VOLUME 9, ISSUE 33 | OCTOBER 22, 2013

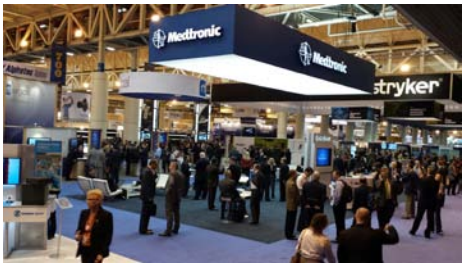
Orthopedics This Week

WEEK IN REVIEW

4 The Ten Best New Spine Technologies for 2013 >> Here they are—the best of the best. The best new technologies for spine care for 2013. Our demanding and exceedingly picky judges sorted through 40 outstanding submissions to pick 10 winners. There were a couple of surprises this year, including the number one vote getter—a new pharma compound!

13 Flippin' Cakes and Poachin' Reps in the Big Easy >> Stryker Corporation says Biomet and a former Stryker sales rep concocted a recipe to flip business and poach sales reps from Stryker to Biomet in New Orleans. The rep, Christopher Ridgeway, accuses Stryker of fabricating a bogus non-compete agreement. It's a rolling boil of a stew in the Big Easy. This week we bring you Stryker's version.

17 Medtronic Shrugged >> For the first time in the history of either NASS or Medtronic, there was no Medtronic Spine booth at the NASS Annual Meeting. No Booth. No product. No sales people. Medtronic sent a powerful message. Corporate support is no longer a 'given' at NASS.



20 The Miracle of Surgery (and Other Stories From the Uganda Spine Surgery Mission – Part III) >> As the team's stay in Mbarara was coming to a close, the cases seemed to grow progressively more difficult. Then something wonderful happened. The team and its leader, Dr. Isador (Izzy) Lieberman pulled off something which can only be described as a miracle—albeit one that came from training, experience and skill—but one that was still no less astonishing.

BREAKING NEWS

24 Walmart and Lowe's Offer **FREE Hip and Knee Surgery**

Auxilium: Positive Results for **XIAFLEX**

Blue Belt's First Sale to Ambulatory Surgical Center

DePuySynthes 3Q: Strong Hips and Knees, Spine Dis-Synergies

Globus Receives Warning Over MicroFuse Putty

Stryker's 3Q "Impressive" Results Point to Ortho Growth

For all news that is ortho, read on

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: God bless the Baby Boomers and their 350 million creaky hips, knees and shoulders. From Stryker to Biomet, ortho recon sales pushed the upper end of analyst estimates for the 3rd quarter. Where's the demand coming from? Here's a clue...these folks are all over 70 years old: Paul Simon, Brian Wilson, Al Jardine, Mike Love, Aretha Franklin, Peter Yarrow and Mick Jagger. They all want to keep moving.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Zimmer	29.28%	6.20%	ZMH derives 75% of its revenues from large joint recon. The recent tick up in demand bodes well for Big Blue.
2	3	Conmed	10.57	9.69	Buyers pushing CNMD up ahead of this week's 3rd quarter report. Market signaling better-than-expected results.
3	2	Exactech	10.05	8.48	Rising recon demand likely to have a disproportionate positive effect on smaller suppliers like EXAC.
4	4	Medtronic	28.78	4.64	Lost in all the hub-bub of NASS was MDT's decision to add amniotic tissues to the product line. A MAJOR new biologic coming to spine.
5	10	Integra LifeSciences	11.70	10.66	Like CNMD and EXAC, buyers jumping in ahead of Q3 reports. Consensus says IART will report down earnings and just 2% sales growth. We'll see.
6	5	Smith & Nephew	20.78	1.46	For the 3rd quarter most analysts expect SNN to report that sales rose 8.1%—which would be exceptional.
7	6	Stryker	18.71	2.34	Sales growth of 6.1% for Q3, up smartly from the 2nd quarter's 4.4%. An 8% pop in U.S. recon sales was the engine that fueled SYK's growth.
8	7	Globus Medical	28.53	0.17	Most analysts think GMED will report something like 12% sales growth for Q3 but only increase EPS by a penny. Really?
9	8	NuVasive	6.30	3.20	Despite a tough year, NUVA has rewarded shareholders exceptionally well in 2013. Innovation is key to keeping momentum going in 2014.
10	9	Johnson & Johnson	26.68	1.91	With SYK's strong report, questions are rising about DePuy/Synthes. Can this behemoth grow at industry average rates?

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MAKO Surgical	MAKO	$29.76	$1,531	76.41%
2	MiMedx Group	MDXG	$5.16	$497	29.65%
3	TiGenix	TIG.BR	$0.37	$47	20.33%
4	CryoLife	CRY	$7.98	$220	19.64%
5	Integra LifeSciences	IART	$44.00	$1,236	10.66%
6	Conmed	CNMD	$37.03	$1,018	9.69%
7	ArthroCare	ARTC	$37.66	$1,064	8.62%
8	Exactech	EXAC	$21.37	$288	8.48%
9	Tornier N.V.	TRNX	$21.19	$1,013	6.54%
10	Zimmer Holdings	ZMH	$88.95	$15,081	6.20%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc.	BAXS	$1.36	$61	-12.26%
2	Orthofix	OFIX	$20.48	$398	-10.41%
3	RTI Biologics Inc	RTIX	$3.58	$201	-3.24%
4	Alphatec Holdings	ATEC	$1.95	$189	-2.99%
5	Symmetry Medical	SMA	$8.15	$304	-2.51%
6	Globus Medical	GMED	$17.39	$1,615	0.17%
7	Smith & Nephew	SNN	$63.98	$11,469	1.46%
8	Johnson & Johnson	JNJ	$91.63	$258,220	1.91%
9	Stryker	SYK	$73.46	$27,778	2.34%
10	NuVasive	NUVA	$25.44	$1,134	3.20%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$20.48	$398	8.23
2	Medtronic	MDT	$56.59	$56,447	15.38
3	Globus Medical	GMED	$17.39	$1,615	15.42
4	Smith & Nephew	SNN	$63.98	$11,469	15.73
5	Zimmer Holdings	ZMH	$88.95	$15,081	16.18

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$25.44	$1,134	90.86
2	Symmetry Medical	SMA	$8.15	$304	32.60
3	RTI Biologics Inc.	RTIX	$3.58	$201	26.68
4	ArthroCare	ARTC	$37.66	$1,064	25.53
5	CryoLife	CRY	$7.98	$220	22.80

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$17.39	$1,615	1.03
2	Orthofix	OFIX	$20.48	$398	1.18
3	Exactech	EXAC	$21.37	$288	1.37
4	Conmed	CNMD	$37.03	$1,018	1.45
5	Zimmer Holdings	ZMH	$88.95	$15,081	1.76

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$25.44	$1,134	9.56
2	CryoLife	CRY	$7.98	$220	5.70
3	Symmetry Medical	SMA	$8.15	$304	2.72
4	Johnson & Johnson	JNJ	$91.63	$258,220	2.71
5	Medtronic	MDT	$56.59	$56,447	2.38

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$8.15	$304	0.74
2	Orthofix	OFIX	$20.48	$398	0.86
3	Bacterin Intl Holdings	BONE	$0.61	$31	0.92
4	Alphatec Holdings	ATEC	$1.95	$189	0.96
5	RTI Biologics Inc.	RTIX	$3.58	$201	1.13

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	$5.16	$497	18.38
2	MAKO Surgical	MAKO	$29.76	$1,531	14.91
3	TiGenix	TIG.BR	$0.37	$47	11.43
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5	Globus Medical	GMED	$17.39	$1,615	4.18

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

The Ten Best New Spine Technologies for 2013

BY ROBIN YOUNG

The winners of the 2013 *Orthopedics This Week* Best New Technology award for spine are Benvenue Medical, Inc., Globus Medical, Inc., Johns Hopkins University/Siemens Healthcare, AFcell Medical, Inc., Orthozon Technologies, LLC, OsteoMed, Paciera Pharmaceuticals, Inc., PhDx Systems, Inc. and Trakya University in Turkey.

This annual award rewards inventors, engineering teams, surgeons and their companies who've created the most innovative, enduring and practical products in 2013 to treat back pain. To win the *Orthopedics This Week* Best New Technology 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 scores 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 2013 *Orthopedics This Week* Spine Technology Awards.

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*)

Our intrepid and detailed panel of surgeon judges was:

- **Dr. Thomas Zdeblick:** Dr. Zdeblick is the chair of the Department of Orthopedics and Rehabilitation and a member of the faculty at the University of Wisconsin School of Medicine and Public Health.

Aesculap, Inc.	Aspen Medical Products, Inc.	Aurora Spine Corporation	AFcell Medical, Inc.
Benvenue Medical, Inc.	Biomet, Inc.	Expanding Orthopedics, Inc.	Globus Medical, Inc.
J2 Medical, LP	Johns Hopkins University/Siemens Healthcare	K2M, Inc.	Lanx, Inc.
Medacta Internatinal SA	Medtronics, Inc.	NLT Spine	Orthofix Biologics/MTF
Orthozon Technologies	Osseon Therapeutics, Inc.	Osseus Fusion Systems	OsteoMed Spine
Pacira Pharmaceuticals, Inc.	PhDx Systems, Inc.	Prism Surgical Designs Pty, Ltd	Thompson MIS
Trakya University, Edirne-Turkey	Vertebral Technologies, Inc.		

- **Dr. Daniel Riew:** 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.
- **Dr. Sigurd Berven:** Dr. Berven is Associate Professor in Residence at the University of California, San Francisco. Dr. Berven is a prolific researcher and clinician with particular interests in pediatric and adult deformity, degenerative conditions of the spine, spinal tumors and spinal trauma. He is also at the forefront of investigating biological regeneration technologies.
- **Dr. Alex Vaccaro:** Dr. Vaccaro is a Professor and Attending Surgeon of Orthopaedics and Neurosurgery at Thomas Jefferson University Hospital and a partner at the Rothman Institute in Philadelphia, Pennsylvania. He is the Vice Chairman of the Department of Orthopaedics.
- **Dr. Stephen Hochschuler:** Dr. Hochschuler is one of America's leading spine experts and co-founder of the Texas Back Institute and Chairman of the Board of TBI Holdings, Inc. Dr. Hochschuler has published numerous research papers in international spine journals and is past-president and board member of the Spine Arthroplasty Society.

So, without further delay, here are the ten best new spine technologies for 2013 arranged in alphabetical order by category:

Continued on page 6 >>

Category: Biomaterials, Biologics and Pharma

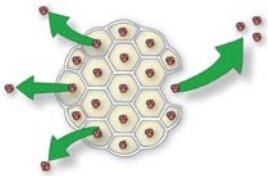
Two Winning Technologies

EXPAREL

Company: Pacira Pharmaceuticals, Inc.

