIA patients. Taken out to 20 years, 50% of the patients needed revision surgery.

"The surgery in this patient population, although performed by only a small number of specialized orthopedic surgeons nationwide, is life-changing for JIA patients," said Mark P. Figgie, M.D., senior author of the study and chief of the Surgical Arthritis Service at HSS, in the November 16, 2014 news release. "Joint replacement can free patients from a life of unrelenting pain. It can enable those in a wheel chair to walk again. Patients can go back to school or work and get their lives back."

"This study followed one of the largest cohorts of patients with JIA to see how they fared 10 years and 20 years after total hip replacement," said Ishaan Swarup, M.D., an orthopedic surgery resident at HSS. "It is also one of the few studies to look at patient-reported measures, such as pain and the ability to perform activities of daily living."

Of the 56 patients involved, 41 patients had undergone bilateral hip replacement, while 15 individuals had only



Wikimedia Commons and Nevit Dilmen

one side replaced; there were a total of 97 hip replacement surgeries. The mean time for follow-up was 12 years.

As noted in the news release, "The researchers found that hip replacement in patients who were 25 or older lasted longer compared to THR in younger patients. There were no other significant differences in implant longevity based on gender or the use of custom versus standard implants. Male patients reported better outcomes with respect to activities of daily living, and patients who had received custom hip implants did worse in their reporting of pain and the ability to perform daily activities."

"We were not surprised that the patients who received custom implants had lower scores, since the very fact that they needed a custom implant meant they had more severe joint deformities and more severe disease," Dr. Figgie explained.

Although a good treatment, Dr. Figgie noted that the longevity of the implants needs to be improved, especially since the patients are so young. "The next step will be to evaluate which factors affect how long the implants last and work on improving implant design and durability," he said.

Asked how you approach this, Dr. Figgie told *OTW,* "In order to analyze the failures, we will review their X-rays and perform retrieval analysis on the implants that were revised here and are in our extensive retrieval collection. We will also perform multivariate statistical analysis to look for factors that lead to failure."

As for factors that might be involved, he stated, "Failures will most likely come from wear of the polyethylene components and loss of implant fixation." — *EH*

America's Joint Registry Issues First Report

Thanks to the release of the first round of data from the American Joint Replacement Registry the United States is beginning to catch up with the UK and Australia who have had such registries for many years. In its report, *Modern Healthcare* noted that the registry is the "first step toward compiling data that could assist providers with assessing how medical devices perform."

Hip and knee joint replacements are among the most performed surgeries in the U.S. The registry data on these replacements include information from only 120 hospitals or 383 hospital participants which represent approximately 4.5% of joint replacements that were done in 2013. The data reflects patients with both private insurance and Medicare coverage. For each surgery the registry records the implant type and its lot number. The *Modern Healthcare* report states that the registry has a goal of tracking 90% of the hip and knee surgeries performed in the U.S.

Data collected to date reveals that patients who had knee replacement surgeries had an average age of 66.7 while those who had hip surgeries were, on average, 67.6 years old. The *Modern Healthcare* writer indicated that the registry managers plan to collect more complex data in future years. — *BY*

Courtesy of the American Joint Replacement Registry

SPINE

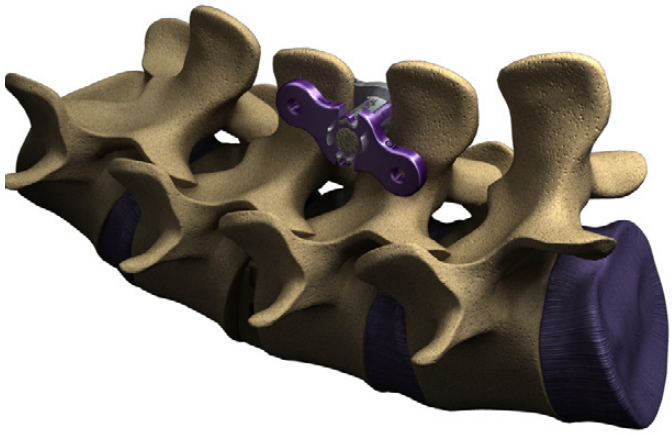
Aurora Spine Device Invades Israel

Doctors in Israel have performed their first surgical implant of Aurora Spine's Zip Ultra Minimally Invasive interspinous device. Professor Reuven Gepstein of the Herzliya Medical Center performed the surgery under local anesthesia.

