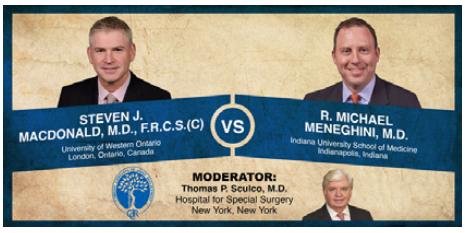
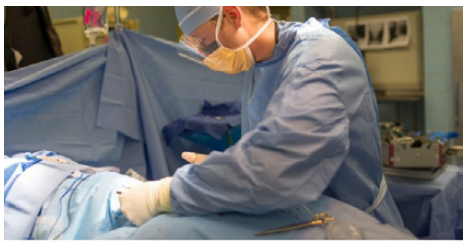
VOLUME 11, ISSUE 34 | OCTOBER 27, 2015

Orthopedics This Week

WEEK IN REVIEW





"Guys! I found some bones in here!"

BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: October can't end soon enough for orthopedic equities. Only Johnson & Johnson and Medtronic—two medical and pharmaceutical goliaths—showed meaningful valuation gains. This earnings season orthopedic companies are reporting single-digit sales growth and profit margins that range from 10% to 30% of sales. Which is both expected and fine. Still, capital flowed out of orthopedics in October. If the January Effect repeats, capital should reverse course in December – January.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Zimmer Biomet	31.22%	(2.87%)	Because of the merger with Biomet, ZBH will be reporting nearly a 60% sales jump for the September quarter.
2	2	Stryker	22.94	(4.21)	Very solid earnings report for Q3 and MAKO was a stellar performer. SYK is clicking along well. Time for another buy?
3	5	Johnson & Johnson	28.44	7.87	There was nothing in the DePuy Synthes report for Q3 which would support JNJ's rise. Institutions are parking $$ here.
4	4	Exactech	10.26	(5.03)	The least expensive equity in orthopedics. Lowest P/E, 2nd lowest PSR, 4th lowest PEG and future P/E.
5	8	Medtronic	27.92	6.35	Medtronic Spine continues to outperform expectations. But that's not why investors bid up MDT's value. Like JNJ, MDT is a safe haven for healthcare $$.
6	7	Smith & Nephew	20.19	(1.79)	SNN CEO Bohuon insists SNN can prosper without merging with a bigger company. Is he protesting too much?
7	9	Orthofix	2.35	(5.80)	VERY nice clinical data regarding the use of Trinity Cellular Bone allograft for foot and ankle procedures.
8	3	Integra LifeSciences	13.74	(13.76)	For Q3 analysts are expecting a slight rise in earnings on down sales. Last year, IART missed the Q3 estimates.
9	10	ConMed	10.78	(21.33)	CNMD's new management missed the Q3 earnings estimate by quite a bit and investors sold off. Analysts are recalibrating their models for CNMD.
10	NR	Globus Medical	30.19	(8.50)	With the recent sell off, GMED is now the 8th least expensive equity in ortho. With these kind of margins and 8-10% sales growth, GMED returns to the PR.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Johnson & Johnson	JNJ	$100.31	$277,769	7.87%
2	MicroPort Scientific	853	$0.43	$610	6.41%
3	Medtronic	MDT	$73.69	$104,169	6.35%
4	CryoLife	CRY	$9.87	$293	3.89%
5	Smith & Nephew	SNN	$35.19	$15,747	-1.79%
6	Zimmer Biomet	ZBH	$94.56	$19,230	-2.87%
7	Stryker	SYK	$94.44	$35,464	-4.21%
8	Exactech	EXAC	$17.57	$247	-5.03%
9	Orthofix	OFIX	$33.78	$637	-5.80%
10	Aurora Spine	ASG	$0.19	$5	-6.16%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	LDR Holding Corp.	LDRH	$23.74	$688	-38.55%
2	RTI Biologics Inc	RTIX	$4.76	$274	-22.22%
3	ConMed	CNMD	$40.34	$1,118	-21.33%
4	Wright Med. Grp N.V	WMGI	$19.40	$2,018	-18.14%
5	TiGenix	TIG.BR	$0.99	$167	-17.31%
6	K2M Group Hldgs	KTWO	$17.83	$737	-14.48%
7	MiMedx Group	MDXG	$8.88	$967	-14.20%
8	Integra LifeSciences	IART	$56.66	$2,066	-13.76%
9	Alphatec Holdings	ATEC	$0.32	$32	-12.33%
10	NuVasive	NUVA	$47.18	$2,309	-12.32%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Exactech	EXAC	$17.57	$247	15.69
2	Globus Medical	GMED	$21.74	$2,067	16.73
3	Zimmer Biomet	ZBH	$94.56	$19,230	17.19
4	Johnson & Johnson	JNJ	$100.31	$277,769	17.54
5	Stryker	SYK	$94.44	$35,464	20.50

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	CryoLife	CRY	$9.87	$293	82.53
2	NuVasive	NUVA	$47.18	$2,309	75.34
3	MiMedx Group	MDXG	$8.88	$967	59.20
4	Smith & Nephew	SNN	$35.19	$15,747	31.43
5	RTI Biologics Inc	RTIX	$4.76	$274	27.55

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$21.74	$2,067	1.47
2	ConMed	CNMD	$40.34	$1,118	1.62
3	Zimmer Biomet	ZBH	$94.56	$19,230	1.62
4	Exactech	EXAC	$17.57	$247	1.76
5	RTI Biologics Inc	RTIX	$4.76	$274	1.84

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$47.18	$2,309	5.07
2	MiMedx Group	MDXG	$8.88	$967	3.95
3	Medtronic	MDT	$73.69	$104,169	3.59
4	Johnson & Johnson	JNJ	$100.31	$277,769	3.54
5	CryoLife	CRY	$9.87	$293	2.75

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$0.32	$32	0.15
2	Exactech	EXAC	$17.57	$247	0.99
3	RTI Biologics Inc	RTIX	$4.76	$274	1.04
4	Xtant Medical Hldgs	XTNT	$3.29	$39	1.09
5	SeaSpine Hldgs Corp.	SPNE	$15.88	$176	1.27

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.99	$167	26.53
2	MiMedx Group	MDXG	$8.88	$967	8.18
3	Wright Med. Grp N.V	WMGI	$19.40	$2,018	5.85
4	Medtronic	MDT	$73.69	$104,169	5.14
5	LDR Holding Corp.	LDRH	$23.74	$688	4.61

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

The Nine Best New Spine Technologies for 2015

BY ROBIN YOUNG

The nine winning companies with the BEST new spine care technologies for 2015 were: 7D Surgical, Aspen Medical, Benvenue, Cytonics, Invuity, Lifenet Health, LinkSpine, SpineWave and Titan Spine.

Photo creation by RRY Publications LLC

Rewarding Innovation and Perspiration

This annual award rewards inventors, engineering teams, surgeons and their companies who've created the most innovative, enduring and practical products in 2015 to treat back pain. To win the *Orthopedics This Week* Best New Spine Technology Award for spine care, a new technology must meet the following criteria:

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

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

We and our panel of surgeons were impressed that inventors—despite ever growing hurdles to innovation and entrepreneurism in spine—still managed to create a solid group of nearly 40 new products to submit for the 2015 *Orthopedics This Week* Spine Technology Awards.

Submitters

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 below.)*

7D Surgical Inc.	Aspen Medical Products	Atlas Spine, Inc.	Augmenta Spine
Aurora Spine, Inc.	Benvenue Medical, Inc.	Biomet Spine	BioStructures, LLC
Cytonics Corporation	DePuy Synthes Spine	Genesys Spine	Intelligent Implant Systems, LLC
Invuity, Inc.	K2M Group Holdings, Inc.	Lifenet Health and DePuy Synthes	LinkSPINE
Medicrea USA	Medtronic Spinal & Biologics	Mighty Oak Medical	Misonix, Inc.
NLT SPINE	Orthofix	Ouroboros Medical, Inc.	Prosidyan, Inc.
Ranfac Corp.	Replication Medical, Inc.	SafeRay Spine, LLC	SafeWire
Simplify Medical, Inc.	Spinal Simplicity	Spine Wave, Inc.	Titan Spine LLC
Vexim	Xtant Medical		

The Judges

Our intrepid and detailed panel of surgeon judges included:

Frank M. Phillips, M.D. *Professor, Director, Section of Minimally Invasive Spine Surgery, Rush University Medical Center.* Dr. Phillips specializes in minimally invasive cervical and lumbar reconstructive surgery. He also has expertise in motion preserving procedures and was a principle investigator in FDA trials on cervical disc replacement. Dr. Phillips is a leader in the field and is a founder, board member and past president of the Society of Minimally Invasive Spine Surgery. Dr. Phillips has participated in the development of and pioneered a number of minimally invasive spinal techniques that are now widely used. He regularly teaches and lectures to spine surgeons nationally and internationally on minimally invasive spinal surgery. Before coming to Midwest Orthopaedics at Rush in 2003, Dr. Phillips served as the director of the Spine Center at The University of Chicago and as a former member of the board of directors of Kyphon, Inc.

Steven Garfin, M.D. *Chair and Professor of Orthopedic Surgery University of California San Diego.* Dr. Garfin has been involved in the design and assessment of new surgical techniques and instrumentation to treat spinal disorders. These include lumbar and cervical anterior plating systems, kyphoplasty to treat painful osteoporotic vertebral fractures, artificial discs, and biologic alternatives to bone grafts. His work has contributed to the development of current international standards in surgical care of the spine. Dr. Garfin has received multiple awards for research, teaching, and clinical care. He has published more than 260 articles, authored 123 book chapters, and edited nine books. Dr. Garfin has served as president, board member or program chair for each of the following national and international surgeon: American Academy of Orthopaedic Surgeons, American Orthopaedic Association, Cervical Spine Research Society, North American Spine Society, the International Society for the Advancement of Spine Surgery.