Kimberly Wilkinson

Description: EXPAREL is a new, single administration drug (a liposomal formulation of bupivacaine) which reduces post-operative pain and opioid requirements up to 72 hours. EXPAREL's formulation is flexible which means it can be used across either minimally invasive small incisions or larger open incisions.



Traditional bupivacaine HCl only provides up to 8 hours of non-opioid analgesia while EXAREL, which encapsulates the bupivacaine in DepoFoam, lasts up to 72 hours.

DepoFoam is a matrix of microscopic aqueous chambers that encapsulate the bupivacaine without altering its molecular structure and then releases it over time.

Opioids are highly effective analgesics but they come with a range of potential adverse events. Studies show that the worse postsurgical pain occurs 24-48 hours post-op. Since EXPAREL lasts up to 72 hours, patients can begin their recovery process with less pain and reliance on opioid rescue medication. Also, there's no need for catheters, pumps, or other external delivery devices when using EXPAREL.

EXPAREL has been used in many spine procedures including lumbar, cervical and interbody fusions; microdiscectomies; and laminectomies. Patients receiving EXPAREL have demonstrated decreased pain scores, opioid use, and PACU time, as well as faster discharge readiness. Some early adopters have converted their standard of care for postsurgical pain from PCA (IV opioid administration) for their opioid-naïve postsurgical patients.

AmnioClear Amniotic Tissue Allograft

Inventors / Engineers: Alex Canonaco and Howard Wolek
Company: AFcell Medical, Inc. and MTF


Alex Canonaco and David Buche

Description: AmnioClear is a graft collagen sheet of human placental tissues which may be placed over the surgical site to cover and protect it during healing. The patent-pending tissue graft technologies provide surgeons with a unique placental collagen three-dimensional matrix that is a superior covering for the surgery site.

Because of the unique form of placental collagen matrices and the particularly high levels of endogenous proteins and beta defensin peptides, the grafts are able to transfer many of the same protective capabilities of the placenta to the surgical site.

Recent advances in understanding the biologic mechanisms of action underlying tissue growth and differentiation (i.e., stem cells and other progenitor biologics), scientists have been able to unravel the mechanisms of action surrounding fetal development and the critical role that placental material plays in ensuring that the fetus is protected from external threats such as infection or maternal rejection.

In human studies, the method used to process and deliver AmnioClear has resulted in a more effective and natural covering than bovine, porcine or polymer based synthetic coverings. In a canine laminectomy model, animals treated with amnion tissue coverings had reduced post-operative fibrotic scarring.

Important Note: I'm the founder of AFcell, which created an obvious conflict of interest. That relationship had no bearing, I think, on scoring. The judges are independent surgeons with zero financial or other interest in RRY publications. And each judge is very independent and objective. All are volunteers—there is no compensation. Finally, I don't ever learn the scores until all judges have voted and the results are compiled by a third party.

Category: Cervical Care

CANOPY Posterior Decompression System

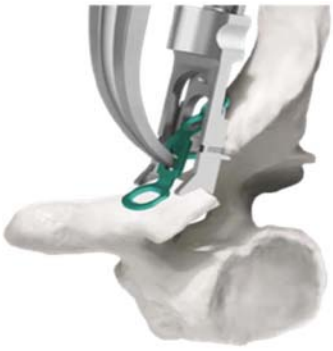
Inventors / Engineers: John Suh

Company: Globus Medical, Inc.

Description: The CANOPY Laminoplasty Fixation & Posterior Decompression System uses spinal fixation plates and screws in laminoplasty procedures. CANOPY implants, which come in various sizes and geometric options, are inserted through a posterior cervical or thoracic approach. Surgeons can use CANOPY's fixation plates with bone graft material. They may also use the hinge plates to stabilize weakened or displaced lamina. The system's screws, which are used to attach the plates to bone, are available in a variety of lengths and diameters. CANOPY also offers graft chambers in radiolucent polymer.

CANOPY is intended for use by the surgeon in the lower cervical and upper thoracic spine (C3 – T3) for laminoplasty procedures. It can hold bone allograft material in place in order to prevent the allograft from expulsion or impinging the spinal cord. CANOPY is a comprehensive posterior decompression system and provides the surgeon with a variety of plate options including a polyaxial screw hole plate design which enables the connection of a screw and rod system. This helps to preserve the posterior elements, protecting the canal and leaving the interspinous ligaments intact, for stability and to help promote fusion through traditional fixation.

(Left to right) Scott Stanton, Kelly Quick, Jason Cianfrani, Sean Cranston



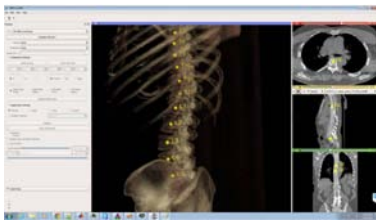
Category: Diagnostics and Imaging

Automatic Labeling of Vertebrae in Intraoperative Images Using LevelCheck: A Tool against Wrong-Level Spine Surgery

Inventors / Engineers: Y. Otake, J.H. Siewerdsen, A. J. Khanna and Z. Gokaslan (Johns Hopkins University, Baltimore, Maryland); G. Kleinszig and S. Vogt (Siemens Healthcare, Erlangen, Germany)

A.J. Khanna, M.D. (center), Gerhard Kleinszig. Dipl. Ing. (left)

Company: Johns Hopkins University/Siemens Healthcare



Description: "LevelCheck" reduces the risk of wrong-level surgery, improves clinical workflow, and reduces the time and cost for the preoperative process by offering an independent check using intraoperative fluoroscopy.

"LevelCheck" is based on a robust geometric alignment of preoperative 3D images and intraoperative 2D images and is possible because of recent advances in high-speed computing. With LevelCheck, the surgeon can accurately localize any structure defined in the preoperative 3D image using intraoperative fluoroscopy. LevelCheck operates without any additional tracking or navigation equipment and can compute registration in as little as 1 second.

Wrong-level surgery (subject to variation and possible underreporting) occurs, according to some analysts, once in every 3,110 spine surgeries, implying that approximately 50% of spine surgeons will encounter a wrong-level error at least once in their career, with an approximate monetary cost of $55,000 per case according to The Joint Commission.

The challenge in spine level localization arises from the difficulty of correctly identifying target vertebrae in the radiographic/fluoroscopic scene and/or via direct visualization. Despite preventative measures in the current standard of care, the incidence of wrong-level surgery persists as the second-most common category of wrong-site surgery. LevelCheck corrects that while also reducing time and cost.

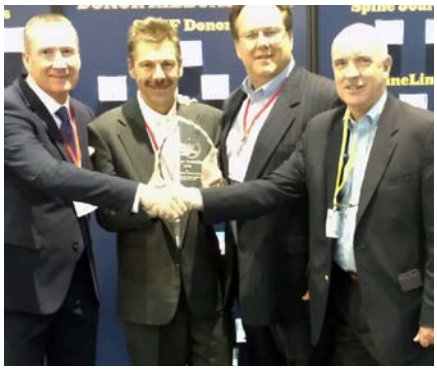
Category: Minimally Invasive Spine Care

Five Winning Technologies

Kiva VCF Treatment System

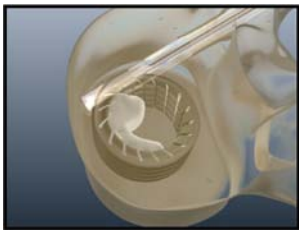
Inventors / Engineers: Laurent Schaller, Steve Golden, Ryan Connelly, Jeff Emery, Tim McGrath, James Lee

Company: Benvenue Medical, Inc.



(Left to right) Robert Weigle, Laurent Schaller, Eric Gilbert

Description: The Kiva VCF Treatment System is a new treatment of painful vertebral compression fractures (VCFs). The Kiva VCF system features a proprietary flexible implant made from PEEK-OPTIMA. Kiva functions as a mechanical support structure and a reservoir to direct and contain the flow of bone cement. It is delivered percutaneously in a continuous loop into the vertebral body through a small diameter, single incision. The amount of the Kiva implant delivered can be physician-customized during the procedure to adjust to various fracture types. Delivered over a removable guidewire, the implant stabilizes and supports the vertebral body and directionally controls and contains bone cement.



The Kiva VCF system is investigational in the United States and in an approved IDE (investigational device exemption) study—the KAST clinical trial, sponsored by Benvenue Medical.

The Kiva VCF Treatment System is designed to:

- Preserve cancellous bone structures
- Reduce bone cement usage
- Support and stabilize the nucleus
- Direct cement flow and act as a barrier against extravasation
- Maintain intra-operative height

A European randomized trial of Kiva and balloon vertebral augmentation was recently published in the February edition

of *Spine* (2013; 38:292-299). This Level I data demonstrated Kiva's superiority over balloons in many key areas:

- Significant restoration of the Gardner angle in patients treated with Kiva (p=0.002) whereas balloon kyphoplasty did not meet significance (p=0.067)
- Lower cement extravasation rates (3% for Kiva and 9.8% for balloon kyphoplasty, p<0.05)
- Lower cement volume (1.8 mL for Kiva and 2.8 mL for balloon kyphoplasty, p <0.001)

Lumiere Retractor System

Inventors / Engineers: Joseph Aferzon, M.D. and Jeffrey Bash, M.D.

Company: Orthozon Technologies, LLC

Description: Lumiere is a state-of-the-art minimally invasive surgical retractor that provides superior access and visibility for physicians. Lumiere uses a powerful built-in fiber optic lighting, translucent retractor blades and full medial access to give surgeons an expandable field of view and greater comfort and flexibility when performing micro endoscopic surgery. Patients who have undergone surgery with the Lumiere minimally invasive technique as opposed to open discectomy have shown a drastic reduction in pain, blood loss, surgical duration, and faster recovery time.

Joshua Aferzon and Madubuike Okafor

The Lumiere Retractor is recommended for minimally invasive discectomies, laminectomies, foraminotomies, transforaminal interbody fusion surgeries and similar techniques. It provides surgeons with maximal access and visibility in tough-to-reach areas. Current tubular retractor technologies suffer from limited visibility and access due to their complex, bulky, and outdated designs. For MIS surgeons looking to access deep anatomy with an easy-to-use tool, the Orthozon Technologies retractor includes rotatable blades to facilitate medial exposure and powerful fiber optic lighting to illuminate the surgical pathway.

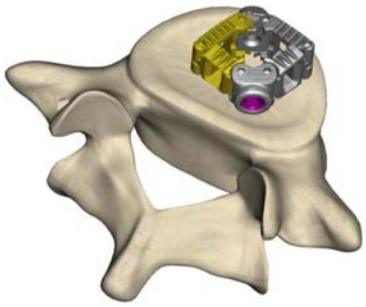
LATIS MIS Expandable Lumbar Interbody Spacer

Inventors /Engineers: Jonathan Perloff, Brian Garvey, Jason Pastor, Robert Wriggins, Christopher Saville

Company: Globus Medical, Inc.

