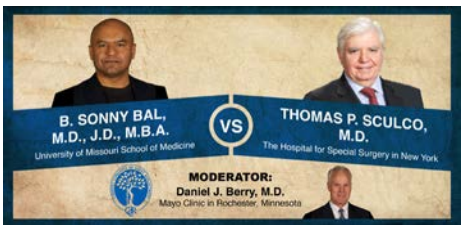
VOLUME 9, ISSUE 6 | FEBRUARY 26, 2013

Orthopedics This Week

week in review



breaking news

For all news that is ortho, read on

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: The consensus of economists is that the U.S. economy will grow 2.0% this year. If sequester happens and $85 billion is cut from government spending, growth declines to 1.5%— says this same panel of economists (National Association of Business Economists). When the expiration of the payroll tax holiday, which took effect on January 1st, takes effect economists say growth slips further to 1.0%. Another recession?

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Globus Medical	29.39%	0.60%	GMED's 2012 results to be released this week. Overall sales up 16% year-over-year. Profitability is the rest of the story.
2	3	Exactech	8.64	(0.70)	Sales for 2012 rose 9% but by Q4 growth seemed to be accelerating slightly. Extremities, however, are the big winner—up 30%.
3	5	Zimmer	25.45	0.04	Two well-known Wall Street brokers (Baird and Argus) are saying that reward potential of ZMH exceeds risk.
4	2	Stryker	23.68	1.34	One Wall Street broker thinks SYK should buy BSX. Off-target but in the right direction. SYK will lead in M&A.
5	6	NuVasive	7.08	2.65	Expectations are low for NUVA. Tomorrow CEO Lukianov will give his usual string of metrics and analysis. We think it will be positive for NUVA.
6	8	Johnson & Johnson	25.58	4.67	New buying interest in the old lady of medical devices—JNJ—just as the sequester looms. Haven in the storm.
7	4	Medtronic	28.65	(2.57)	Overall, missed Wall Street's earnings expectations but spine was looking stronger than it has in a long time.
8	10	Conmed	10.51	7.56	Very nice report for Q4—sales rose 8.4% which beat expectations and earnings met the top end of guidance. Solid.
9	9	Symmetry Medical	5.63	(2.89)	SMA's stock was hit pretty hard after missing Wall Street's expectations. SMA is making important strategic moves that aren't reflected in quarterly reports.
10	7	Integra LifeSciences	13.73	(5.39)	FDA warning letter, which should be easily dealt with, plus an earnings miss has really put pressure on IART.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Conmed	CNMD	$31.00	$883	7.56%
2	Wright Medical	WMGI	$22.63	$899	5.90%
3	MiMedx Group	MDXG	$4.52	$392	5.12%
4	Johnson & Johnson	JNJ	$76.25	$213,143	4.67%
5	NuVasive	NUVA	$17.85	$777	2.65%
6	Alphatec Holdings	ATEC	$1.72	$156	2.38%
7	Stryker	SYK	$62.70	$23,839	1.34%
8	Globus Medical	GMED	$13.36	$1,218	0.60%
9	Orthofix	OFIX	$36.95	$714	0.22%
10	Zimmer Holdings	ZMH	$74.14	$12,863	0.04%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	$0.99	$42	-31.72%
2	RTI Biologics Inc	RTIX	$3.65	$204	-12.26%
3	TranS1	TSON	$2.41	$66	-7.66%
4	MAKO Surgical	MAKO	$11.27	$518	-6.08%
5	Smith & Nephew	SNN	$54.03	$9,777	-5.41%
6	Integra LifeSciences	IART	$40.00	$1,082	-5.39%
7	TiGenix	TIG.BR	$1.17	$118	-4.11%
8	Symmetry Medical	SMA	$10.43	$384	-2.89%
9	Medtronic	MDT	$44.72	$45,228	-2.57%
10	CryoLife	CRY	$6.12	$168	-2.55%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$36.95	$714	12.19
2	Medtronic	MDT	$44.72	$45,228	12.42
3	Smith & Nephew	SNN	$54.03	$9,777	13.41
4	Zimmer Holdings	ZMH	$74.14	$12,863	13.94
5	Johnson & Johnson	JNJ	$76.25	$213,143	14.89