Stephen Hochschuler, M.D. *Co-founder and Chairman of the board of*

the Texas Back Institute. A graduate of Columbia College in New York, Dr. Hochschuler received his medical degree from Harvard Medical School. Dr. Hochschuler has been in private practice since 1977 and is licensed in seven states. In addition, he is a clinical instructor at the University of Texas Health and Science Center Southwestern Medical School. He has founded several medical-related companies. Dr. Hochschuler is a member of numerous national and international professional organizations including the American Academy of Orthopedic Surgeons; the American Pain Society; North American Spine Society; and the Southwest Chapter of the Society of International Business Fellows. Internationally, he is a member of the International Intradiscal Therapy Society; the International Society for Minimal Intervention in Spinal Surgery; the International Society for the Study of the Lumbar Spine; and is a founding board member of the Spinal Arthroplasty Society. He has also been a founding board member of The American Board of Spine Surgery and The American College of Spine Surgery.

James D. Schwender, M.D. *Spine surgeon at Twin Cities Spine Center* and has served as president for the Society for Minimally Invasive Spine Surgery. He is a fellow of the Scoliosis Research Society and member of the North American Spine Society. In addition to his clinical practice, Dr. Schwender is one of the most prolific and respected researchers in spine surgery care. His presentations on minimally invasive spinal trauma surgery, biologics in lumbar fusion and safety in spinal procedures are a fixture at many surgeon society meetings. Dr. Schwender earned his medical degree at State University of New York and completed his residency in orthopaedic surgery at the University of Vermont. He was recently selected by his peers as one of the top 28 spine surgeons in the United States.

So, without further delay, here are the nine best new spine technologies for 2015 arranged in alphabetical order.

Continued on page 7 >>

7D Surgical Inc. — Envision 3D™: Image Guidance System

Inventors: Victor Yang, M.D., Ph.D., PEng, FRCSC, Beau Standish, PEng, Ph.D., Adrian Mariampillai, Ph.D., Michael Leung, MSc, Peter Siegler, Ph.D.

(L to R) Beau Standish, Ph.D., P.Eng., Robin Young, Victor Yang, M.D., Ph.D., P.Eng

Envision 3D™ is an all optical intraoperative 3D image-guided surgical navigation system which does NOT have x-ray radiation. That's right, no radiation. 7D's image-guided surgical technology incorporates the form factor and function of the operating room surgical light and shines a special pattern onto the exposed patient anatomy. While this pattern is not visible to the operating room staff it **is** detectable by 7D's Aurelia device which then creates a highly accurate and detailed 3-dimensional surface.

In just seconds, the intraoperative image is registered with the patient's pre-operative CT or MRI scan.

Now, for the first time, surgeons can have real time 2D or 3D visualizations of the patient's anatomy overlaid with the spatial positioning of the surgical tools with, again, no radiation. And with no diminution of image accuracy and detail.

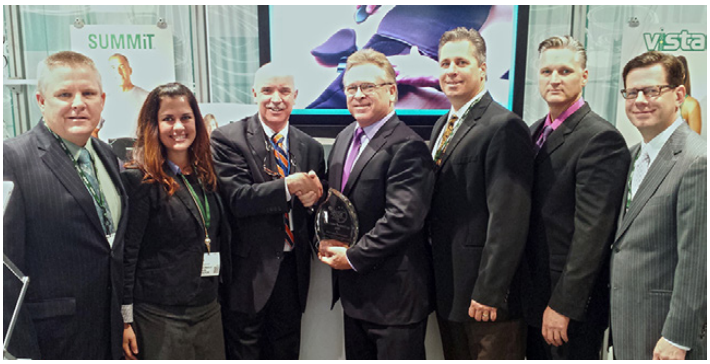
Set up time for the Envision 3D™ is 1-2 minutes versus 15-30 with other imaged guided surgical navigation systems. Faster workflow, easier usability, extreme accuracy and no radiation risk.

No wonder Envision 3D™ from 7D is one of the best new technologies in spine for 2015.

Aspen Medical Products — Peak Scoliosis Bracing System

Inventors: Joel Perez, Geoffrey Garth, Steven Burke
Engineering Team: Pawel Buczek, Joe Horvath

The Peak Scoliosis Bracing System is a new type of bracing system which applies force to the patient's spine by way of thoracic and trochanter pads on one side of the brace and by the belt, with or without a lateral pad, on the other side. The applied forces of this unique brace synergistically promote better alignment, reduced body lean and maximum pain relief.



(L to R) Tom Manix, Jennifer Ketchersid, Robin Young, Dan Williamson, Andrew Purner, Colin Cashin, Jeff Freed

The brace's SlickTrack tightening system has an independent upper and lower mechanism which delivers direct compression where needed. As the patient tightens the brace, the back panel naturally conforms to the patient's lordosis.

Fundamentally, the Peak Scoliosis Bracing System is an unloader brace for the spine. It uses a traditional 3-point pressure system but does not rely on anterior or posterior struts. This minimalist structure allows the Peak system to be positioned unobtrusive laterally, beneath the arm.

Each brace is fit to the patient.

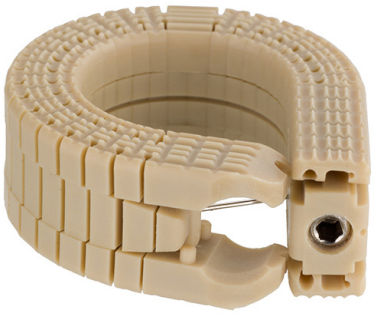
Benvenue Medical, Inc. — Luna 360 Interbody System

Inventor: James Lee, Jeff Emery, Laurent Schaller

Engineering Team: Andrew Huffmaster, Doug Lorang, Tim McGrath

(L to R) Jeff Emery, Rob Weigle, Robin Young, Rick Simmons

Benvenue's Luna 360 is an expandable PEEK-OPTIMA interbody implant that forms an ALIF footprint from a mini-open or MIS posterior approach. It is designed to deliver anterior column stability, strength and fusion with minimal neural retraction.



One of the Luna's key features is that it has a controlled, non-impaction delivery capability and a generous graft window that allows the surgeon to insert bone grafting material post expansion. This is a very important attribute as any spine surgeon can attest.

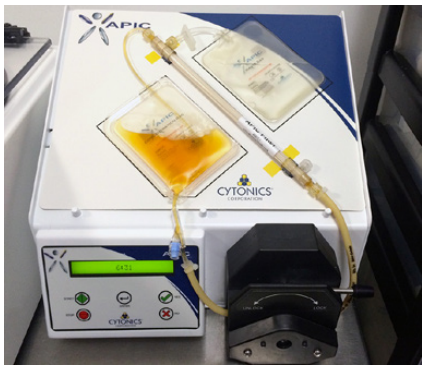
But words alone can't convey the uniqueness of the Luna 360 invention. Here is what it looks like. In particular, notice the footprint and that huge interior space for bone graft material.

The differences from currently available expandable interbody cages should be immediately obvious—as they were to this year's spine award judges.

Cytonics Corporation — Autologous Protease Inhibitor Concentrate (APIC) – CF System

Inventors: Lewis Hanna, Ph.D., Shawn Browning, Ph.D., Gaetano Scuderi, M.D. Katie Dent

(L to R) Shawn Browning, Ph.D. and Gaetano Scuderi, M.D.



The APIC-CF is a system for concentrating and purifying the naturally occurring serum protein Alpha-2-Macroglobulin (A2M) from a patients' blood at point of care. A2M is a potent inhibitor of ALL KNOWN enzymes that degrade collagen and proteoglycans in cartilage. Importantly, in vivo efficacy of the APIC-CF was demonstrated to inhibit osteoarthritis in a rabbit model. The ability of APIC-CF to inhibit the protease and catabolic enzymes involved in collagen and proteoglycan degradation in cartilage has shown that APIC-CF is also efficacious at inhibiting the proteoglycan degradation inherent in disc degenerative disease (DDD)

A study of 24 patients with lower back pain and MRI positive for DDD were treated with concentrated autologous A2M with highly positive outcomes. The 13 males and 11 females were first tested for a biomarker associated with lumbar disc disease (fibronectin-aggrecan complex or FAC). Twelve discs were FAC positive in 10 patients out of 40 discs tested. When A2M was injected in FAC positive patients, the VAS improvement was 4.9 +/- 0.9, versus 1.5 +/-1.2 in patients with negative FAC. Similarly ODI scores in patients treated with A2M improved an average 37 +/- 9.3 points in FAC positive patients versus 9.4 +/- 11.9 in FAC negative patients.

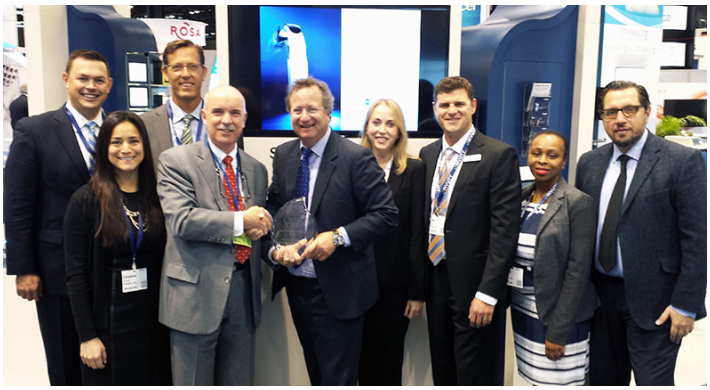
Cytonic's products bridge the gap between the presence of a biomarker for DDD pain and clinical outcomes. APIC-CF is a true theranostic and has widespread implications for disruptive treatment of degenerative disc disease.

Invuity, Inc. — Waveguide XT System

Inventors: Alex Vayser

Engineering Team: Michael Boutillette, Vladimir Zagatsy

The Waveguide XT is a "Drop-In Illuminator" meaning that it can ride along your retractor (it is compatible with any retractor) to shine brilliant, thermally safe light anywhere along the incision to illuminate the entire surgical cavity.