Scott Stanton, Sean Cranston, Jonathan Perloff, Conor Fleming and Mark Fromhold

Description: The LATIS Spacers are lumbar interbody fusion devices which provide structural stability in skeletally mature patients following discectomy. What sets the LATIS Spacers apart is their linked segments which allow the spacer to take a new configuration once implanted and are available in a variety of sizes to accommodate patient anatomy. For example, the Spacers allow lateral expansion that changes the footprint of the device from a narrow rectangle to a diamond. The design also allows insertion through a posterior, transforaminal, or lateral approach with a final footprint equivalent to spacers inserted through an anterior approach.



LATIS comes in three starting footprints: 10x32mm, 10x37mm, and 10x42mm. Each narrow rectangular spacer can be opened in vivo to the desired shape, reaching a square configuration of 23x23mm, 26x26mm, and 29x29mm, respectively, at maximum expansion.

LATIS can be implanted alone or in pairs depending on the surgical need, approach, and anatomical requirements.

LATIS implant consists of 6 links (green) joined by 6 pivot pins (gray) and a locking set screw (purple) contained within link 6.

The interior of the spacers are open and may be packed with autogenous bone graft material following expansion to promote fusion. Graft material is injected through the hole in the posterior wall of link 6 using a funnel tube which is passed by the surgeon through the holder. Once graft is injected, the holder is removed from the implant. LATIS Spacers are offered with or without a lordotic option and in various sizes to accommodate patient anatomy.

PrimaLIF Lateral Lumbar Interbody Fusion (LLIF) System

Inventors / Engineers: Corbett Stone, Ephraim Akyuz, Stuart Goble, Bryan Howard, Daniel J. Triplett, Charlie Forton, Nathan Erickson, Andrew Fauth, Jason Glad

Company: Osteomed

Charlie Forton, Doug Schmierer and Scott Nelson

Description: PrimaLIF LLIF is an innovative and unique lateral access lumbar interbody fusion system which features a radial blade retractor expansion design, independent blade length adjustment, and both direct and fluoroscopic visibility. The PEEK implant has an anatomically matched shape to maximize endplate contact as well as a self-distracting tip for easy insertion and tantalum radiographic markers for optimal placement confirmation.

PrimaLIF is a complete system and includes a full set of disc prep instruments, retractor and table mount, insertion and trialing instruments as well as all implant sizes and footprints.

One of the problems with current methods of lateral access is that it requires dilation of the access space prior to the insertion of the retractor. As a result, the tips of the dilation tubes and retractor blades are exposed to soft tissue structures and exiting nerve roots. These gaps between the distal ends of

the dilation tubes and retractor blades as they twist and tear through the psoas muscle subsequently expose the patient to soft tissue and potential nerve damage, further elevating the need for continuous intra-operative monitoring during the entire sequence.

By contrast, the PrimaLIF retractor radially dilates from the inside out by nesting the retractor blades to the size of an initial probe, then expands them simultaneously using dilators. This unique method of lateral access allows the retractor blades to be placed before dilation occurs, not after.

By dilating from within the retractor, the outwardly expanding blades provide a protected channel through the psoas, allowing for sequential dilation in an environment designed to protect the soft tissue and nervous plexus. While other retractors will have gaps between retractor blades in their final position, a final access ring placed between the blades in the PrimaLIF retractor holds them in position. This ring provides an enclosed circular surgical site without any gaps, greatly reducing tissue creep. With improved access and a reduced risk of nerve injury, users can easily deploy the PrimaLIF retractor and focus on their discectomy and interbody insertion.

TrackMyBack app

Inventors / Engineers: Geoff Mather and Ian Cowgill

Company: PhDx Systems, Inc.

Geoff Mather and Ian Cowgill

Description: The new TrackMyBack app is a patient and physician tool to better engage and evaluate spine patients' health status pre- and post-treatment. The app utilizes the convenience of a smartphone to obtain continuous spine patient outcomes data with increased accuracy.

By using an expansive spine patient outcomes database of over 15,000 patients and procedures, the app utilizes data modeling algorithms to

set patient and physician expectations for how the patient's health may improve over time.

In the future, management plans to add motion sensors and geolocation to further understand spine patients' functional status over time. The app provides patient education and sets expectations for how ones pain and function may improve over time. The clinician will benefit by:

1. Seeing early follow-up data collected outside of the standard clinical follow-up intervals
2. Evaluate how a patient progresses in relation to a large population of patients with similar demographics, diagnosis, and procedure.

Currently, patient reported outcomes (PRO) data for spine procedures is collected at standard clinical visits (ex, 6 weeks, 3 months, 6 months, 1 year, 2 year, etc.). Important PRO data elements such as Visual Analog Scale Pain (VAS), SF-36, Oswestry Disability Index (ODI), and Euro-QOL (EQ-5D) are often used to evaluate new products and procedures for regulatory approval and policy decisions.

With this app, data may be collected at earlier and more frequent time periods. By using a smartphone app such as TrackMyBack, the resulting rich data stream eliminates the potential for data variability while also increasing user compliance.

Category: Thoracolumbar Care

Interlocked Double Sacrum Screw System

Cumhur Kilinçer, M.D., Ph.D.

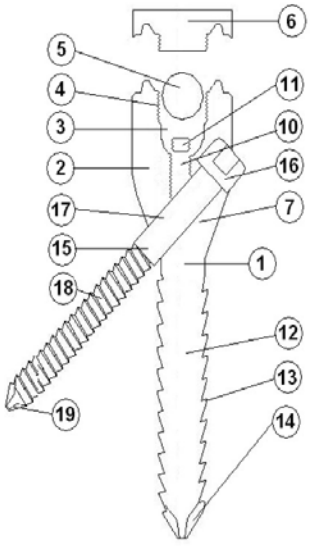
Inventors / Engineers: Cumhur Kilinçer, M.D., Ph.D., TRAKYA UNIVERSITY, Edirne-TURKEY and Tasarimmed Tibbi Mamuller San. Tic. Ltd. Sti.

Description: The Interlocked Double Sacrum Screw System is a sacral anchor and consists of one primary (thicker) screw aimed to purchase the sacral body, and a secondary (thinner) screw which passes inside the neck of the primary screw and purchases the sacral ala (sacral wing). The two screws are locked inside with a nut. The design is elegant, very simple, and intuitive.

Pedicle screw is the most frequently used spinal implant. Sacrum has notoriously high rate of screw loosening (pull-out), especially in long-segment instrumentations. This design aims to overcome the infamous problem of sacral screw loosening by purchasing the sacral body and the ala simultaneously. There were historical attempts to obtain combined purchase of both sacral body and ala regions. Those designs failed due to their bulky designs and difficulty of applications. The Interlocked Double Sacrum Screw System enables the surgeon to increase the pullout resistance of sacral screws in a simple and efficient way.

Loosening of sacral screws is a frequent problem with serious consequences. To prevent this problem, surgeons frequently prefer to support the sacral screws with interbody fusion procedures, which may require an additional surgery such as anterior lumbar interbody fusion (Alif) or Axialif. Although the Interlocked Double Sacrum Screw System may still be used in combination with these solutions, it may obviate the need for an additional surgery in selected cases, and decrease the rate of screw loosening greatly comparing to regular screws. The implant has major advantages comparing to regular pedicle screws:

1. Triangulated two screws has much more holding power comparing to one screw
2. The system can be used as a part of ordinary pedicle screw system.



In closing, thank you to all of the companies that submitted their technologies for the 5th annual Best Spine Technologies award. Every year the judges surprise us with their insights and preferences. Clearly this year, MIS was the strongest category. Who knows, a new category will emerge. Until then, keep innovating. ♦

Flippin' Cakes and Poachin' Reps in the Big Easy

BY WALTER EISNER

Illustrated by Louis Raemaekers/gutenberg.org

On September 10, 2013, Stryker Corporation fired Christopher Ridgeway, the company's district sales manager in New Orleans. The reason given by the company? Malfeasance.

The company says Ridgeway used secret code words to engineer an elaborate scheme devised by rival Biomet, Inc. to move his Stryker customers to Biomet. The "flipped" customers were referred to as "pancakes."

Stryker Sues

Ten days after firing Ridgeway, Stryker filed a lawsuit in federal court against Biomet, Ridgeway and Richard Steitzer, a former Stryker sales rep in New York, for Breach of Contract and Fiduciary Duty, Misappropriation of Trade Secrets and Tortious Interference.

The Stryker Complaint states the company uncovered an "ill-conceived and long-planned scheme by Biomet, using Stryker representatives in both New York (Steitzer) and Louisiana (Ridgeway), to erode Stryker's customer relationships and raid sales teams from Stryker's Neuro Spine ENT ("NSE") business unit and Craniomaxillofacial ("CMF") division.

During the course of his September 10, 2013 exit interview, Stryker claims Ridgeway "brazenly announced that he devoted only 50% of his time to what he referred to as the 'Stryker dog and pony show' and instead parlayed his Stryker contacts to divert opportunities, and potential Stryker employees, to his personal side businesses."

Allegations

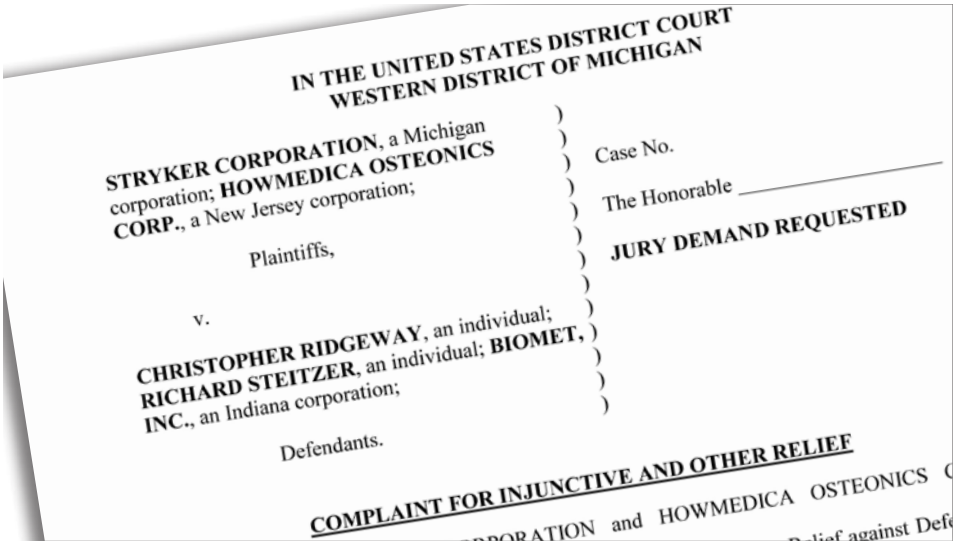
As Stryker employees and since leaving their employment, Stryker's suit alleges that Ridgeway and Steitzer conspired with Biomet to:

1. Convert existing Stryker employees to work for Biomet
2. Prevent Stryker from successfully hiring and retaining new employees in order to secure Biomet's foothold in certain territories
3. Sabotage Stryker's existing customer relationships to convert business to Biomet
4. Secretly channel Stryker's confidential information to Biomet, including its customers' preferences, margins, sales quotas and targets, and financial performance in the territories.