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$22.63	$899	205.73
2	NuVasive	NUVA	$17.85	$777	63.75
3	Symmetry Medical	SMA	$10.43	$384	31.61
4	ArthroCare	ARTC	$35.86	$1,006	23.44
5	Exactech	EXAC	$18.50	$246	21.76

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$36.95	$714	1.06
2	Conmed	CNMD	$31.00	$883	1.31
3	RTI Biologics Inc	RTIX	$3.65	$204	1.35
4	Globus Medical	GMED	$13.36	$1,218	1.41
5	Zimmer Holdings	ZMH	$74.14	$12,863	1.45

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$22.63	$899	20.31
2	NuVasive	NUVA	$17.85	$777	6.21
3	CryoLife	CRY	$6.12	$168	5.10
4	Symmetry Medical	SMA	$10.43	$384	2.63
5	Johnson & Johnson	JNJ	$76.25	$213,143	2.32

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.72	$156	0.79
2	Symmetry Medical	SMA	$10.43	$384	0.93
3	RTI Biologics Inc	RTIX	$3.65	$204	1.15
4	Conmed	CNMD	$31.00	$883	1.15
5	Exactech	EXAC	$18.50	$246	1.20

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.17	$118	102.73
2	MiMedx Group	MDXG	$4.52	$392	50.52
3	MAKO Surgical	MAKO	$11.27	$518	6.13
4	Globus Medical	GMED	$13.36	$1,218	3.67
5	TranS1	TSON	$2.41	$66	3.43

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

Dr. Scuderi's Incredible Journey From Crash Victim to Visionary

By Jeff White

Wikimedia Commons and Artur Andrzej

Accelerating his Ducati up the ramp onto I-95 on a bright sunny day in 2005, fellowship-trained spine surgeon Guy Scuderi could not know his life was about to change forever. To avoid the boneheaded pedestrian strolling on the interstate ramp, Scuderi dipped the yellow rocket to the left into what those who haven't experienced it call "a controlled slide." Scuderi then saw his surgical career of eight short years disappear with the skin from his hands and the bone of his right kneecap. Return to the work he loved seemed impossible.

What followed was a year of living with pain, enduring multiple surgeries to repair his hands and patella, and twice daily Silvadene cream applications to subdue the road rash. The forced inactivity allowed Scuderi's active mind to turn to a particular riddle that had frustrated him in his practice. Where, precisely, is the location of pain?

When an entire category of surgical intervention is based on subjective patient reporting, then how scientific can it be?

Where, Precisely, Is Back Pain?

It has now been eight years since the accident. Asking that deceptively simple question during his recovery led Scuderi to morph from chronic pain patient, to researcher, to entrepreneur and back to surgeon. Along the way, he experienced the highs and lows of hope, success and even failure.

CYTONICS® CORPORATION

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Today his research firm (Cytonics Corporation) has a biomarker assay for pain which, in turn, attracted an investment from a Fortune 500 firm. And last month, at the Orthopedic Research Society (ORS) Annual Meeting in San Antonio, Scuderi unveiled an autologous therapy for osteoarthritic pain.

How did this unexpected journey to entrepreneurship happen? More importantly, has Scuderi and his team found THE answer?

An Unexpected Journey to Entrepreneurship

Scuderi began his quest to find the elusive pain generator with the assumption that there must be some compound that appears in the degenerative cascade with the pain (after all, chondral degeneration from OA [osteoarthritis] or DDD [degenerative disc disease] at some point becomes painful). And if such a biomarker could be located, could it then become a "pain test" which would locate the real source of the pain?