Lindsey Fujita, Greg Brown, Paul Davison, Robin Young, Philip Sawyer, Brett Robertson, Mark Miles, Iesha Powell, Alex Vayser

Think of it. For the first time a surgeon can direct light—cool, brilliant, bright—into and throughout the entire surgical cavity by way of attaching the light source to the actual instruments like retractors.

The core technology behind these remarkable technologies as Invuity's patented Photonic technology which directs and shapes lights into broad, uniform, volumetric and thermally cool illumination. The light output comes via fiber optic cable which is coupled with a solid core optical polymer to maximize light output while minimizing heat. The complex geometry of the cable's microstructures eliminates shadows and glare. Result: broad, uniform and brilliant, redundant illumination where you want it. In the surgical cavity.

LifeNet Health & DePuy Synthes — ViviGen

Inventors: Silvia Chen, Roberto Bracone, JingSon Chen

Engineering Team: Bart Gaskins, Dennis Phelps, Payal Sohoni, Joe Peterfeso, Mike Tyskowski, Mark Evans, Heather Germany, John Hartzell

Heather Cannon, Roberto Bracone, Barton Gaskins, Payal Sohoni, Rony Thomas, Robin Young, Heather Pierce, John Spranger, Pam Kasanowsky, Michelle Mahoney, Daniel Osborne, Silvia Chen, Ph.D., Jeff May, Tom Sanders, Patrick Gazzolo, Mark Moore

ViviGen is the first cellular allograft to focus on recovering, processing and protecting viable lineage committed bone cells. New evidence supports the use of bone cells instead of MSC's for bone healing. It is made of viable cryopreserved cortico-cancellous bone matrix and demineralized bone. Because of its properties, ViviGen can be considered to be an alternative to autograft.

The key to ViviGen's ability to achieve the highest level of bone cell viability and to identify factors that might reduce cell viability is LifeNet's care in selecting the right cell lineage, processing the allograft from recovery to implantation which maintains cell viability and, finally, the meticulous way in which LifeNet scrutinizes each processing step.

Finally, ViviGen's bone cells are preserved for grafting in the operating room in such a way as to maintain 96% cell viability post-thawing.

LinkSPINE — FacetLINK HEMI

Inventors: Harm-Iven Jensen, Helmut D. Link

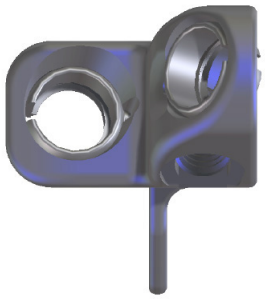
Engineer: Harm-Iven Jensen

FacetLINK HEMI is a rigid plate which has been designed in such a way that the surgeon can cross-connect the transfacet pedicle screw on the ipsilateral side of a microdecompression to a translaminar facet screw on the contralateral side.

(L to R) Isabell Castro, Robert Jay Jones, Massimo Calafiore, Fabian Schöllchen, Robin Young, Brad Alger, Dennis Farrell, Dr. Christopher Chaput, Nick Kriska, Juliana Castro, Len Tokish, Gretchen Snow, Riccardo Signoretti

In short, FacetLINK HEMI is a very unique, less invasive way to stabilize the spine following a unilateral microsurgical decompression approach.

Bilateral decompression is an increasingly popular approach since it significantly reduces surgical site morbidity. LinkSPINE's new FacetLINK HEMI offers more functionality to this MIS approach by giving the surgeon instrumentation which can access the surgical site via the same incision and facilitate the crossover technique.



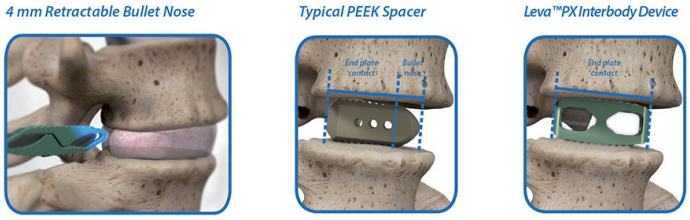
Again, FacetLINK HEMI allows the surgeon to perform the crossover technique via the small, bilateral decompression incision. This less invasive approach avoids the lateral soft tissue dissection and retraction which is otherwise necessary to implant conventional, pedicle screw based instrumentation.

SpineWave — Leva™ PX Interbody Device

Inventors: Hughes Malandain

Engineering Team: Hughes Malandain

(L to R) Peter Barreiro, Claire Battista, Robin Young, Hugues Malandain and Ty Hollister



The Leva PX is an expandable titanium interbody cage which has been designed in such a way as to optimize the surgeon's ability to insert maximum amounts of bone graft material. Being that it is titanium, the Leva PX is structurally strong and being expandable it also helps to restore disc height.

Words aside, the picture really tells the story of this very different implant.

The Leva PX is a one-piece titanium implant (far left image) which opens up (no gears, no screws) into a spacer (far right image). Up to 68.5% of the implant volume can be packed with bone graft material. And the surgeon can also pack bone graft into the surrounding, evacuated disc space.

Finally, the Leva PX has a 4mm Retractable bullet nose which makes for easy insertion.

Titan Spine LLC — nanoLOCK Surface Technology

Inventors: Mark Berg, Jennifer Schneider, Peter Ullrich, Chad Patterson

Engineering Team: Michelle Gallagher, Kelly McDonnell, Kenneth Ruggow

(L to R) Mark Berg, Robin Young, Jennifer M. Schneider

Many companies talk nanotechnology, but only Titan Spine's nanoLOCK has the FDA imprimatur for nanotechnology. And this year's panel selected it as one of 2015's best technologies for spine surgery.

Titan's nanoLOCK surface technology provides texture at the nano scale as well as the macro and micro scales and that particular ability has been shown in numerous studies to upregulate osteogenic and angiogenic growth factors. Who needs BMP2?

Titan's next generation nanoLOCK surface technology will be commercially launched in Q4, 2015.

The great promise of putting this type of surface technology at the nanomaterial level is faster bone healing and angiogenesis following interbody fusion surgery. This approach works at the cellular level through a biochemical process. It is, fundamentally, an active participant in the fusion process.

Again, this is the **first** FDA-cleared nanotechnology for the treatment of spinal disease. In addition, the core material is titanium and titanium alloys, which are well known to deliver superior biocompatibility and mechanical properties to implants in the spine. Now, with nanoLOCK, it also delivers osteogenesis and angiogenesis. ♦

Syria to HSS: One Physician's Journey

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

Syria. It's in the headlines every day. But there is a Syrian in New York City who doesn't read such things. For now, at least, he must put his head down…and read medical journals.

The following is a story of unusual trials, a long journey, and an outstanding level of dedication to patient care and to the pursuit of a better life.

Bassel Diebo, M.D.

His life in Syria was unpredictable and terrifying. To survive a day was a creative endeavor. Sometimes there was no anesthesia for his patients. At times, bombs fell around his hospital as he tried to pull shrapnel out of someone's leg. But even as Bassel Diebo, M.D. cared for the patient in front of him, he knew that he would find a way out of the madness.

Bassel Diebo, along with his two younger brothers, grew up in Latakia on the Mediterranean Sea. His father is a pharmacist and his mother devoted herself solely to the care of her children. After finishing high school at the National Private School of Latakia, he relocated and began studying at the Aleppo University, School of Medicine. At the age of 26, Dr. Diebo left Syria after completing two years of training in general surgery at Ibn Al Nafees Hospital in Damascus, the capital of Syria. Ibn Al Nafees is a busy hospital affiliated with Syrian Ministry of Health that is located at the border of Damascus and the suburbs. This makes it the hospital of choice for emergency cases coming from Damascus' hot zones. Now, at the age of 29, Dr. Diebo is a postdoctoral fellow at Hospital for Special Surgery (HSS), Dr. Diebo is solidly focused on his promising new life and on the future. Describing the origin of this journey, Dr. Diebo tells *OTW*, "Before all hell broke loose I had been communicating with Elian Shepherd, M.D., an orthopedic spine surgeon in Merryville, Indiana. Eventually, our clinical discussions turned to my future. Given that I could not envision a future as a physician in Syria, Dr. Shepherd said to me, 'If you can get here, you will have one.'"

"There is no American embassy in Syria, so I went to the German embassy. When they told me that it would be eight weeks before I could obtain a visa, I traveled to Jordan and presented myself at the American embassy in Amman. Two weeks later I was on a plane to a new life in Merryville, Indiana. That was Christmas 2012."

"When I landed in Dallas for a layover, some guy stopped me and asked if I was alright. I guess nearly two years of war and strife were evident."

"In order to function well and integrate into my new life, I had to disconnect from Syria…no news, nothing. I began

observing Dr. Shepherd at Methodist Hospital and stayed there for seven months. I learned what the expectations were for interacting with patients, something that is pretty different than in Syria. The quality of care is so much better here, and it was truly refreshing to see that bedside manner is viewed as a very important part of clinical care. At that time I would observe two or three cases in the OR per day, then help out in the spine clinic the rest of the day."

"In March 2013 I attended the annual meeting of the American Academy of Orthopaedic Surgeons and met Dr. Virginie Lafage of New York University, who basically interviewed me in the hallway. She asked, 'Do you have a research background?' 'No' 'Have you contributed to any publications?' 'No.' I had one PowerPoint presentation to my name. But then she dug further and discovered that I am a very motivated learner. 'I will give you a trial,' Dr. Lafage said."

Dr. Diebo did not disappoint. He moved to New York in October 2013, passed her trial, and settled in at NYU to begin conducting spine research. Today, he has had his name on nine publications, several chapters/books and has been on 'the podium' at numerous scientific conferences including the American Academy of Orthopaedic Surgeons and Scoliosis Research Society annual meetings. He is a reviewer for American and international spine journals. "I loved it," he says. "There was an incredible team, but no one worked harder than Dr. Lafage. Her passion for excellence meant that she often didn't leave the lab until 3am. I made sure that I didn't leave until she did. I grew a lot at NYU."