"These continuing malicious and opportunistic actions have resulted in the loss of significant business with expected losses exceeding $3 million," claims the lawsuit.

The Plot

In June 2013, Ridgeway allegedly informed his sales representatives that Biomet expressed interest in bringing the Stryker CMF and NSE sales teams to Biomet and that Biomet would "offer us a lot of money."


IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN

STRYKER CORPORATION, a Michigan corporation; HOWMEDICA OSTEONICS CORP., a New Jersey corporation;

Plaintiffs,

v.

CHRISTOPHER RIDGEWAY, an individual; RICHARD STEITZER, an individual; BIOMET, INC., an Indiana corporation;

Defendants.

Case No.

The Honorable

JURY DEMAND REQUESTED

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

Stryker

According to the lawsuit, over the course of the next few months, Ridgeway was in conversations with Biomet regarding moving Stryker business to Biomet. He was nervous about Stryker finding out his plans, and used the code word "pancake" to discuss the business he planned to "flip."

Secret Hotel Meeting

These efforts came to a head on July 3, 2013, when Ridgeway and another sales rep went to a hotel room at the Roosevelt Hotel in New Orleans where Biomet allegedly wanted to show them its product offerings and discuss possible employment.

therooseveltneworleans.com

The sales rep was in the midst of servicing a Stryker client, to which Ridgeway told the representative to "forget" that client and "come to the hotel."

During the course of the meeting, Stryker claims Ridgeway identified to Biomet certain specific Stryker customer preferences and needs, product usage, and also provided a comparison evaluation of Biomet's presented products versus Stryker's existing products. "This information constituted Stryker's confidential information and was information that Ridgeway was not authorized to disclose to Biomet," states the Complaint.

Biomet also identified that its strategies were to rapidly produce competitive products to Stryker to meet customer demand and to move Stryker's business to Biomet, utilizing Ridgeway's Stryker experience and access to Stryker's customers.

Stryker claims Biomet worked with Ridgeway in an effort to bypass Stryker's non-compete, using Ridgeway as a go-between between Stryker's employees, including Sheldon Green and Lauren Border, and Biomet.

Flippin' Recipe

Stryker also claims that Ridgeway used his knowledge of Stryker's confidential and proprietary information to enter the market and sell his genetic testing devices to Stryker's customers and diverted Stryker's funds to promote his personal business.

Between July 3, 2013 and September 6, 2013, Ridgeway said that he intended to move Stryker's business to Biomet en masse and that to make this move work he would have to reach agreements with Stryker's customers before leaving Stryker's employment to start purchasing from Biomet.

As part of his plan, Ridgeway allegedly requested that one of his sales representatives "make a sheet for all accounts that list of administrators, director, team leads, docs SPD and PO people." The sales representative did not assist Ridgeway in making this list, but Ridgeway created such a handwritten list that he considered to be his "business plan" for Biomet. The "business plan" iden-

tified these key Stryker relationships, and also included information related to the value of each account, and the amount of medical device sets that Biomet would need to have ready for him if he was going to flip the business.

Ridgeway, according to the complaint, shared this business plan with Biomet, resulting in Biomet preparing sets for Ridgeway prior to his departure from Stryker, and planning to make those sets available to Ridgeway while he was still a Stryker employee.

Moreover, Stryker claims that in mid-July, Ridgeway sent a list of Stryker's CMF and NSE customers to Green. No valid basis existed for Ridgeway to share this information with Green as Green's territory was solely in Georgia and Green had not requested a transfer to Louisiana.

Side Businesses

In early September 2013, Stryker said it learned that Ridgeway was devoting at least 50% of his time to operating two medical supply side businesses, through which he was "exploiting relationships with Stryker's customers to sell other medical devices." Stryker also said it learned that Ridgeway was requiring other Stryker employees to participate in such sales endeavors for his side businesses.

Ridgeway allegedly formed and operated a company named Stone Surgical LLC in November 2009.

With Stone Surgical, Stryker claims Ridgeway assisted his brother, Patrick Ridgeway, as a distributor and Area Sales Representative for distribution of genetic testing products for National Molecular Testing Corporation.

Ridgeway also formed a company known as UTC Laboratories, LLC, now known as Renaissance RX, with his brother, among others.

As late as November 2012, Stryker alleges that Ridgeway was inviting other sales representatives who reported to him for Stryker, to participate in Natural Molecular. Included in this behavior, Ridgeway provided certain Stryker sales representatives with reports on product offerings and information related to Natural Molecular.

In August 2013, Stryker claims government complaints related to Natural Molecular forced Ridgeway to shut down this company, but Ridgeway began offering a similar product through Renaissance RX.

Ridgeway allegedly leveraged the relationships he developed through the sale of Stryker's products as an entry for him to make sales of Natural Molecular's genetic testing products.

Failure to Service

Stryker says that in addition to the over 50% of time that Ridgeway dedicated to his side businesses, he also failed to adequately service Stryker's businesses, including but not limited to:

1. Refusing to hire qualified candidates necessary to support the South Louisiana market, rejecting all 33 candidates who interviewed with or applied for employment with Stryker
2. Attempting to hire and actually hiring employment candidates for the benefit of his side businesses
3. Making the branch so hostile that four employees have resigned in the past 20 months, resulting in an 80% turnover rate during that time period.

One potential employee was allegedly never placed through the formal interview process. Rather, Ridgeway took him on sales "ride-a-longs." Although the potential employee sent a formal "thank you" letter to Stryker for the opportunity to interview, Ridgeway instead hired him to work for his side businesses.

$3 Million Solicitations

On September 23, 2013, Green resigned from Stryker. Although he has to date refused to disclose his current employer—despite contractual obligations to do so—Stryker claims Green was observed attempting to sell Biomet products in a number of Louisiana hospitals, uncovered emails from Ridgeway to Green in mid-July divulging Stryker's Louisiana customers, and a September 8, 2013 email from Biomet to Green soliciting Green for employment.

Also in Green's resignation letter, despite claiming to provide two-weeks notice, Stryker claims Green abandoned a procedure scheduled for that day, threatening that "a competitor" would take the business if Stryker could not attend the procedure and proceeded to ignore Stryker's repeated attempts to reach him by cell phone and email.

Prior to September 6, 2013, Ridgeway allegedly solicited two Stryker doctors for his genetic testing company, as well as for the benefit of Biomet. These two doctors, if they were to stop doing business with Stryker, would put at risk approximately $3 million in Stryker's business.

By September 6, 2013, Stryker claims Ridgeway confirmed that the conversion of the Stryker business was a done deal, that he had an operational staff in place, and that he would be ready to turn the business over to Biomet by October.

It was not until September 8 that Stryker first learned of Ridgeway's plan to leave for Biomet and his alleged attempts to move Stryker's business en masse to Biomet. By the September 10 Ridgeway was fired.

Allegations Only

There has been no trial and Stryker's claims are just allegations. Stryker declined to comment for this story. But Ridgeway has responded and we'll bring you his side of the story in the next installment of this ongoing lawsuit. ♦

Medtronic Shrugged

BY ROBIN YOUNG

Is the North American Spine Society (NASS) turning into a dystopian community where surgeons and companies are no longer welcome to engage in open and fair scientific discussion and debate?

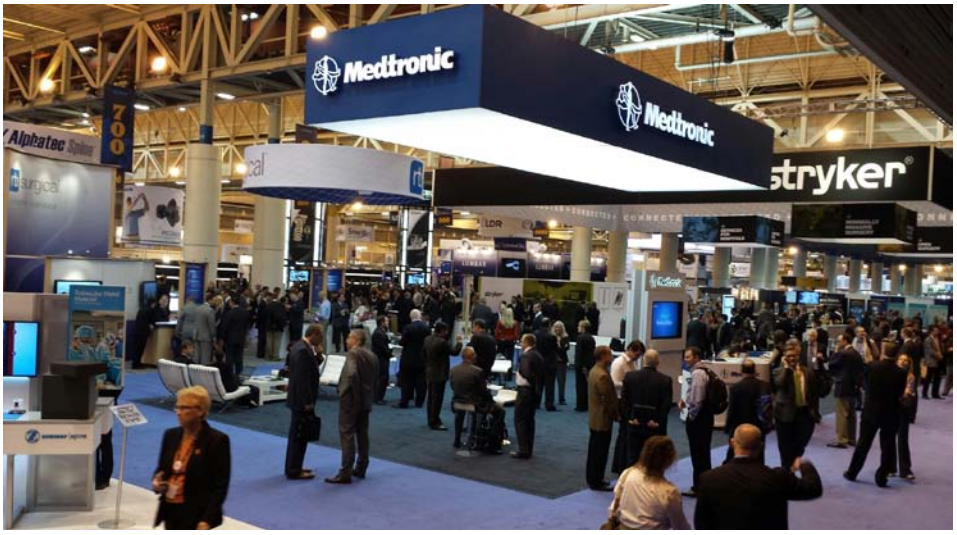
To Medtronic, Inc. (and, indeed, a growing group of senior surgeons and company executives), the answer appears to be "yes."

For the first time in the history of either NASS or Medtronic, there was no Medtronic Spine booth at the NASS Annual Meeting. No Booth. No product. No sales people.

The only Medtronic presence in NASS's exhibit hall was a square open space filled, not with implants, or instruments or biologics, but chairs, tables and sofas.

The only Medtronic personnel in the space were the firm's medical affairs group and they were there to talk. Not sell. Talk.

Doug King, president of Medtronic Spine explained the company's decision this way; "We believe that the recent editorials and publications, including those supported by the North American Spine Society as well as the potentially unbalanced panel presentations at this year's NASS Annual Meeting could add to surgeon confusion on this topic (rhBMP2). Therefore, Medtronic is repurposing our exhibit space at this year's NASS Annual Meeting. Our entire space will be devoted to our Office of Medical Affairs (OMA) personnel, who are trained and authorized to answer questions related to the scientific and clinical evidence supporting our Spinal products."



Exhibition Floor at NASS / Source: RRY Publications, LLC

The financial impact of Medtronic's decision on NASS and, indeed, New Orleans, was significant. Millions of dollars in hotel rooms, airfares, restaurants, temporary worker and NASS fees were slashed.

What happened?

NASS's open support for Dr. Eugene Carragee's campaign against surgeons, BMP-2 and Medtronic, specifically, was a factor, no doubt. But the tipping point was likely NASS's decision to stack the educational programs with anti-Medtronic members.