"The Zip Ultra Mis fusion system is a very intuitive and easy to use system that allows me to perform a short and safe surgery while avoiding the risk of nerve impact," said Gepstein. "The surgery was quick with minimal pain and the patient's recovery time is expected to be extremely rapid."

"We are very excited that Aurora now offers our Zip Mis system portfolio in Israel," said Trent Northcutt, President and Chief Executive Officer of Aurora Spine. "We believe that the fusion system will change spine surgery with a true minimally invasive approach designed to achieve reproducible, superior patient outcomes."

Aurora Spine's interspinous fixation implant for spinal fusion consists of a one-step locking mechanism, articulating spikes and various sizes to accommodate variations in patient anatomy which, company officials say, eliminates the use of a set screw. —*BY*



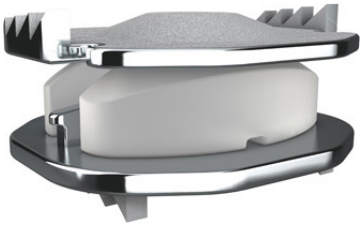
Courtesy of Aurora Spine

LDR Device Fares Well in *JAMA* Study on Cervical TDR

Move over, standard of care… Mobi-C is coming through. LDR Holding Corporation has announced a new study showing that its Mobi-C Cervical Disc is more cost-effective than two-level anterior cervical discectomy and fusion (ACDF). The study, which appears in *JAMA Surgery,* states that cervical total disc replacement is cost-effective for two-level cervical disc disease, and that over a four year period it imparts a greater quality of life at less cost. The Mobi-C Cervical Disc is the only cervical disc that is FDA-approved for one and two-level use.

Working with the University of California Davis Health System Neurosurgery Department, the study's lead author, Jared Ament, M.D., M.P.H., used clinical data from the two-level Mobi-C vs. ACDF randomized controlled trial in order to assign health states for the patient population. As indicated in the October 29, 2014 news release, the research team "generated Quality-Adjusted Life-Years (QALY) and Incremental Cost-Effectiveness Ratios (ICER) for both treatment groups. An intervention with a lower cost to QALY saved ratio (ICER) would be preferred over an intervention with a higher ratio. The ICER of CTDR [cervical total disc replacement] over ACDF is $24,594 per QALY, lower than the commonly used U.S. ICER threshold of $50,000 per QALY, suggesting that CTDR is a 'highly cost-effective option.'"

In the news release Christophe Lavigne, president and CEO of LDR, stated, "The statistical superiority of Mobi-C compared to ACDF for two-level indications has been demonstrated through the IDE [investigational device exemption] for the overall composite primary effectiveness endpoint at 24 months,



Mobi-C Cervical Disc/LDR Holding Corporation

and the PMA [pre-market approval] for two-level indications was approved by the FDA in 2013. In today's U.S. healthcare environment we knew it would be important to determine the cost-effectiveness of Mobi-C as compared to ACDF, the historical standard of care. We are excited to have this very important economic analysis of Mobi-C published, especially in such a prestigious journal as *JAMA Surgery.* The principal finding of this study, that Mobi-C appears to offer improved cost-effectiveness for two-level replacement (based on the 24 month outcomes), is an important factor for consideration by healthcare providers." — *EH*

PEOPLE

Hartman Takes Over ConMed

After 22 years of training at Stryker Corporation, including serving as CFO and interim CEO, Curt Hartman is running his own ship.

After a tumultuous 2014, ConMed Corporation announced on November 10, 2014 that Hartman has been chosen to be the next president and CEO of the company. Hartman joined the company's board in March 2014 after a shareholder fight and was appointed interim CEO in July 2014.

Hartman at Stryker

Hartman joined Stryker in 1990 as a manufacturing engineer. In 1999 he became general manager of Stryker Instruments. Ten years later the engineer became Stryker's chief financial officer before being named interim CEO when then-CEO Stephen McMillan abruptly left Stryker. The ConMed announcement said that Hartman's hands were on a number of initiatives at Stryker which included the successful completion of multiple acquisitions, debt offerings, share buybacks and "an enhanced dividend policy while innovating the business model to address the changing healthcare landscape."

Mark Tryniski, ConMed's chairman said the board's decision was based not only on Hartman's previous industry experience and demonstrated results, "but also on the leadership qualities he has displayed while in the role of Interim Chief Executive Officer at ConMed. Curt has a thorough understanding of our business and operations, and a deep appreciation for the hard work and talent of our employees. We...believe that he will lead the company effectively into its next chapter of growth, profitability and improved performance."