Dr. Diebo, who passed the first part of the United States Medical Licensing Examination (USMLE) last month, says, "Dr. Frank Schwab, the new chief of spine at HSS, has also been a stellar role model for me. He and Dr. Lafage asked me to join them at HSS and here I am. After taking the second part of the USMLE I plan to apply for a spine residency (either through orthopedic surgery or neurosurgery). I enjoy trauma surgery because I like the instant decisions that you have to make. And I certainly had to make many of those as a doctor in Syria."

Asked to reflect on how his early years as a physician may differ from those of his American colleagues, Dr. Diebo paused, then said. "Syria was tough. I think that I have been tested more than most physicians my age."

As for going home to work in Syria, Dr. Diebo says it would be enormously difficult to return. "There are too many factors that get in the way. Aside from the war, the politics and the lack of resources profoundly inhibit the lives of physicians. To practice good medicine, how much money are decision makers willing to pay for research? How much are they willing to pay to improve the quality of care? The answers are '0' and '0.'"

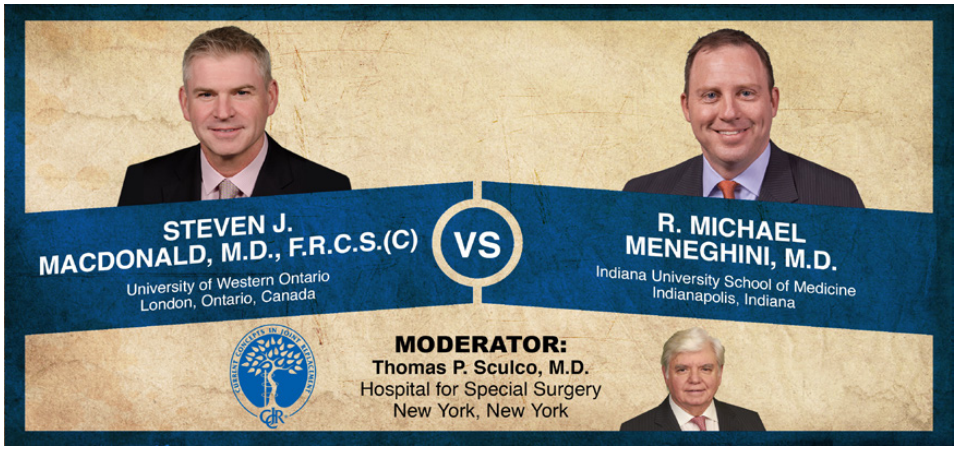
"My physician colleagues from Syria and I just want this war to end. While it is hard to encourage people to leave, I will say that if they ever decide to do so they will find the community here and in Europe welcoming. Maybe it is a Syrian thing, but we like to help… and when we come to a new community we try our best. I encourage research and clinical programs to take a chance on my Syrian colleagues. Frankly, I think we are so grateful to have a chance in the U.S. that we are willing to outwork anyone around us and do our absolute best."

"I am so grateful to the American government for giving Syrians a chance to work and have a temporary protective status. In this land everything is possible. I was very fortunate to connect with Drs. Lafage and Schwab as they have the rare gift of knowing how to empower others. With the HSS team, I am part of the International Spine Study Group (ISSG), which is one of the world leaders in spine research and innovations. Life is inclusive here…you just have to show motivation and honesty." ◆

MacDonald v Meneghini: Femoral Head Materials: *No Difference in Outcomes*

BY OTW STAFF

This week's Orthopaedic Crossfire® debate was part of the 16th Annual Current Concepts in Joint Replacement® (CCJR) – Spring meeting, which took place in Las Vegas this past May. This week's topic is "Femoral Head Materials: No Difference in Outcomes." For the proposition is Steven J. MacDonald, M.D., F.R.C.S.(C), University of Western Ontario, London, Ontario, Canada. R. Michael Meneghini, M.D., Indiana University School of Medicine, Indianapolis, Indiana opposing. Moderating is Thomas P. Sculco, M.D., Hospital for Special Surgery, New York, New York.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. MacDonald: This debate is about whether we should be using a cobalt chrome head or a ceramic head. If you look at the bearing selection and where we are in 2015, it's interesting. Six or seven years ago, hard-on-hard bearings, metal-metal, ceramic-ceramic were almost one-third of the U.S. market and a good portion of the global market too. Today, however, the vast majority of primary total hips are highly crosslinked polyethylene and the head mix is about 50% cobalt chrome, 50% ceramic.

So what about the femoral ball? What should we be doing there? The Australian Registry's most recent report has a quarter of a million primary total hips in it which are broken down by type of bearing surface and basically the best performing bearing with the lowest 10-year cumulative revision rate remains cobalt chrome on highly crosslinked polyethylene at 4.3%. Ceramic-on- highly crosslinked polyethylene data was similar at 4.6%. Those are the numbers from a big national registry database. We also learned from the Australian Registry that ceramic-on-ceramic larger heads did well. Also metal-on-metal smaller heads did well. Highly crosslinked polyethylene, there seems to be a little bit of a sweet spot with a 32mm head having the lowest cumulative revision rate. So the 32mm head is 3.8% and both the 28mm and 36mm are about 1% point higher.

The trends in Australia are very similar to what you see in the U.S. Decreased use of cobalt chrome, increasing use of ceramic. But not all ceramics are created equal. Really what we're talking about is the Delta ceramic head. So why choose a Delta head over a cobalt chrome head? I've already explained there's no evidence for decreased revision rate and there's lots of registry data around the world and case reports showing the same thing. So you can't claim a decreased revision rate using a Delta head. I think really there's no evidence for decreased clinically relevant wear rates. Obviously, we don't know what the 25-30-40 year experience will be, but after two decades, almost, of use…15-16 years of highly crosslinked polyethylene both are performing exceeding well.

One of the main issues is that the Delta ceramic head comes at a significant price premium. In my institution, it's a $600 upcharge, and you might think that's pretty cheap, that's Canadian market, but that's a 2.5 times upcharge over what it would cost for a cobalt chrome head. So why choose Delta over cobalt chrome?

One answer to that question is trying to minimize the risk of taper corrosion. This came to light with the Rush publication three years ago. Does a ceramic head decrease the risk of trunion corrosion? I would put it to you that in 2015 we have absolutely no idea quite frankly. Let's be very clear regarding corrosion. It's multi-factorial. Likely ball diameter,

taper design, contact area, preparation of the taper, impact force. All of these things probably have somewhat of a mitigating role.

Delta ceramic is not the ultimate solution. Pseudotumors have been described with the Delta ceramic. Prosthetic head femoral fracture rate—quite frankly, it's pretty uncommon with the current generation of ceramic heads. The Australian registry reporting 1 in 70,000 Delta heads.

In summary, those choosing a Delta head…they don't have clinical evidence of superiority, they are hoping for a lower corrosion rate and somehow accept the cost differential. I think those choosing a cobalt chrome head are probably just inherently more intelligent.

Dr. Meneghini: I think as we know ceramic and cobalt chrome femoral heads both have a long history of success and survivorship. There's minimal difference between the two on wear rates, osteolysis, and survivorship. Paul Lachiewicz just reported at the Hip Society meeting a wear rate of 0.027 mm/year with cobalt chrome heads on highly crosslinked polyethylene. There are small osteolytic lesions but good wear rate at 10-14 years.

The Australian Registry data shows that highly crosslinked polyethylene with cobalt chrome and ceramic femoral heads are very, very similar. The 2012 Norwegian Registry Alumina ceramic 92.3%, and cobalt chrome, just slightly better at 94% survivorship at 8 years. No dramatic difference between the two.

Let's talk about the trunion. Trunionosis has re-emerged as a failure mechanism in total hip arthroplasty. We're still struggling to figure out the incidence. We're still struggling to find out the etiology. Bearing friction torque's an option. The mechanical stresses we know relate to it. It's a mechanical phenomenon that starts in the taper geometry with implant stiffness, high offset stems and large heads all playing a role.

As Steve mentioned, it just came to light in JBJS-Am 2012 (Cooper et al.)—10 patients, 3 different manufacturers, and varying degrees of soft tissue necrosis. And all of us in our practices were seeing it to a certain degree. Then just recently Carli et al. (Hip Int 2015) decided to go look and see if they could cumulate the total incidence in the peer-reviewed literature and came up with 778 cases in 24 articles.

There was a correlation with large heads and small tapers, and universally the treatment was a conversion to a ceramic head and a polyethylene liner. That's how

you treat the problem and you'll see that consistently. McGrory just reported on a consecutive series, one manufacturer, but a variety of stems, over 1,000, with a 1.1% incidence of head-neck corrosion and associated with an adverse local tissue reaction (ALTR). Three patients had irreversible tissue damage. You can factor that into your cost benefit analysis. And the authors recommended ceramic heads. The other thing I would make you aware is that fretting corrosion is a time-dependent phenomenon. The longer those tapers are in contact, the greater chance it will occur as the years go by.

There is some biomechanical data to support the increased stresses on these tapers. It was published in 2006, out of the Harvard group…larger head diameter against highly crosslinked polyethylene. All transmit greater forces to the taper. We have similar work that we presented along the same lines.

Another biomechanical study (Schmidig, et al., J Arthroplasty 2010) showed that increased head size raises the frictional torque. So again, you're transmitting those forces to the taper. I agree we don't know the incidence yet, but it's a phenomenon we should be concerned about. At least be aware of.

We have some retrieval data also supporting this. Journal of Arthroplasty, 2013, 36mm heads had greater fretting corrosion compared to 28mm cobalt chrome heads. So you're seeing some similarities. It's not that we haven't narrowed it down completely…we're getting closer to it…but there are some factors that we have to consider and I think most of us still use larger femoral heads when we can. So that factors into our bearing choice as well.

And then as Steven mentioned, the Steve Kurtz article looking at ceramic corrosion risk, there was less fretting corrosion in the ceramic heads compared to the cobalt chrome heads. It's not a matter of argument at this point. We know ceramic corrodes less.