Not an Overnight Decision

Two and half years ago the editor-in-chief of *The Spine Journal*, Dr. Eugene Carragee, decided to devote an entire issue of the *Journal* to a retrospective critique of 13 early studies of BMP-2 (InFuse). Dr. Carragee was lead author of the study. He asked Dr. Chris Bono to sit in for him as the editor of *The Spine Journal* for that single issue and Dr. Bono bears partial responsibility for what ultimately emerged.

Dr. Carragee's critique omitted key data from two studies (Dimar and Boden) which would have argued against his conclusions. He also employed data from *The Wall Street Journal* in a manner which misled readers and damaged the reputations of a long list of prominent spine surgeons.

Carragee's 2011 retrospective critique was, in fact, deeply flawed and methodologically suspect.

In order to both set the record straight and to elevate the discussion to a more scientifically and methodologically sound level, Medtronic sponsored a $2million comprehensive retrospective review of all BMP-2 studies at Yale University, later also the University of Washington.

While the Yale study was progressing, the problems with the original 2011 *The Spine Journal* study were being widely discussed and disclosed in this publication and from the podiums at various spine surgeon meetings—most notably at the Cedars Sinai meeting where Dr. Paul Anderson presented the damning critique directly to Carragee who was also on the podium.

Many times NASS was asked to investigate the problems with Carragee's 2011 study. Many times NASS was asked to stop actively promoting via its press office the Carragee campaign against Medtronic and BMP-2.

But nothing seemed to register. No committees were formed to check allegations of methodological error. No adult stepped in tone down NASS's support for Carragee's partisan campaign against Medtronic or BMP-2.

No one made sure that NASS stayed, at least, neutral.

Here, for example, are comments the NASS PR department issued on Carragee's behalf earlier in 2013:

- "The YODA (Yale University Open Data Access Project) report published today in the *Annals of Internal Medicine* is the latest shock in a series of re-examinations of Medtronic's ill-fated biologics product."
- "Ten years after BMP-2's introduction, we cannot identify a single well-proven area of benefit, but we know it can kill you in the cervical spine and probably can promote cancer, which can then kill you."
- "The hyperbolic fever of BMP-2 promotion before its current fall from grace turned spinal conferences into Elmer Gantry-styled revival meetings."
- "Many of us feel like 10-year-olds after the Black Sox series: "Say it ain't so, Joe."
- "BMP-2's fifteen minutes of fame had ticked by. The cost: maybe 15 billion dollars, maybe cancer, maybe worse."
- "In the end, less than one percent of the 250 participants voted for

the old dream…people seemed kind of bored. Older guys thought of the Black Sox, groaned as they got up. Young guys glanced at the time (how confident the reps had seemed). But their attentions had moved away from the carnival hoopla of yesteryear. In the end, people yawned and some chuckled to themselves and…finally… left the room."

What is NASS's Role?

Medtronic and the other corporations who exhibit and support NASS through their advertising and sponsorships would like the society to foster open and fair scientific discussion. They would also like NASS to stop taking sides against them.

Yes, companies are commercial entities. Yes, companies are partisan for themselves. But…it is also in their self-interest to support authentic, vigorous and scientifically valid discourse. Despite the negative stereotypes promulgated by Dr. Carragee and *The Spine Journal*, companies and their executives are honest, have integrity and try to earn the trust of their surgeon customers with good science and a commitment to better patient outcomes.

Are there company executives who behave badly? Absolutely. Are there journal editors who behave badly? Yes. The fact that one such editor heads up NASS's own journal is creating an increasingly polarized North American Spine Society.

NASS's role is at its annual meeting is to foster open, fair and scientifically solid programs where alternative points of view are respected and heard.

Didn't happen in 2013. So Medtronic sent a powerful message.

Who knows, maybe this is a trend. Maybe corporate support is no longer a 'given' at NASS. ♦

The Miracle of Surgery (and Other Stories From the Uganda Spine Surgery Mission – Part III)

I LIEBERMAN, J TEICHMAN AND D LIEBERMAN

As the team's stay in Mbarara was coming to a close, the cases seemed to grow progressively more difficult. Then something wonderful happened. The team and its leader, Dr. Isador (Izzy) Lieberman pulled off what can only be described as a miracle—albeit one that came from training, experience and skill—but one that was still no less amazing and astonishing.

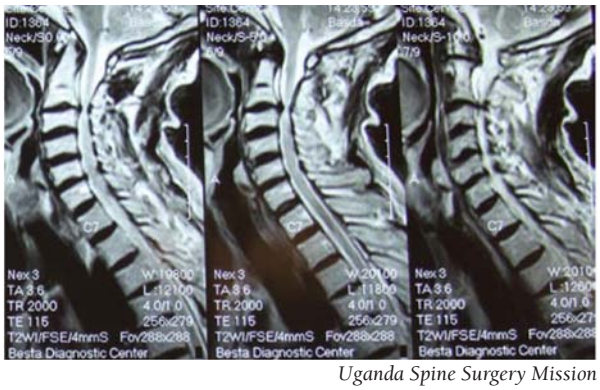
(Excerpts from the team blog)

Uganda Spine Surgery Mission

C Walks Again

Today's first surgical patient doesn't have a first name. At least, as far as his medical records at Mbarara are concerned, his first name is C.

C is a sixty-five year-old man who is, for all intents and purposes, a wheelchair-bound quadriplegic. Degenerative changes in his cervical spine (the bones of his neck) have compressed and damaged the spinal cord at that level, leaving him with paralysis in his legs, a loss of bowel and bladder function, minimal function in his right hand and none in his left that has progressed over three months. Lying flaccid on the operating table awaiting his anesthetic, C asked me whether the operation would allow him to walk again. I passed the question on to Dr. Lieberman.



Uganda Spine Surgery Mission

I was astonished to hear that indeed, Dr. Lieberman hoped the operation would accomplish just that.

Similar to Prudence's operation, Dr. Lieberman approached C's vertebral column through the side of his neck, navigating around some critical anatomy. He handed me a retractor he was using to push aside a vessel and asked, "What are you holding right now?" "The common 18 carotid," I replied, referring to the main artery carrying blood to the head. "Correct," he said, "if you slip, the patient will have a stroke."

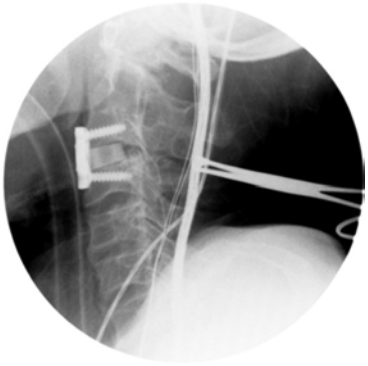
My hand cramped up a bit while standing there. Unlike most of the operations so far, C's progressed without any surprises from our hosts (finally, no power outages!) and before we knew it his decompression (making more room for the spinal cord) and reconstruction (rebuilding and fusing the bones together) was complete.

Ida

Ida was not a new patient. Dr. Lieberman had operated on her cervical spine last year. She now returned with pain, weakness and tingling in her legs caused by spinal stenosis (when the spinal canal is narrowed and compresses the nerves in the cord). Last week, Ida had walked into our clinic slowly and with an unsteady gait, supported by her son who has since not left her side at the hospital for more than 20 min-

utes to stretch his legs. She wore a kind expression on her face, which along with her son's iconic NY Yankees baseball cap, have made lasting impressions on us. Now, as Ida was assisted onto the surgical bed, I thought about her son who was undoubtedly pacing outside the double doors to the surgical wing, sporting his distinctive cap.

During Ida's surgery, Dr. Lieberman carved out space around the compressed portions of the spinal cord and secured screws and rods in place to stabilize the spine. The highlight of my week came next, when Dr. Lieberman allowed me to secure a few screws and to help suture the incision. It's a small thing for a surgeon, but as a medical student it was the first time I would leave my physical mark on a patient. The fact that it was kind-faced Ida who would carry the scars of those stitch marks made it even more meaningful.



Uganda Spine Surgery Mission

The following day, I went to visit Ida and her son in the private surgical wards. Aside from a bit of pain, she was in great shape. As her son walked me out to the corridor, we chatted about their experience throughout his mother's care. They had tolerated the crowded mini bus system over the 300 kilometer trip from Kampala to see us in Mbarara, only to find themselves completely disoriented and without instruction upon arrival at the hospital. Once admitted (to the private ward, no less), they had to provide their own food, bathing basin and other essentials. There were showers for those in the private ward, but no accommodations for a bed-ridden spine surgery patient.

After speaking with Ida's son, it was clear to me that in Mbarara and perhaps Uganda at large, a patient must be his or her own advocate. Without a middle man to coordinate between patient and doctor, the patient's own initiative determines the outcome of his or her care. In fact, when it was time for Ida's surgery, no nurse came to retrieve her. Exasperated, her son walked his mother to the surgical ward and received her stretcher after the operation was complete.

The lesson of the day was embedded here: As part of the surgical team, I had a narrow view of our patient's experi-

ence; as far as I knew, she had showed up to our clinic, arrived at the hospital for admission several days prior to surgery, and had made her way to the operating table just as was meant to be. But in between those encounters, Ida and her son had fought to get attention from uninterested nurses and administrators and had navigated a non-intuitive system in their efforts to seek optimal health care.

Quote of the day; "God lives right there" – Lieberman to Jennifer as she was retracting the carotid artery.

Scheurmann's Disease

Our next patient was a 14-year-old girl with a large thoracic kyphosis (an over-pronounced curve in her upper back). Her condition was consistent with Scheurmann's disease, a pathology of abnormal bone growth causing wedge-shaped vertebra that exaggerate the normal thoracic kyphosis. With her deformity, the young girl found it painful to carry baskets of food on her head as is common practice here.

Uganda Spine Surgery Mission

Dr. Lieberman's plan was to straighten Catherine's curve with metal rods anchored to the spine with vertebral screws. There were several power outages throughout the surgery, during which Dr. Lieberman could not use his ultrasonic bone cutter. Nevertheless, he adapted the procedure to the tools that he had until power returned. He would not be derailed by a simple power loss!

Our determination to get through the day unscathed met another challenge that afternoon. The autoclave (the machine that sterilizes our equipment between surgeries) failed during its cycle, leaving us with potentially still contaminated equipment for the operation.

Our next patient had two-level spinal stenosis and lay prepped and sleeping on the operating table while Dr. Lieberman, Rob and Sherri brainstormed

alternatives. They decided to rerun the sterilization (a 45-minute cycle) while still proceeding with the operation using alternative tools. Rob scoured the hospital's sterilized equipment room for substitutes while Sherri went through some of our own tool sets set aside for other procedures. With some creative ingenuity the decompression surgery (laminotomies and foraminotomies) got underway, and 60 minutes into the operation we received our freshly-sterilized equipment.