Focus on Operation Performance

"Through a renewed focus on operating performance and innovation, we will drive revenue and earnings growth, and build ConMed into the first choice for our customers' needs," added Hartman.

ConMed Renewed

For ConMed 2014 has been a makeover year as dissident shareholders led by San Francisco-based Voce Capital sought to wrestle control of the company away from the founding family, the Corasantis. Coppersmith Capital joined the fray and became the company's largest shareholder. Coppersmith reached an agreement with Eugene Corasanti, founder of ConMed and its long-time CEO, agreed to resign as Chairman of the Board and also agreed to not stand for re-election as a director in 2015.

ConMed

"ConMed is a medical technology company with an emphasis on surgical devices and equipment for minimally invasive procedures. The Company's products are used by surgeons and physicians in a variety of specialties including orthopedics, general surgery, gynecology, neurosurgery and gastroenterology. Headquartered in Utica, New York, the Company's 3,600 employees distribute its products worldwide from several manufacturing locations." The company "has a direct selling presence in 16 countries outside the U.S. and international sales constitute more than 50% of the company's total sales." — *WE*

Curt Hartman/Stryker Corporation

Orthopedic World's Sudden Loss: Max Link, Ph.D.

Max E. Link, Ph.D., a veteran of the device industry, has passed away unexpectedly at the age of 74. Dr. Link was chairman of the board of directors of Alexion Pharmaceuticals, Inc. He was also serving as a director and the chairman of the board of directors at Celsion Corporation, as well as chairman of the board of directors at CytRx Corporation.

Leonard Bell, M.D., chairman and chief executive officer of Alexion, said of his old friend, "Max's career was especially unique because he drove innovation on behalf of patients across so many areas of healthcare, including medical devices, pharmaceuticals—and Alexion's field, biotechnology. We were very fortunate to have had Max as a key member of our Board of Directors since our inception in 1992, and as Chairman since 2002. In our earlier years, Max provided invaluable guidance during the many challenges we faced as a biotech startup. As Chairman, he was a key guide in our transition from a development-stage company to our current multinational commercial platform, where we serve patients with life-threatening disorders across nearly 50 countries."

"Max was committed to, and excited by, innovation. Likewise, he was a strong believer in the power of entrepreneurship and saw this as a vital engine for

Max E. Link, Ph.D., courtesy of CytRx Corporation

meeting patients' needs. Beyond the wisdom and broad, global experience he brought to his role as a business leader, Max had the gifts of being a true friend, mentor, confidant and guide. Most importantly, he helped to drive the development of a wide array of innovative therapies—our own and those of other companies—that are in use every day, and benefitting patients around the world."

Dr. Link served as Amedica Corporation's chairman of the board of directors from October 2003 until his retirement in August 2014.

Sonny Bal, M.D. chairman and CEO of Amedica, said of Dr. Link, "He was a very private, quiet, and decent man…a gentleman. I really liked Max, and I had a lot of respect for him. He had a thoughtful, nuanced approach to problems, as well as a calm and reflective demeanor. He was always a class act."

Michael Houston, director of investor relations at Amedica, noted, "Dr. Link believed in Amedica from the beginning, and his board leadership allowed us to achieve the credibility and success necessary to execute on our mission to improve patient outcomes by providing innovative medical devices which utilize our proprietary silicon nitride technology. He commanded respect from the healthcare community and was very instrumental in helping us mature our strategic relationships from the beginning."

Gregg Honigblum, managing director at Westlake Securities noted, "Max was one of the most intelligent and respected icons in the healthcare field. He treated people with the greatest respect and never had a bad word to say about anyone. His integrity was his greatest attribute and he will be truly missed."

Dr. Link held a number of top leadership positions with Sandoz Pharmaceuticals (now Novartis), including serving as chairman of the board of Sandoz Pharma, Ltd., CEO of Sandoz Pharma, and a member of the Executive Board of Sandoz, Ltd., Basel. In addition, he served as CEO of Corange, Ltd., the parent company of Boehringer Mannheim Therapeutics, Boehringer Mannheim Diagnostics and DePuy Orthopedics. More recently, Dr. Link had served as chairman and CEO of Centerpulse AG, a medical implant company later acquired by Zimmer Holdings, Inc. He was actively involved as a director in numerous development-stage companies within the biopharmaceutical and medical device fields. Dr. Link earned a Ph.D. in economics from University of St. Gallen (Switzerland). — *EH*

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