Ceramic head fracture…I think Steve gave up on that one…there's no doubt the fracture risk is very minimal with the newer versions and the registry data supports that very clearly.

In summary, there's no difference between ceramic and metal heads with respect to wear rates and osteolysis, and there's currently no registry difference in survivorship between the

ceramic and metal heads, at this current time. As we continue to follow it, and as people become more educated on that painful hip that they decide to dismiss and get out of their clinic… when we start to see that those patients may have an issue that we originally weren't familiar with, this data may change over time.

Moderator Sculco: Steve, in your current practice, what percent of your femoral heads are ceramic and what percent are cobalt chrome? And what's your selection criteria?

Dr. MacDonald: In our current practice, 98% of the time we're using a cobalt chrome head. People in their 40s and 30s we use a Delta head.

Moderator Sculco: You've been doing joint replacement for many, many years, what's your gut about corrosion?

Dr. MacDonald: I think there's been two prime drivers—change from 28mm heads to 32-36mm and that does put increased stress on the taper. And there's been subtle taper changes that haven't been fully disclosed to maximize, if you will, the way a ceramic head fits. But I also think it's a multitude of things, quite frankly, that have led to this. We've always seen corrosion. If anybody's been a revision surgeon… we've always seen it. So it's not new. The issue is we're seeing reports of corrosion two years, three years, the reason driving the revision is the soft tissue reaction. That's new. I certainly did not ever see that described until the last 2-3 years. I wouldn't have seen that 5-10 years ago—never a case.

Moderator Sculco: So Michael, you use ceramic in everybody. Is that correct?

Dr. Meneghini: Yep.

Moderator Sculco: How do you justify that to your hospital administrators when, as Steve pointed out, the cost is so much greater?

Dr. Meneghini: Yeah, I actually feel very, very strongly about this. We have a gain sharing program where we share in the profitability of our cost savings measures and I still use ceramic heads

because I believe it's the right thing to do. I think that series from McGrory is a good sort of beginning—over 1,000 hips and he followed them for a long time with about a 1% incidence. That's not huge. But it's something I don't want to deal with, so if I have a choice and I can minimize 1% complications in my patients, I absolutely will do that. And I'll justify it to my administrators that way.

Moderator Sculco: The cost will be considerably greater though for that little 1% potential problem. Don't you think?

Dr. Meneghini: Yeah, can't get away from it. Sometimes we have to spend money. I know nowadays we don't want to spend any money, but at some point, you have to bear the cost of a good outcome. If any of you have been in surgery where the abductors are gone and you see the soft tissue destruction from a reaction, it's pretty horrific and I think that's what we want to avoid if we can.

Moderator Sculco: What do you do when you revise a patient who has corrosion? You get in there and there's corrosion along the trunion, you have a low threshold for actually removing the stem? Do you just change the head?

Dr. Meneghini: In general, if we can keep the stem, then we will, but if the corrosion is really severe and the taper is badly damaged, we pull it.

Moderator Sculco: You pull it out. And what's your go to head of choice at that point? Ceramic?

Dr. Meneghini: Ceramic, of course.

Moderator Sculco: What's your thought on that, Steve? You're going to go back in. There's a little bit of damage on the trunion. It's not very great. How do you handle that? You don't think it's bad enough to take the stem out.

Dr. MacDonald: I would leave the stem. Do a ceramic head with a titanium sleeve. Let's face it. Taking out a cementless stem, it can go really well, and it can go really poorly. And the ones that go poorly, functionally they're not quite exactly the same. We don't know the long-term answer of the titanium sleeve on the Delta head, but that's what I would do to get the best short-term patient outcome.

Moderator Sculco: Very good job. ♦

Please visit www.CCJR.com to register for the 2015 CCJR Winter Meeting, December 9 - 12 in Orlando, Florida.

COMPANY

Stryker's Solid Quarter – MAKO Cruising

Stryker Corporation's orthopedics business grew by 5.8% on a constant currency basis, reaching $1.019 billion in the third quarter.

Knees and hips were up over 3%, while trauma and extremities climbed by 9.1%. Spine was slower, growing only 1.9%. Sales were impacted negatively by 5.5% due to impact of foreign currency. Net sales included a 7.7% increase in unit volume, partially offset by 2.2% lower pricing.

Stryker Corporation 3Q15	Sales $ in million	% Change*
Orthopedics Sales	**$1,019**	**5.8%**
Knees	$331	3.5%
Hips	$309	3.1%
Trauma/Extremities	$320	9.1%
Spine	$184	1.9%

Source: Stryker Corporation
** In constant currency*

The Robots

The company sold 17 MAKO robotic systems during the third quarter and is preparing for a limited launch of its total knee application after gaining FDA approval in August. Those sales bring the year-to-date total to 41, in both existing and new competitive accounts. The company anticipates that the majority of the MAKO installed base will be updated with the total knee software and be fitted with the necessary hardware by the end of 2016.

Recon Market

Based on results from DePuy Synthes and Stryker (and estimates of others) Needham & Company analyst Mike Matson estimate that the recon market grew by 2% during the quarter versus 1% in the second quarter on a constant currency basis. He estimates that global knee growth was 2% and global hip growth was 2% in the third quarter. That means Stryker was taking some market share in hips and knees.

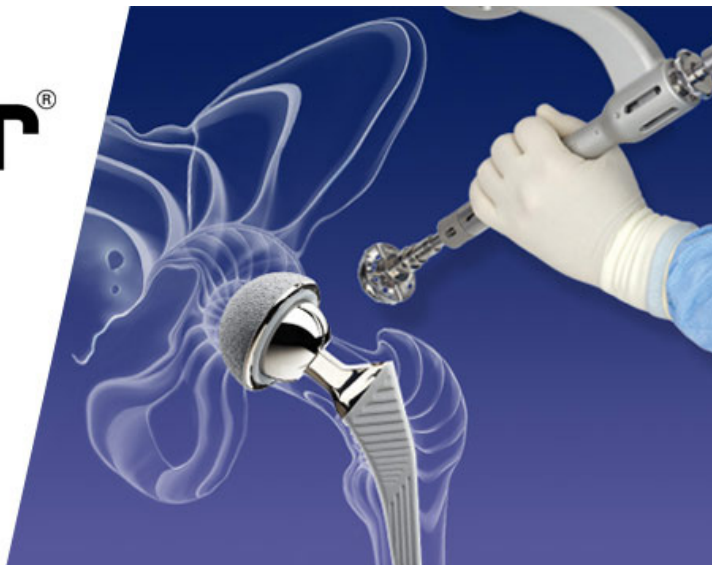
BMO Capital Market analyst Joanne Wuensch said orthopedics is a tale of two geographies this earnings season. In the U.S., Stryker sales were up 9% (despite facing tough comps), with trauma and extremities up 15% (including foot and ankle up nearly 20%); hips, up 5.7%; and knees, 5%.

The U.S. 6% spine growth slowed from the previous year, but management is happy with the business unit's momentum. U.S. spine implants were up mid-single-digits driven by recent new product launches.

Outside the U.S., it was a different story, said Wuensch, as sales (on a constant currency basis) were up just 0.5%, trauma and extremities were up 1.5%; hips, down 0.4%; and knees, up 0.2%. Wuensch added that the foreign sales story was different for each large orthopedic company. "For Stryker, Europe 'had a terrific quarter,' delivering mid-single-digit growth, but tougher macroeconomic issues in China and Brazil weighed on the segment."

Stryker management maintained its 2015 organic sales growth guidance of +5.5% to +6.5%.

"We delivered another solid quarter with organic sales again exceeding 5%," said Kevin A. Lobo, chairman and CEO. "I am pleased with our disciplined execution as we work with our customers to make healthcare better." — *WE*



Courtesy of MAKO Surgical and Stryker

K2M Jumps Into 3D Printing

K2M Group Holdings is getting into the 3D printing business using titanium powder.

The company introduced Lamellar Titanium Technology at the 2015 North American Spine Society (NASS) Annual Meeting in Chicago.

Titanium Powder

The technology, according to the company, starts with a titanium powder where the implants are grown through the selective application of a high-energy laser beam, allowing for the incorporation of both a porosity and surface roughness that pre-clinical data have associated with bone growth activity.

The first products to use the technology are the Cascadia AN and TL Interbody Systems. The company recently received 510(k) clearance from the FDA and a CE Mark in Europe for those systems.

Tom Morrison, M.D., a neurosurgeon at Polaris Spine & Neurosurgery Center in Atlanta, Georgia, said this technology is an, "innovative alternative" to many traditionally manufactured PEEK and titanium designs in the interbody space. He added that the Cascadia platform provides a balance of roughness and porosity that may allow the bone to grow into the implant.

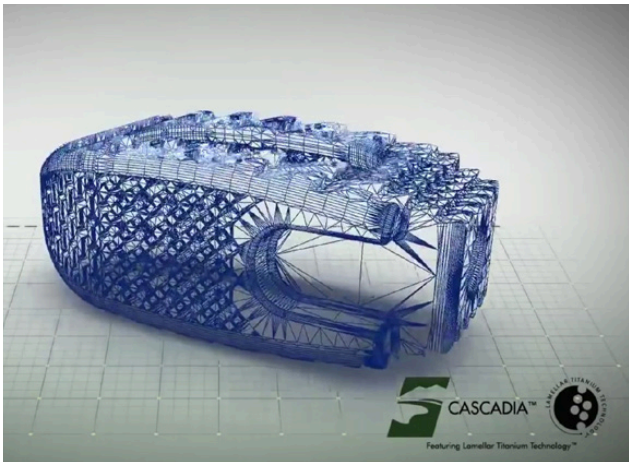
Technical Specifications

The company says the technology incorporates titanium with a surface roughness of 3–5 microns that is designed to allow for direct bony ongrowth. "This surface roughness has been shown, in peer-reviewed research and pre-clinical data, to increase osteoblastic activity compared to smooth titanium and other biomaterials, such as PEEK."