The Faculty Dinner Before Leaving

That evening, the hospital and university invited us to a buffet dinner at the Agip Motel. Those in attendance included the surgical team from the hospital, the university and hospital accountants, and two of the vice deans from the Faculty of Medicine. After the meal, each of our hosts in turn spoke of their gratitude to Dr. Lieberman and his team. They expressed their hope that the continued presence of the mission would allow them to build competence and expertise in spine surgeries, ultimately establishing Mbarara as the pinnacle spine surgery center of East Africa. After a week of hard work in the operating room, the team was moved to see the appreciation and long-term vision of our host institution. After all, we weren't simply there to operate on eleven patients and call it a week. The mission was established to provide spine care to the less fortunate and train those who serve these patients. As the saying goes, "Give a man a fish and he will eat for a day. Teach a man to fish and he will eat for a lifetime."

Uganda Spine Surgery Mission

After dinner, the team gathered in our hotel lobby and discussed the lessons of the day over a bottle of wine. Today taught us that surgery can be seen as a series of small failures that simply require some creativity and perseverance to overcome. Back home in the U.S. and Canada, the autoclave failure would have resulted in a canceled surgery. But here in Uganda, with limited time and even more limited resources, we could not afford to delay the operation.

Quote of the day; "robot shmobot" – Lieberman to team after placing screws the old school way.

Thanks to the Sponsors

These remarkable team members could not have treated as many patients as they did without the generous support of the following people and companies.

Society Sponsors: Health Volunteers Overseas (Orthopaedic Overseas)
Corporate Sponsors: Globus Medical; J&J DePuy Synthes Spine; Misonix
Philanthropic Sponsors: MedWish International; AmeriCares; Ve'ahavta Organization
Team:
Isador Lieberman M.D. - Orthopedic Surgeon
Zvi Gorlick M.D. - Primary Care Physician
Sherri LaCivita - Surgical Technician
Robert Davis - Equipment Technician: Synthes Spine
Danielle Lieberman - Chef, Photographer, Scribe
Jennifer Teichman - Medical Student
Locations: Mbarara Regional Referral Hospital
Local Physicians:
Dr. Deo Bitariho (Department of Orthopaedics - Mbarara)
Dr. Emanuel Munyarugyero (Department of Anaesthesia - Mbarara) ♦

COMPANY

Stryker's 3Q "Impressive" Results Point to Ortho Growth

Stryker Corporation's reconstructive net sales popped 6.5% (on a reported basis), to $949 million during the third quarter of 2013. Hip sales rose 5.5%, knees were flat, trauma was up 18.1% and even spine was up 4.1%.

"We are pleased," said Kevin Lobo, the company's president and CEO. The company also jumped feet first into robotics during the quarter by acquiring MAKO Surgical Corp.

Net sales in the quarter grew by 9.6% due to increased unit volume and changes in product mix and 1.2% as a result of acquisitions. Net sales in the quarter were unfavorably impacted by 1.6% due to changes in price and 2.7% due to the unfavorable impact of foreign currency exchange rates on net sales. Excluding the impact of acquisitions, reconstructive net sales increased 8.0% in constant currency over the prior year.

BMO Capital Market analyst Joanne Wuensch called the results, "pretty impressive."

Trauma and Extremities Shine

Wuensch said trauma and extremities sales were once again a highlight, including a 22.7% delivery increase in the U.S. "In this segment, foot and ankle sales were up a whopping 39%, with the segment now annualizing above $100 million. While management does believe that it is capturing some 'meaningful' share, it is also reflective of a healthy market."

Psychology Today and RRY Publications

Stryker Corporation 3Q13	Sales $ in million	% Change
Reported Reconstructive Sales	**$949**	**6.5%**
Knees	$315	3.4%
Hips	$304	3.5%
Trauma/Extremities	$277	14.4%
Spine	$183	3.8%

Source: Stryker Corporation

Market Growth

Wells Fargo analyst Larry Biegelsen observed that with Stryker's report, more than 50% of the hip and knee makers have reported quarterly results. Based on that, Biegelsen estimates, that on a constant currency basis, the worldwide knee market accelerated to 3.5% in the third quarter from 2% in the second quarter, while hips accelerated to 7.1% during the quarter from 3.7% in the second quarter.

He speculates this has been driven by an improving macroenvironment, potential pent-up demand, potential patient uncertainty ahead of the implementation of Obamacare, and continued increased seasonality.

Stryker management also said the hip, and particularly the knee market, improved during the quarter and is optimistic that there will be continued improvement in knee volume going forward.

Recalls, Charges and Taxes

The company took charges of $313 million related to the voluntary recall of Rejuvenate and ABG II modular-neck hip stems and the recall of the Neptune Waste Management System. The charges for the Rejuvenate and ABG II recall in the quarter bring the total charges recorded for this recall to $700 million.

The company also said the medical device tax cost them $0.03 per share.

Lobo on Obamacare

In a recent *Wall Street Journal* interview, Lobo addressed the tax and implementation of Obamacare. He said the move away from pay-for-service to paying for outcomes is a positive trend. "There are many sensible elements of this legislation that I think will have long-term benefits, but clearly the med-device tax is the one area that is very punitive for us."

He added that he believes the knee replacement business could benefit from the new law, because that's a more elective procedure. "We're hopeful that those patients will start to come into the health care system and the knee volumes would grow."

—*WE (October 18, 2013)*

Globus Receives Warning Over MicroFuse Putty

Globus Medical, Inc. received a Warning Letter on September 27, 2013, from the FDA over its MicroFuse Putty.

According to an October 15, 2013 Globus SEC filing, the warning came after an inspection at the company's Audubon, Pennsylvania, facility that occurred from May 7, 2013 until June 4, 2013.

The company said the FDA cited deficiencies in response to a letter sent by the company to the agency following the Form 483, List of Investigational Observations delivered to the company after the inspection. "These deficiencies relate to the Company's MicroFuse Putty manufactured between October 25, 2012 and December 20, 2012, and mechanical testing of the Company's MicroFuse Putty, procedures to control environmental conditions in a clean room at the Company's facility, and internal procedures for medical device reporting," read the Warning Letter, according to the company.

The FDA had not posted the Warning Letter on its website as of October 17, 2013.

The Globus SEC filing said the warning letter does not restrict the company's ability to manufacture or seek 510(k) clearance of products.

The company says it is currently addressing the deficiencies cited by the FDA in the warning letter and intends to work expeditiously to address each of the outstanding issues. The company believes that the FDA's concerns set forth in the warning letter "can be resolved without a material impact to the company's financial results. However, the company cannot give any assurances that the FDA will be satisfied with its response to the warning letter or its proposed resolution of the outstanding issues."

Analyst: "Not Much Impact"

Our friends at *MassDevice* reported on October 15, 2013 that Leerink Swann analyst Richard Newitter said in a note to investors that the warning letter is unlikely to have much of an effect on Globus, because its putty business is so small.

Newitter's note stated, "We estimate MicroFuse comprises <1% of GMED's total sales, and we would note that biologics has been an area where GMED's portfolio has been most lacking; thus not a growth driver for the company. In fact, in our view biologics remains very much a future growth opportunity for GMED. Warning letters are never a good thing, but again MicroFuse is not a key product for GMED. We checked in briefly with management, and the company is currently addressing the deficiencies cited by the FDA in the warning letter and intends to work quickly to address the issues."

—WE (October 17, 2013)

Image created by RRY Publications LLC

DePuySynthes 3Q: Strong Hips and Knees, Spine Dis-Synergies

Johnson & Johnson's DePuySynthes reported sales were down .3% to $2,283 million for the third quarter of 2013. Currency took a 1.4% bite. Excluding currency, sales rose 1.1%.

Pharma overtook devices during the quarter as the company's largest business, prompting Bank of America analyst Bob Hopkins to call Johnson & Johnson (J&J) a "one-legged stool."

Strong Hips, Knees and Spine Dis-Synergies

Hips and knees showed "strong numbers" according to Wall Street analysts, with hips up 6% and knees up 3%, excluding currency. According to Joanne Wuensch, BMO Capital Market analyst, spine sales, excluding currency, experienced "dis-synergies" with the Synthes integration and dropped 2%.

The company said hip sales were up 7% in the U.S. driven by demand for primary stem offerings. Knee sales were driven by a demand for company's fixed bearing knee and revision knee platform. Spine was down 10% in the U.S. Hopkins said the Synthes integration problems have "no real turn in sight."

The Orsinger Show

The October 15, 2013, quarterly call with Wall Street analysts was the Michel Orsinger show as J&J management focused on orthopedics.

Orsinger, the former head of Synthes, now the worldwide chairman of DePuySynthes, said there was "clear progress" in addressing U.S. spine disruptions and the "successful integration continues." He said the company's primary goal during the integration was to minimize customer disruption. "Based on feedback from customers, we believe we have achieved this in all, but one platform. As we combine two different sales forces with two different sales models in U.S. spine, we have experienced some disruptions in that business and we continue to take corrective measures."

Caption

DePuySynthes 3Q2013	Sales ($ in millions)	% Change
Total Reported Sales	**$2,283**	**1.1%**
Knees		3.0%
Hips		6%
Spine		down 2%
Trauma		1%

Source: Johnson & Johnson
** Constant Currency*

New Products and Services

He also highlighted successful new product launches, noting the Attune knee, VALCP mid-foot/hind-foot plating, MatrixRIB system and the Synflate vertebral balloon augmentation systems.

In addition to new products, Orsinger pointed to a new value-added program called Care4Today Orthopedic Solutions to help hospitals reduce the length of stay for joint replacement patients. The program integrates patient education, a change management program for hospitals and home recovery support. "The first impressive results from the pilot show reduced patient length of stay and excellent patient and staff feedback."

Changing Customer Values

The key goal in discussions with the company's customers is how DepuySynthes can provide value in the form of more holistic solutions. "So far the industry has been very much focused on surgeons and patients, obviously, delivering good clinical outcomes. Now the healthcare delivery system needs to find new ways to do so in a more cost effective way. Hence we are driving now not only a strong R&D pipeline but a pipeline of new programs and services, collaborating together with the partners. We don't have all the answers today. But we understand more and more of their needs."

Orsinger told analysts that while he is not entirely satisfied with the quarter's results, "we have had some important wins. Joint reconstruction, especially in the U.S., is performing very well and we believe we grew market share in hips. Furthermore we generated double-digit growth in emerging markets with the best results coming from China, Russia and Brazil."

Overall, management expects the orthopedic market to increase 2%-4% compounded annually between now and 2017.

—WE (October 16, 2013)

Blue Belt's First Sale to Ambulatory Surgical Center

Blue Belt Technologies, Inc. has made its first sale to an ambulatory surgical center and reported the first use of the company's unicondylar knee system.

The company announced on October 15, 2013 that the Thomas Jefferson Riverview Surgical Center, at the Navy Yard in Philadelphia, Pennsylvania, entered into an agreement to purchase Blue Belt's Navio robotic-controlled surgical system. The Jefferson Surgical Center is a multi-specialty ambulatory surgery center, developed by area physicians, Thomas Jefferson University Hospital and Nueterra Healthcare. It is the first surgery center in the U.S. to purchase and use the Navio system to assist in precision partial knee replacement surgery.