Interconnected pores in the diametrical range of 300–700 microns, according to research cited by the company, are ideal for allowing bone ingrowth through porous biomaterials. K2M's technology incorporates 500 micron diameter pores that run through the walls of the implant, forming continuous channels from endplate to endplate to serve as a conduit for bony integration.

The Cascadia systems, according to the company, have been designed with radiographic imaging quality in mind. The porosity inherent with the technology in conjunction with the proprietary design of the Cascadia interbodies "results in an approximately 70% porosity overall, and therefore a decreased radiographic signature when compared to equivalent traditional nonporous titanium designs."

Eric Major, K2M's president and CEO, called it a "breakthrough technology." — *WE*



K2M Group Holdings

BIOLOGICS

Bold Trial Targets Osteogenesis Imperfecta in Fetuses

A bold new clinical trial will begin in January when doctors inject stem cells into fetuses in an attempt to ease the symptoms of osteogenesis imperfecta (brittle bone disease). The study will look at whether the stem cells, which are able to transform into a range of tissues, will moderate or cure the disease.

Wikimedia Commons and ShakataGaiNai

About one in every 25,000 newborns is afflicted with brittle bone disease which is presently incurable. Scientists from Sweden's Karolinska Institute and London's Great Ormond Street Hospital are conducting the trial.

Errors in the developing baby's DNA causes the disease which results in missing or poor quality collagen—the material that gives bones their structure. The scientists hope the donated stem cells will provide the proper instructions for the development of the baby's bones.

The disease can be fatal for babies born with multiple bone fractures and those who survive face the risk of up to 15 fractures a year along with brittle teeth, impaired hearing and growth problems.

During the clinical trial, 15 babies still in the womb will get an infusion of stem cells. The study investigators hypothesize that the new cells will develop into bone, cartilage and healthy muscle tissue. The protocol for the study calls for infants to be infused again after they are born. A control group of 15 babies will have the treatment only after birth and the number of fractures will be compared with untreated patients.

"If we could reduce the fracture frequency, strengthen bones and improve growth, it would have a huge impact," Cecilia Gotherstrom, Ph.D., of the Karolinska Institute, told the BBC.

Doctors will administer the first infusion of stem cells to fetuses between weeks 20 and 34 of pregnancy.

Lyn Chitty, a pathologist at Great Ormond Street Hospital, told the BBC that genetic tests would be performed to target the flaws that cause the disease. "It is a serious disease. Our goal is to see if inside the womb the stem cell therapy can improve the condition and reduce the number of fractures."

"It is the first trial and, if successful, it will pave the way for other pre-natal treatments when parents have no other option," Gotherstrom said. — *BY*

LARGE JOINTS

Knee OA: Women Have More Sensitivity, Overall Pain Than Men

New research from the University of Florida and the University of Alabama shows that among patients with osteoarthritis (OA) of the knee, women experienced greater sensitivity to things such as lower tolerance to heat, cold, and pressure…they also had greater widespread pain than men.

The study was led by Emily Bartley, Ph.D. of the University of Florida. She told *OTW,* "I was actually fortunate enough to work with Roger Fillingim during my postdoctoral training at the University of Florida. He was conducting an ongoing study with colleagues at the University of Alabama at Birmingham called UPLOAD (Understanding Pain and Limitations in OsteoArthritic Disease), with the main focus of the study being to explore ethnic differences in pain and disability in adults with knee osteoarthritis. While this was very exciting work, I had a longstanding interest in how sex differences mold the experience of pain and used this project as an opportunity to examine this particular issue. Sex differences have always been intriguing to me, not only in terms of pain, but also in the relative degree of divergence that exists between men and women in overall disease susceptibility. Pain is one of the #1 health problems in the nation, and when you look at epidemiological studies women have a significantly higher prevalence of pain when compared to men. However, when I began exploring the literature, I was surprised to find little existing research examining sex differences in knee osteoarthritis, which is stunning because knee OA is a very common condition in older adults. Therefore, I felt that this was an area worthy of addressing and seemed like a natural extension to my already established interests."

"Interestingly, there were no sex differences in clinical pain, regardless of women being more pain-sensitive in general to the laboratory pain assessments. In fact, the only notable difference between men and women was that women reported greater widespread pain. While it is unclear why there was not a stronger concordance between self-reported pain and experimental pain sensitivity, it could be that the magnitude of sex differences in real-time assessment of pain are simply stronger than retrospective pain report in knee osteoarthritis."

As for any hypotheses regarding these sex differences, Dr. Bartley commented to *OTW,* "While it would be wonderful to have a clear-cut answer to this question, it not entirely clear why these sex differences were found as this is an

Pixabay and Unsplash

area that is highly complicated. Perhaps women with knee osteoarthritis may have a higher degree of central sensitivity to their pain, relative to men. This mirrors a previous study by Glass and colleagues, 2014, which found that women had greater knee pain and widespread pain than men regardless of radiological findings. Therefore, perhaps women's knee pain has a stronger central contribution to it than men. In other words, the greater pain sensitivity observed in our female participants may be due to an amplification of pain signals in the central nervous system. However, remember that a number of factors affect sex differences in pain and that pain is, in fact, a biopsychosocial problem. Therefore, it is difficult to determine the extent to which other factors such as genetics, hormones, gender roles, etc. may have influenced these responses." — *EH*

Bones: An Orthopedic Surgeon's Perspective

Orthopedic surgery is serious business for patients. But surgeons don't have to take themselves too seriously.

We're proud to present periodic articles from *GomerBlog.com*, a satirical medical news website created by a bunch of wannabe stand-up comedians who ended up in healthcare. "Through humor and poking fun at ourselves," says the Gomerguy, "we hope to change the way medicine is practiced in a positive way. Hopefully we can help get you through your day…even if we only make you laugh a few minutes before changing room 312's bedpan, or admitting that obnoxious drunk at 2:13am."

Our first presentation, "*Bones: An Orthopedic Surgeon's Perspective*," is from Mark Mildren, M.D., an orthopedic surgeon in Loma Linda, California,

"Guys! I found some bones in here!"

gomerblog.com/2014/09/bones/

and reprinted with permission from Dr. Mildren and GomerBlog.com.

Bones: An Orthopedic Surgeon's Perspective

Bones. I like bones. I like big bones. I like small bones. I like bones. I like long bones. I like short bones. I like old bones. I like young bones. I like misshapen bones. I really like broken bones. I like bones sticking out of skin. I like bones about to stick out of the skin. I like all sorts of bones. I like them. I like bones.

Sometimes bones are broken. I like to fix bones. Sometimes I break bones to fix bones. Sometimes I put screws in bones. Sometimes I put plates on bones. Sometimes I put wire around bones. Bones. I like to take broken bones and make them straight. Unless it is not a straight bone. Then I do not like to make it a straight bone.

The lungs confuse me. The heart confuses me. Kidneys confuse me. The pancreas confuses me. Bones do not confuse me. Unless it is the skull. That confuses me. Teeth confuse me. They are bones. I do not like them as much. Ancef is good. I like when anesthesia gives it. Sometimes gentamycin is good too. Not as good as bones. I like bones.

If you consult me about a deep cut, I will ask if there are broken bones. If you consult me about a crush injury, I will ask if there are broken bones. If you consult me about an infection, I will ask if there are broken bones. If you did not get xrays, I will get them to look at the bones.

gomerblog.com/2014/09/bones/

I like muscles too. Sometimes I cut muscles to get to bones. I do not like nerves. They are not bones. They get in the way of bones.

After I finished with my medical school, I was deeply intrigued by the pathophysiology of complex disease processes and the underlying pharmacokinetic changes of our current treatment strategies, but now, I like Bones." — WE

Wales Cracks Down on Obese and Smokers

Santa needs to lose the weight and the pipe.

New rules from the Welsh government say that if a patient who is obese and/or a smoker and is scheduled for orthopedic surgery in Wales, they must lose weight and stop smoking before surgery.

The move is an attempt to curb the rise in orthopedic referrals which have risen by 30% since 2005. According to Caroline White, writing for *Onmedia,* that is more than double the increase in all other specialties put together.

Orthopedics is the biggest single planned care service in Wales, she reports, with more than half a million trauma and orthopedic outpatient consultations every year. There are around 40,000 routine planned treatments. The growing prevalence of obesity as well as advances in clinical practice are believed to be behind the rise in referrals to hospitals for treatment.

Smoking is known to worsen the outcomes of some foot and ankle procedures, White noted. Numerous studies have shown that the rates of postoperative complications and length of stay are higher in patients who smoke.

The ruling by the Welsh government is not totally heartless. Smokers and those with a body mass index of 35 or more will be supported to join a weight-loss or stop-smoking program before having their surgery. The Wales' Planned Care Programme Board drew up the National Orthopaedic Implementation Plan. It stipulates that local health boards must provide a suitable range of stop smoking and weight reduction support services and appropriate referral mechanisms for patients.

Wikimedia Commons and Thomas Nast

Peter Lewis, Wales' national clinical lead for planned care, said. "Understanding patient-reported outcomes and addressing the key issues that can impact on them, such as lifestyle factors, is a fundamental component of volume-based medicine and benchmarking Welsh healthcare systems against best-in-class organizations in the UK and abroad." — *BY*

EXTREMITIES

Nerve Transfer Surgery Treats Paralysis

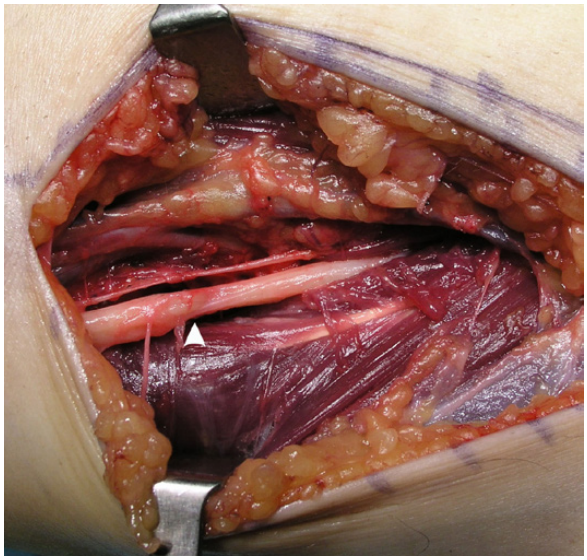
Three years ago Michael Bavlsik, M.D. suffered a crushed spine in a highway collision. The injury left him paralyzed but he did retain some movement in his arms. That fact, according to Durrie Bouscaren, writing for *St. Louis Public Radio*, made Bavlsik a candidate for nerve-transfer surgery.

At Barnes Jewish Hospital, Ida Fox, M.D., a plastic and reconstructive surgeon at Washington University in St. Louis, took a healthy nerve from Bavlsik's shoulder and, bypassing the spinal cord, rerouted it to his tricep.

She followed that with a second surgery in which she took a nerve in his upper arm and connected it to a nerve in his hand. The healthy nerves began to regrow at a rate of one inch per month. It has now been a year since the surgery on the nerves ad Bavlsik has enjoyed continued improvement in the use of his wrists, elbows and the strength of his grip.

According to Bouscaren, since 2009, about a dozen people with spinal cord injuries have undergone nerve transfer surgery to improve hand and wrist function at Barnes Jewish Hospital. The vast majority of patients were able to regain significant use of their hands, arms or grip strength a year after the surgery.

"I tell patients it's like untapped gold," Fox said. "There's all this stuff that's there that is below the level of spinal cord injury and is staying alive. I think, hopefully, once the nerve grows down to the new root and your brain starts talking to it that you'll get some of the function that we saw is available there."



Wikimedia Commons and Kuebi

According to the National Spinal Cord Injury Statistical Center, about 276,000 Americans are living with a spinal cord injury. About half of those injuries are at the cervical level on the upper part of the spine, which often means a person cannot move their legs or hands, but may retain some movement in their shoulders and elbows.

Raj Rao, M.D., an orthopedic surgeon at George Washington University and spokesperson for the American Academy of Orthopaedic Surgeons, said that there are few options to help people with spinal cord injuries improve movement and functionality, and nerve-transfer is one of them. But most are work-arounds, and don't treat the actual injury itself.

"Even if the treatment has the potential to work, it has to work in an area that's developed so much scar tissue because of the original injury," Rao said. "There have been multiple things tried, including an injection of stem cells, but nothing is really proven to be effective in well-controlled studies."

Furthermore, Rao said, people with spinal cord injuries at the C6 and C7 vertebras are often able to see increased functionality below the level of their injury without major interventions, so it can be a challenge to tease out which improvements are the results of a surgery, and which would have happened naturally.'

Fox agrees, saying that, "This is definitely a stop-gap measure. But anything we can do to improve quality of life right now, without needing a big electronic device or something fancy, mechanical, or a splint that gets in the way or is cumbersome, is really a wonderful gift to give." — *BY*

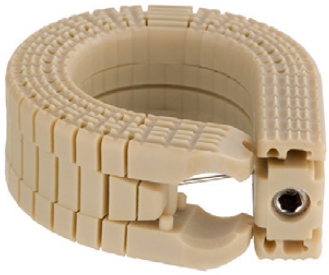
SPINE

Benvenue Medical Launches Luna 3D in the U.S.

The spine gurus at Benvenue Medical, Inc. have made the U.S. commercial launch of the Luna 3D Interbody Fusion System happen. In conjunction with this rollout, which took place at the recent North American Spine Society (NASS) Annual Meeting, the company accepted the 2015 Spine Technology Award for Luna in the Minimally Invasive Spine and Thoracolumbar Care categories.

"Luna 3D is a significant improvement over other available static and expandable TLIF cages," said Michael Wang, M.D., chief of neurosurgery at University of Miami Health System, in the October 14, 2015 news release. "Due to the implant's cannula delivery, implantation is possible through a narrow surgical corridor, resulting in minimal nerve root retraction and tissue dissection."

As indicated in the news release, "Luna 3D is a new expandable interbody designed for minimally invasive surgery (MIS), mini-open or open posterior approaches. Luna 3D's controlled, atraumatic insertion through a 6-8 mm cannula is designed to minimize nerve retraction and mitigate implant migration. In-situ 3D expansion provides zero-impaction delivery, intended to preserve and protect vertebral endplates. Once in the disc space, Luna 3D expands to 25 mm in diameter and up to 13 mm in height. Bone graft is inserted into the Luna 3D cage after expansion, thereby optimizing this critical aspect of fusion surgery."



Luna 3D Interbody Fusion System, courtesy of Benvenue Medical, Inc.

Asked what kind of comments and/or questions they received at the recent NASS meeting, Rick Simmons, vice president, Sales & Marketing at Benvenue Medical, told *OTW*, "We received a lot of interest from surgeons at NASS in the launch of our Luna 3D Interbody Fusion System. We received questions about the training that is available, as well as questions about details on the limited rollout to date. Many surgeons told us they have been dissatisfied or not trialed previous expandable devices for the following reasons: large entry into tight spaces, lack of controlled placement, impaction required for placement, subsidence concerns, foot print limitations, volume of bone graft within device and minimal biologics after expansion. They commented that Luna 3D was a very thoughtful design, addresses several of these challenges and capabilities of posterior access fusion surgery with ALIF surgical principles. They also asked about the instrumentation that we have available to perform a thorough discectomy for placement of the Luna."

As for next steps, Simmons commented, "Benvenue Medical is very focused on the full-scale product launch of Luna 3D and making sure the trainings go well. Some of what we have coming in the future include a lordotic version of the Luna, a new discectomy system, publication of biomechanical data and continuing to execute on our clinical data collection plans." — *EH*

SeaSpine Launches Cambria NanoMetalene Device

SeaSpine Holdings Corporation has announced the launch of its Cambria NanoMetalene cervical interbody body fusion device, an implant that is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD).

According to the October 15, 2015 news release, "NanoMetalene is an ultra-thin layer of commercially pure titanium molecularly bonded to a PEEK-OPTIMA implant. It is applied in a proprietary high-energy, low-temperature surface process and encompasses the entire implant, including the center graft aperture."

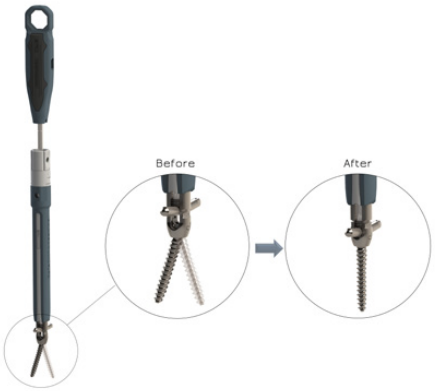
"Cambria NanoMetalene offers the benefits associated with traditional PEEK-OPTIMA devices such as a modulus of elasticity similar to bone and radiolucency for postoperative imaging, which allows surgeons to view the operative area and determine the extent of fusion of the vertebral bodies . With a molecularly bonded titanium surface on an uncompromised PEEK-OPTIMA implant2, SeaSpine provides customers an interbody solution offering the best of both materials."

SeaSpine CEO Keith Valentine told *OTW,* "There were a number of technical hurdles to overcome when this patented and proprietary process was developed in collaboration with our technology partner: hurdles such as preparation of the PEEK implant for treatment, chamber design, consistency of surface application, and a reproducible finishing process. The result of this collaboration is a high quality, NanoMetalene application that is bonded to the PEEK at an atomic level using a low temperature, high energy process. Surface adhesion testing indicated that the bond strength between the titanium and PEEK surface exceeded that of the PEEK substrate itself. To further confirm the excellent bond strength of our ultra-thin titanium surface, we put our NanoMetalene products through extensive destructive testing, insertion/expulsion testing, as well as several other biomechanical tests. Our testing revealed no surface delamination, even under full plastic deformation of the devices. Additionally, our destructive testing confirmed that NanoMetalene does not alter the exceptional strength of the PEEK substrate. The NanoMetalene implants also retain the modulus advantages for bone as well as superior imaging characteristics compared to 100% titanium or titanium spray-on coated devices." — *EH*

Cambria NanoMetalene cervical interbody body fusion device, courtesy of SeaSpine Holdings Corporation

Safe Orthopaedics: FDA Approves Marketing of New Implant

Safe Orthopaedics has announced that the FDA has approved the marketing of the company's new implant in the U.S. The product, known as the One-Step System, is meant for repairing traumatic spinal injuries and allows simultaneous fracture correction and spine stabilization.



Courtesy of Safe Orthopaedics

As noted in the October 13, 2015 news release, "The innovative self-correcting screw mechanism offers gradual, automatic and reproducible vertebral fracture reduction with a surgical procedure similar to that of a standard thoracolumbar fusion, open or MIS [minimally invasive surgery]. Often caused by a trauma, vertebral fractures require swift surgical treatment. Designed for one-time use, the new One-Step System combines implants with single-use surgical instruments and is ready for use at all times, thus eliminating unnecessary delays."

"The product was successfully launched in Europe in July 2015 shortly after the CE Mark was obtained. To date, more than 20 operations have been successfully performed in 5 Hospitals in France and the Netherlands. Additional

Austrian and British Hospitals are about to initiate such operations."

Asked about the development process, Dominique Petit, Founder, COO & CTO of Safe Orthopaedics, told *OTW*, "In order to restore the patient sagittal balance, spinal trauma procedure was performed using fixed pedicle screws, but they are very difficult to work with. To simplify the surgery, specifically during the rod insertion, the poly-axial screw is now more common but with a potential trade-off on spinal realignment. The One-Step System from Safe Orthopaedics combines all advantages of fixed and poly-axial pedicle screws. Surgery remains simplified but the implant provides automatic and controlled spinal correction."