Jess H. Lonner, M.D., associate professor of Orthopaedic Surgery at Thomas Jefferson University and attending orthopaedic surgeon, Rothman Institute, said the center has "now solidified itself as arguably the nation's most innovative and cutting-edge outpatient surgical facility. Rothman Institute has been one of the few groups nationwide performing a large volume of partial knee replacements on an outpatient basis, and now with Riverview offering the most advanced and precise image-less robotic technology available for partial knee replacements—Navio—we are able to offer a unique service for many patients suffering with arthritis of the knee."

Eric Timko, Blue Belt's president and CEO, said he believes that the precision and economics of the Navio system, paired with the company's optimized Stride knee system, make it a perfect fit for building an orthopedic robotics program in any outpatient setting. "This Navio site will be an excellent model and example of the benefits of adopting new technology into any burgeoning orthopedic environment."

First Surgery

The Navio system is a CT-free, open platform surgical system that utilizes patented precision free-hand sculpting technology to deliver the precision of robotic-assisted bone preparation directly into the surgeon's hands. On October 9, 2013, Dr. Lonner utilized the Navio system to perform the world's first partial knee replacement utilizing Blue Belt's proprietary stride unicondylar knee system. "In treatment of a patient presenting with medial osteoarthritis, Dr. Lonner used Navio to create a surgical plan, resurface the patient's diseased bone and implant a Stride prosthesis to restore function to the patient's knee and reduce the pain associated with osteoarthritis," stated the company's announcement.

The system incorporates patented technology to provide precise robotic control to surgeons via an intelligent, handheld, computer-assisted bone cutting tool.

—WE (October 15, 2013)

Blue Belt Technologies, Inc./Navio System

LARGE JOINTS

Walmart and Lowe's Offer FREE Hip and Knee Surgery

In an attempt to both improve medical care and lower costs for their employees, several large employers—including Walmart and Lowe's—have launched a national Employers Centers of Excellence Network (ECEN) that will offer no-cost (to the patient) knee and hip replacement surgeries for their employees.

The four participating centers are Johns Hopkins Bayview Medical Center in Baltimore, Maryland; Kaiser Permanente Orange County Irvine Medical Center in Irvine, California; Mercy Hospital in Springfield, Missouri; and Virginia Mason Medical Center in Seattle, Washington.

David Lansky, president and chief executive officer of Pacific Business Group on Health Negotiating Alliance (PBGHNA), told *The Suburban Times* of Lakewood, Washington, "These companies are working to help make sure that their employees get higher quality care and incur lower costs. The Employers Centers of Excellence Network is designed to serve as a model for delivering high quality health care with transparent and predictable costs."

The national Employers Centers of Excellence Network will provider knee and hip replacement surgeries for the more than 1.5 million employees and their dependents enrolled in Walmart's, Lowe's and other large employers' medical plans. Employees will be covered at 100% without deductible or coinsurance, plus travel, lodging and living expenses for the patient and a caregiver.

Wikimedia Commons and Ricardo Bob

The program is voluntary and employees or their covered dependents can still choose to receive care from local providers and incur routine costs.

"This national program is about providing our associates with exceptional care and reducing their medical costs so that they pay nothing out of pocket when they use one of the designated facilities," said Sally Welborn, senior vice president of global benefits at Wal-Mart, "Each of these providers has a proven record of practicing evidence-based medicine with above average positive patient outcomes in knee and hip replacement procedures."

—*BY (October 14, 2013)*

EXTREMITIES

Auxilium: Positive Results for XIAFLEX

Auxilium Pharmaceuticals, Inc. has announced results from Year 4 of the **C**ollagenase **O**ptimal **R**eduction of **D**upuytren's - **L**ong-term **E**valuation of **S**uccess **S**tudy ("CORDLESS"). These data indicated that the overall recurrence rate at Year 4 was 42.1% for patients previously treated successfully with XIAFLEX for Dupuytren's contracture. The study assessed 623 joints in adult Dupuytren's patients with a palpable cord from earlier Auxilium studies, indicating that 57.9% of patients previously successfully treated with XIAFLEX did not experience disease recurrence based on the study's definition.

Wikimedia Commons, Akira Kurosawa, Sandik

In the CORDLESS study, recurrence was defined as a 20 degree change of contracture with a palpable cord or when the treated joint underwent medical/surgical intervention. Of the 623 joints that were successfully treated with XIAFLEX, only 12.8% of those joints received medical or surgical intervention through Year 4. Of the joints that received medical or surgical intervention by Year 4 of the study, patients were most commonly retreated with XIAFLEX.

"As a doctor who frequently treats patients with Dupuytren's contracture, I am encouraged by the recurrence rates seen among patients treated with XIAFLEX, a non-surgical therapy," said Clayton A. Peimer, M.D., Clinical Professor of Surgery, Michigan State University Medical School/ Marquette General Healthcare. "These data represent an important piece of information physicians, patients and payers can consider when determining the most appropriate treatment option for their patients."

Through four years of follow-up, the adverse event (AE) profile of Dupuytren's contracture patients successfully treated with XIAFLEX revealed no new long-term AEs. Of the 86 serious AEs reported through four years of follow-up, only one was considered related to XIAFLEX (decrease in ring finger circumference due to Dupuytren's contracture resolution).

Dr. Peimer told *OTW*, "My coauthors and I were gratified to learn that Dupuytren's patients who were successfully treated with enzyme injection to correct deformity and restore function—rather than requiring surgery and extended therapy and disability—do as well or better in the longer term than those who had operations. The use of collagenase to treat this disease has also caused reexamination of the natural history of the diagnosis and those findings now allow our patients options and choices that have only been a dream of treating physicians for two centuries."

Dr. Peimer added, "Our experience and these data—in addition to earlier published, peer-reviewed studies—show that collagenase is an effective and safe alternative for surgery for Dupuytren's contracture; and it offers correction/improvement as durable as with an operation but without many of the surgical risks and extended disability. Scientifically, we know that both surgery and collagenase injection will correct Dupuytren's contracture deformities; we know that neither will cure nor alter the long-term course of the disease. Realistically, why would we recommend surgery when we can offer patients the same benefits with an injection?"

—EH (October 14, 2013)

President and Nobel Winner Chooses Springfield for Orthopedic Care

The Land of Lincoln hosted the president of Liberia, Ellen Johnson Sirleaf, when she came to Springfield's Memorial hospital for surgery on her arm October 4.

Besides being president, Ms. Sirleaf is co-recipient of the 2011 Nobel Peace Prize.

The surgery was performed by Saadiq El-Amin, M.D. and an orthopedic surgeon and Southern Illinois University (SIU) medical school's chair of surgery, Michael Neumeister, M.D. El-Amin had met the Liberian president when he was on a medical mission trip to Liberia in 2012. The president's son, James Adamah Sirleaf, M.D. an emergency room doctor, had asked him to examine his mother because she was having trouble with her arm.

In June when President Sirleaf was in New York City to address the United Nations she asked El-Amin to come to New York to again take a look at her arm. He told her that she needed surgery. It was decided then that she would have the surgery in Springfield, Illinois. "Of all the places in the world she could have gone," El-Amin told Dave Bakke, a writer for the *State Journal Reporter*, "she came here because she felt comfortable with that."

Before the surgery the hospital staff held a dinner for their patient so she could meet the people who would be taking care of her and gave her a portrait of Lincoln. El-Amin said, "This was a great opportunity for SIU and Memorial. She could have easily done the surgery in New York. The most impressive thing was that everyone stepped up and did what they were supposed to do. Nobody else's care was affected that day. We still ran a normal OR. We still had patients getting imaging done. We protected her safety and protected everyone else's care."

"This story is his story," said Adamah Sirleaf, who accompanied his mother to Springfield. "It's about his kindness. Dr. El-Amin made it all happen and he did it undercover. He respected the president's privacy."

Liberia President Ellen Johnson Sirleaf/Wikimedia Commons

"He said to me once, 'Dude, this is your mother.' That's what it comes down to. It was him caring for my mother. Forget the presidency. Forget the Nobel Prize and all of that. She's my mother. The whole staff was respectful and kind to her. She was touched by it."

—BY (October 15, 2013)

TRAUMA

Touch-Sensitive Prosthetic Limbs: Progress!

New research at the University of Chicago is laying the groundwork for touch-sensitive prosthetic limbs that one day could convey real-time sensory information to amputees via a direct interface with the brain.

University of Chicago Medical Center

"To restore sensory motor function of an arm, you not only have to replace the motor signals that the brain sends to the arm to move it around, but you also have to replace the sensory signals that the arm sends back to the brain," said the study's senior author, Sliman Bensmaia, Ph.D., assistant professor in the Department of Organismal Biology and Anatomy at the University of Chicago, in the October 14, 2013 news release. "We think the key is to invoke what we know about how the brain of the intact organism processes sensory information, and then try to reproduce these patterns of neural activity through stimulation of the brain."

Bensmaia's research is part of Revolutionizing Prosthetics, a multi-year Defense Advanced Research Projects Agency (DARPA) project that seeks to create a modular, artificial upper limb that will restore natural motor control and sensation in amputees. Managed by the Johns Hopkins University Applied Physics Laboratory, the project has brought together an interdisciplinary team of experts from academic institutions, government agencies and private companies.

Bensmaia and his colleagues at the University of Chicago are working specifically on the sensory aspects of these limbs. Using monkeys, the researchers identified patterns of neural activity that occur during natural object manipulation and then successfully induced these patterns through artificial means. The first set of experiments focused on contact location, or sensing where the skin has been touched. The animals were trained to identify several patterns of physical contact with their fingers. Researchers then connected electrodes to areas of the brain corresponding to each finger and replaced physical touches with electrical stimuli delivered to the appropriate areas of the brain. The result was that the animals responded the same way to artificial stimulation as they did to physical contact.

When the researchers focused on the sensation of pressure they developed an algorithm to generate the appropriate amount of electrical current to elicit a sensation of pressure. Again, the animals' response was the same whether the stimuli were felt through their fingers or through artificial means.

Finally, Bensmaia and his colleagues studied the sensation of contact events. When the hand first touches or releases an object, it produces a burst of activity in the brain. Again, the researchers established that these bursts of brain activity can be mimicked through electrical stimulation.

The result of these experiments is a set of instructions that can be incorporated into a robotic prosthetic arm to provide sensory feedback to the brain through a neural interface. Bensmaia believes such feedback will bring these devices closer to being tested in human clinical trials.