Asked about their plans for this product in the U.S., CEO Yves Vignancour commented to *OTW*, "Working with key spinal trauma surgeons we would like to establish the one-stem system as a first-line option for thoracolumbar trauma patients." — *EH*

LinkSPINE: First U.S. Implantation of Facet-LINK HEMI

LinkSPINE has announced the first U.S. implantation of the FacetLINK HEMI. According to the October 9, 2015 news release, the titanium HEMI device is a low-profile plate that cross connects a Transfacet pedicle screw on the ipsilateral side of a Micro-Decompression to a Translaminar pedicle screw on the contralateral side. It is designed to provide rigid bilateral fixation through a tissue sparing, unilateral decompression approach.

Faheem Sandhu, M.D., professor of Neurosurgery and director of Spine Surgery at Medstar Georgetown Hospital, performed the first U.S. HEMI case at Medstar Southern Maryland Hospital in Clinton, Maryland. "As a neurosurgeon focused on minimally invasive spine surgery, I will often perform a microsurgical decompression through a unilateral approach and use the 'crossover technique' to decompress the contralateral recess," explained Dr. Sandhu. "This approach enables me to address bilateral symptoms through a small exposure and to keep the posterior ligamentous structures completely intact. The HEMI's ability to secure robust bilateral fixation through this microsurgical decompression is an attractive feature to me. The patient is doing great in the early post-operative period."

LinkSPINE President Massimo Calafiore stated, "The FacetLINK platform is designed to fit within the bounds of a surgeon's preferred decompression exposure, requiring no additional dissection beyond what was planned for the decompression itself. The HEMI requires only two screws to secure a low profile one level construct versus four screws which are needed when using conventional pedicle screw instrumentation."

As indicated in the news release, "The Facet-Link Stabilization Platform is intended to stabilize the spine as an aid to fusion through immobilization of the facet joints. The system is indicated for use with bone graft, at single or multiple levels, from L3 to S1 (inclusive). The platform is indicated for the treatment of spondylolisthesis, degenerative disc disease (DDD) as defined as back pain of discogenic origin as confirmed by radiographic studies, and degeneration of the facets with instability."

Mr. Calafiore told *OTW,* "The HEMI device is a less invasive fixation implant that is designed for placement with a minimal amount of fluoro. Given its small size and low profile, the bilateral fixation the HEMI provides is impressive."

"FacetLINK forms the foundation of LinkSPINE's 'Midline Choice' implant platform. Additional products are under development which will integrate with FacetLINK to provide intraoperative flexibility to choose a less invasive stabilization construct based upon patient pathology, anatomy, and surgeon preference. We will continue to focus upon patient outcomes and surgeon feedback to guide our product development efforts."

A company spokesperson stated: "We are grateful and extremely honored to be chosen as a winner in the minimally invasive spine surgery category for the

FacetLINK HEMI and Massimo Calafiore; Courtesy of LinkSPINE

2015 Orthopedics This Week Spine Technology Awards. Our focus has been and will remain upon the patient, and continuing to develop simple, elegant solutions that reduce surgical morbidity and improve outcomes. We are excited about the opportunity to continue innovating toward a comprehensive "Midline Choice" platform that offers the surgeon a robust set of implant choices that can be tailored to various anatomical and pathological scenarios. — *EH*

SPORTS MEDICINE

New App Lets Docs Address Injuries From the Sidelines

Want quick, accurate help on the sidelines or in the locker room? Cleveland Clinic to the rescue! Sports medicine physicians, led by Kurt Spindler, M.D., vice chairman of Research at Cleveland Clinic's Orthopaedic & Rheumatologic Institute, have developed a first-of-its-kind app called "Sideline Guidelines."

The app contains medical information to aid in diagnosis, in assessing an individual athlete's post-injury ability, making return-to-play decisions, and planning training schedules. The app, currently formatted for iPhone, can be used by sports medical professionals including fellows, residents, physicians, athletic trainers, and physical therapists.

Dr. Spindler joined Cleveland Clinic in 2014, after 23 years as head team physician, director of Sports Medicine, and vice chairman of orthopedics at Vanderbilt University. Dr. Spindler is also director of Orthopaedic Clinical Outcomes, and the academic director of Cleveland Clinic Sports Health.

Also participating in the development of this app were nationally renowned physicians and sports medicine experts from other specialties such as cardiovascular health, neurology and neurosurgery, abdominal/gastrointestinal, dermatology, dental, ear, nose and throat, and emergency medicine practitioners.

Dr. Spindler told *OTW*, "This app is a game-changer for medical professionals and athletes. With this app medical professionals will be better equipped

Courtesy of Cleveland Clinic

to assess a situation by using the app as a decision-making guide. It was created with input from current and former head physicians for the Cleveland Cavaliers, Cleveland Browns and Cleveland Indians; top specialists from Ohio State, Vanderbilt and other universities helped compile the database."

"The app opens up into three main sections. These are Emergency, Search, and Tools. In emergencies section are sudden death, heat illness, pulmonary emergencies, environmental (lighting etc.), and orthopaedic emergencies. This section is included for rapid reference. One scenario where it can be used is if an athlete has a head injury and suspected concussion. The diagnosis is not necessarily difficult; however the medical professional should refer to Sideline Guidelines app to review any potential red flags. For instance, what if it's a not a case of a simple concussion but rather an intracranial bleed." — *EH*

Football – America's Most Dangerous Game

Jimmie Andrews, America's pre-eminent sports doc, put pen to paper to speak truth about the #1 source of injuries to America's children. Football.

Yes, football is one of the most popular sports played by young athletes—but it is also the most dangerous game.

In 2007 nearly one million children (920,000 to be exact) under the age of 18 were treated for football-related injuries, according to the U.S. Consumer Product Safety Commission.

James R. Andrews, M.D., founding partner and medical director of the Andrews Institute for Orthopaedics & Sports Medicine in Gulf Breeze, Florida, writes a blog about football injuries in which he claims that while some injuries are unavoidable, many can be prevented or at least minimized.

Wikimedia Commons and Peter Rimar

Despite the use of protective equipment, major injuries such as concussions, spinal injuries, fractures and knee injuries, occur with regularity. Andrews claims that few injuries occur during game situations. The reality, he writes, is that most occur during practice. That is because players spend much more time in practice than they do in a competitive game.

Andrews notes that concussions are one the most serious and most common

football injuries. He insists that there is no such things as a "ding" to the head anymore. "If a young athlete expresses any change in his mental state, including confusion, amnesia, headache, struggling for balance, numbness or tingling, nausea, vomiting or drowsiness, he should be removed immediately and not allowed to return until he has been evaluated by a health care professional."

To limit injuries to players Andrews wants coaches to cut back on the number of full-contact practices they schedule and eliminate drills that put players at high risk of injury. That means only a small percentage of practices should be devoted to full contact. Many injuries, he says, can be prevented or minimized and made less severe with changes in how practice sessions are conducted. — *BY*

PEOPLE

David Stokes, M.D., Thomas Cadier, M.D., and Tuan Bui, M.D. Join OrthoAtlanta

David Stokes, M.D., Thomas Cadier, M.D., and Tuan Bui, M.D. have joined OrthoAtlanta. The orthopedic surgeons joined OrthoAtlanta effective September 1, 2015, choosing to close their practice, Orthopedic Surgery, P.C., and move their practices and patients to OrthoAtlanta.

Dr. Stokes graduated with honors from the University of North Carolina, Greensboro, and East Carolina University School of Medicine. After completing his orthopedic residency at the University of South Alabama, College of Medicine, Dr. Stokes completed a prestigious sports medicine and arthroscopy fellowship at the Mississippi Sports Medicine and Orthopedic Center in Jackson, Mississippi.

Dt. Stokes told *OTW,* "Upon joining the OrthoAtlanta team in September, I hit the ground running, acclimating my staff and myself to the new facility and systems. My existing patients have welcomed the new facilities and faces. I have been actively engaged in the community, continuing to foster local referring physician relationships and establishing new connections with area businesses."

Dr. Bui graduated with honors from Emory University with a Bachelor of Science, Biology, and completed his Master of Medical Science degree and orthopedic surgery residency at Emory University School of Medicine. He holds his Doctor of Medicine degree from Drexel University College of Medicine, Philadelphia, Pennsylvania. Dr. Bui pursued a prestigious spine surgery fellowship at OrthoCarolina in Charlotte, NC.

Dr. Bui told *OTW*, "I have been very fortunate to serve patients in the Lawrenceville and John's Creek, Georgia, communities for the last four years. I have been able to develop many close personal relationships to my patients here. I have been able to help many people and their family members as well as friends. I look forward to continuing to serve as a healer in the area. By joining OrthoAtlanta, I will have more access to technology and resources for better options of treating my patients. OrthoAtlanta has a very positive reputation within the community. I trust that in joining this practice I will be able to continue with this tradition."

A college honors graduate, Dr. Cadier received his medical degree from Loyola University Medical School, Stritch School of Medicine in Chicago, before serving in the U.S. Navy. In 1974, Dr. Cadier moved his family to Atlanta to complete his orthopedic residency at Emory University.

When asked about his longtime expertise in treating horseback riders, Dr. Cadier told *OTW,* "Horseback riding injuries are similar to what we would see in bicyclists, skiers and the like. However, a major difference is the athlete is on a thinking animal when the injury occurs. The horse may have a different opinion than the rider on what to do at a given time. This decision-making can be split second, and have significant consequences."

"Many equestrian athletes, perhaps more often than other athletes, tend to be more insistent on getting "back in the saddle" as soon as possible. To help riders through their period of convalescence, it helps to know the physical demands of the various equestrian sport disciplines from polo to fox hunting to competitive shows to basic trail riding."

"Working around horses for 35 years in various riding capacities, I incorporate both medical expertise and empathy to guide a previously injured rider seeking to get back in the saddle and resuming the sport they love safely and efficiently." — *EH*

Top to Bottom: David Stokes, M.D., Thomas Cadier, M.D., and Tuan Bui, M.D. / Courtesy of OrthoAtlanta

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