—EH (October 18, 2013)

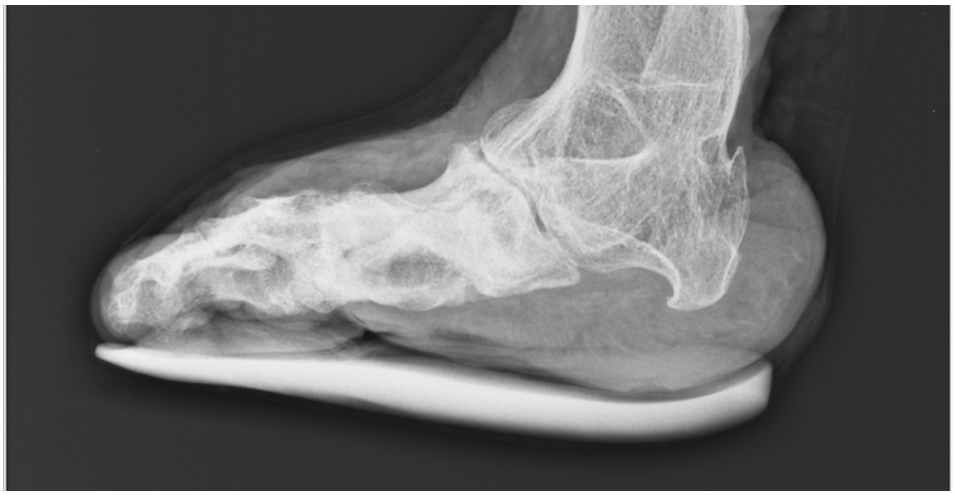
Bone Delayed Union Product Enters Trials

Bone Therapeutics SA has received clearance from the Competent Authorities in Belgium and the United Kingdom for a Phase I/IIa trial of its allogeneic cell therapy product ALLOB for the treatment of delayed union fractures.

A delayed union fracture is defined as a bone that has not healed within the expected normal period of time, three to four months, after the initial injury and is at risk of non-healing. Around one million patients are affected by delayed union each year. Traditional options for the treatment of impaired fracture healing typically involve highly invasive surgery, which can require months of rehabilitation with no guarantee of success.

According to a report by Bone Therapeutics ALLOB is an allogeneic (where cells are derived from a healthy, universal donor, rather than the patient) and osteoblastic (bone-forming) cell therapy product. ALLOB has shown safety and efficacy in preclinical studies and company officials believe that it has the potential to become a first-line treatment for impaired fracture healing, thanks to its minimally invasive percutaneous administration, avoiding the need for surgery.

The study is a six-month open-label trial to evaluate the safety and efficacy of ALLOB in the treatment of delayed union fractures of long bones. Thirty-two patients will be enrolled in 10 centers. They will receive a single percutaneous administration of ALLOB directly into the fracture site. ALLOB-treated patients will be assessed in comparison to baseline at two weeks and at one, three and six month intervals using clinical and radiological evaluation.



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Enrico Bastianelli, CEO of Bone Therapeutics said, "This new clinical trial clearance from the Competent Authorities in Belgium and the UK is an important milestone in the development of ALLOB and further validates Bone Therapeutics' clinical, regulatory and manufacturing capabilities. The only way to address delayed union fractures currently is invasive surgery. With ALLOB's bone regenerative mode of action and minimally invasive administration, Bone Therapeutics' allogeneic product could become a first-line treatment."

Company officials note that ALLOB also has the potential for systemic applications as in osteogenesis imperfecta, a rare genetic bone disease characterized by bone fragility and fractures. ALLOB has been classified as a tissue engineered product.

—BY (October 14, 2013)

SPINE

Interventionalist Spine Surgeons Call to Arms

The Society of Advanced Spinal Intervention (SASI) is holding its first meeting in Memphis, Tennessee, on Saturday, November 16, 2013.

Turf War

In the scope of practice turf war between interventional pain physicians and board certified orthopedic and spine surgeons, the interventionalists have been treated as a step-child by established surgical societies. So they are forming their own society to develop and implement a program of education and training which they hope results in accreditation that will serve as the gold standard for physicians in the field of spinal intervention.

One of the meeting presenters, Richard Kaul, M.D., is the target of an attempt by the New Jersey Attorney General to take away his medical license because he performs procedures allegedly outside his training as an interventionalist. The former president of the North American Spine Society (NASS) and neurosurgeon Greg Przybylski, M.D., was the state's star witness in testifying that surgeons with Dr. Kaul's credentials "deviate" from standards established by NASS.

Wikimedia Commons/Low Back Pain

New Standards

Solomon Kamson, M.D., SASI's president, will present the new SASI-endorsed standard for MISS (minimally invasive spine surgery), called the "Rule of Five [ROF]." Those five rules are:

1. Fluoroscopic guidance and interpretation
2. Minimal muscle dissection
3. Must qualify for outpatient
4. Minimal blood loss (150 cc)
5. Time from completion of surgery to discharge of less than 12 hours

SASI

Through an October 14, 2013 press release, the society states that, "As the ROF becomes the internationally accepted standard, SASI is committed to working with other societies and organizations to promote better understanding, training, proctoring and credentialing of future generations of talented MIS surgeons. SASI and its network of member physicians are actively monitoring developments in landmark MIS-related court cases, which are ongoing and are the result of the spine turf wars. These are the battles evidenced by a plethora of lawsuits over what constitutes safe, effective standards and practice of medicine related to surgical treatment of back and neck pain."

The society calls itself a, "unifying global society whose mission is to educate, train, and credential physicians from multidisciplinary backgrounds on a worldwide scale. Focused on the implementation of a cost-effective healthcare delivery model for interventional pain medicine, interventional radiology, neurosurgery, and orthopedic spine surgery, SASI aims to develop and implement a world-class program of education and training resulting in accreditation that will serve as the gold standard for physicians in the field of spinal intervention."

Panelists

Anthony Yeung, M.D., founder of the Desert Institute for Spine Care in Arizona, and a board certified orthopedic spine surgeon who specializes in diagnosing and treating the causes of back pain and sciatica from painful degenerative conditions of the lumbar spine, particularly herniated lumbar discs and pain from bulging discs with annular tears, will be the meeting's special guest panelist.

Dr. Yeung is an internationally renowned endoscopic spine surgeon, the first to utilize endoscopically guided laser for painful degenerative conditions of the lumbar spine, and the developer of the FDA cleared Yeung Endoscopic Spine System (YESS).

Other panelists will include:

Daniel Bennet, M.D., - Minimally Invasive Spine Surgeon, Colorado
Jeffrey Randolph, Esq. - Healthcare Law Expert, New Jersey
Solomon Kamson, M.D. - SASI President, Minimally Invasive Spine Surgeon, State of Washington
Richard Arjun Kaul, M.D. - Minimally Invasive Spine Surgeon, Kashmir, India
Kent Remley, M.D. - Minimally Invasive Spine Surgeon, Indiana
Brant Breen - CEO and Founder of Qnary, New York
Walter Eisner - Senior Writer, *Orthopedics This Week*, Panama

The one-day seminar will be held at MERI, the Medical Education Research Institute in Memphis. For further information, contact: Kelley Blevins, 917-488-7124; media@sasiglobal.org.

—*WE (October 16, 2013)*

Invuity Introduces Retractor System

Last week, Invuity, Inc. introduced its Breiten Illuminated Retractor System at the North American Spine Society (NASS) Annual Meeting in New Orleans. Breiten combines highly engineered retraction devices with innovative Eigr Illumination Technology that projects thermally cool, brilliant, white light uniformly throughout the surgical cavity. Breiten is designed for anterior cervical discectomy and fusion (ACDF), anterior cervical corpectomy and other spinal procedures where visualization may be challenging.

"Traditional lighting sources are inadequate when operating through the smaller incisions used in the anterior approach to cervical discectomy, fusion and corpectomy," said Richard D. Guyer, M.D. in the October 9, 2013 news release. Dr. Guyer is past president of NASS and chairman of the Texas Back Institute Research Foundation. "Invuity's Eigr Illumination Technology allows me to optimize my illumination for the individual patient and procedure, ensuring I have appropriate visualization of the surgical target and, therefore, the best outcomes for my patients."

"With the spine market continuing to grow significantly, we are committed to providing a portfolio of devices that help meet surgeons' needs for improved visibility, thereby helping to enable a variety of less invasive procedures to be performed," said Invuity Chief Executive Officer Philip Sawyer.

Breiten's low profile design enables surgeons to work efficiently in deep, dark cavities through smaller incisions, without dependence on a headlight. The color-coded system is available in multiple blade configurations for varying patient anatomies and surgeon

Invuity, Inc.

preferences and is radiolucent for maximum visibility during fluoroscopy.

The Breiten Illuminated Retractor System is an all-inclusive set optimally designed for cervical and lumbar spine surgeries and enables unsurpassed visualization of the disc space.

Regarding the Eigr Saber Waveguide with Yankauer, Sawyer told *OTW*, "The Eigr Saber Waveguide with Yankauer came out of the success of our Eigr Saber with Frazier suction platform. We initially developed the Eigr Saber handheld illuminator built on a Frazier suction platform for spine surgeons to improve visualization during lumbar and cervical spine surgery. When orthopedic surgeons saw the potential to improve their visualization in deep joint spaces, we developed a device with a larger lumen suction—the Eigr Saber Waveguide with Yankauer—specifically for them, for use across the many sub-specialties in orthopedic surgery, including orthopedic reconstruction and trauma."

As for the Breiten, Sawyer noted, "We identified an unmet need in anterior cervical discectomy and fusion procedures, where traditional lighting sources were inadequate when operating through the smaller incisions used in the challenging anterior approach, even when using a microscope. In response, we developed the Breiten Illuminated Retractor System, which combines illumination with retraction and provides a variety of blade sizes and tips so surgeons can optimize illumination for the individual patient and procedure. As a result, surgeons can now visualize the critical anatomy around the spine and into the disc space with startling clarity."

—EH (October 15, 2013)

Renovis Surgical Launches Spinal Implant

The FDA has granted 510(k) clearance to Renovis Surgical Technologies, Inc.'s porous titanium spinal implant. Called the Tesera Stand-alone ALIF Cage, the device uses additive manufacturing to create porous surfaces that, the company affirms, aid with bone in-growth from the vertebral endplates. The Tesera ALIF implant is the first in a family of spinal and orthopedic implants from Renovis to feature this platform technology.

Company officials explain that the Tesera ALIF cage begins as a titanium alloy powder, which is melted by electron beam into a solid structure, layer by layer, transitioning into a porous structure at the surfaces. The implant is one piece, rather than multiple pieces bonded together. Officials claim that this device is the first stand-alone anterior spinal cage to feature a true porous structure, rather than a spray-on coating or surface etching.

Renovis introduced the Tesera ALIF cage at this year's North American Spine Society meeting in New Orleans. The company was founded in 2009 and is located in Redlands, California with manufacturing in Austin, Texas.

—BY (October 14, 2013)

Courtesy of Renovis Surgical Technologies, Inc.

Orthopedics This Week

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