To start, Scuderi looked at synovial fluid samples from as many volunteers and friends as he could find: those with back pain, knee pain, no pain; colleagues, employees, even family members at his youngest daughter's third birthday party. Like most researchers, Scuderi's early experiments failed. His first published paper in 2006 described those early failures but one reader, Dr. Jason Cuellar, a Ph.D. spine researcher and medical student at Stanford University Medical Center, was intrigued and suggested certain refinements for the experiments. Additional scientists and clinician researchers on both coasts joined the effort and the quest was on. Scuderi's co-investigators include the Scripps Institute, Carragee, Vaccaro, Golish, Anderson, and other noted clinician-researchers.

But Scuderi needed even more skills and more help to tackle this difficult problem. Starting Cytonics in 2006, he raised funds from friends and family made two key hires: a president and an experienced R&D leader. This team of three created a specialty cartilage research lab focused on biologic solutions for chronic musculoskeletal disease like OA and DDD. The focus of the five Ph.D.s and the other researchers and clinicians is to *understand the links between cartilage degeneration and pain better than anyone and attack those links with biologic solutions.*

Changing the Question

While many firms research and develop ways to regenerate damaged cartilage, Scuderi and his Cytonics' team of proteomics and biochemical scientists redefined the question to focus on cartilage degeneration and the phenomenon of pain cascades. Changing the question pushed the team to look past the biology and more directly at pain's chemistry. That, in turn, brought the team to fibronectin-aggrecan complex (FAC). FAC is a cartilage breakdown material that exists in painful discs and joints but not in asymptomatic ones… a compound that Scuderi stubbornly believed must exist.

Could FAC be the skeleton key to finding the pain generator, stopping the

pain or perhaps, even interrupting the disease cascade itself? Maybe.

With FAC pinpointing back pain generators, Scuderi and his Cytonics team created their first product—the FAC test ("FACT"), "Molecular Discography"—a nod to the spine community's love-hate relationship with discography.

In 2010 FACT Molecular Discography was awarded *OTW*'s Best Spine Diagnostic and Best Spine Pain Management products.

First You Diagnose…

It's now been four years since Cytonics published its first diagnostic tests of FAC. Many more tests have followed. But, as every physician knows, first you diagnose, then you treat. At this past January Orthopedic Research Society Meeting in San Antonio, Cytonics introduced its first *therapeutic* program—the Autologous Platelet Integrated Concentrate ("APIC").

APIC is an autologous treatment for pain and degeneration associated with any chondral injury, osteoarthritis, for example.

Cytonics' APIC's system concentrates platelets, growth factors but, unlike PRP (platelet rich plasma), also certain protease inhibitors from the patient's blood. In a poster presentation at this past ORS Cytonics showed that APIC appeared to prevent FAC and other cartilage degenerative compounds. From the podium, Dr. Cuellar offered evidence that a platelet rich, leukocyte poor APIC also slowed the progression of OA in preclinical models, and that a cell-free APIC had a chondroprotective affect in rabbits in an ACL tear model.

Publish or Perish...or Publicize

Cytonics' research has generated 15 articles in *JBJS*, *Spine*, *Arthroscopy* and other peer-reviewed journals but has gone relatively unnoticed as the company wrestles with the sometimes incompatible goals of building strong IP through robust (but sometimes secretive) scientific evidence to build value—versus promoting their findings to create a clinical following as market launches approach.

Other researchers have described aspects of cartilage degenerative cascades, and even studied their relationship to pain. A complete understanding of the relationship between cartilage degeneration associated with diseases like OA and DDD, and pain, however, has remained elusive.

Scuderi, however, is resolute: "Musculoskeletal pain is often due to a biochemical inflammatory cascade independent of anatomical abnormalities. MRI identification of variations in anatomy can lead to unnecessary and risky treatments including steroid injections. Payers have made it painfully clear to surgeons that they believe this to be the case." The team seems to have filled in some important pieces to the puzzle by finding the new FAC protein complex that is both a byproduct and an agonist in the degeneration/pain cascade…and then creating ways to stop its production.

New research seems to support Scuderi's position.

More Evidence of Pain Biomarkers

A research team at Rush Medical Center in Chicago led by Dr. Anne-Marie Malfait gained national visibility when they found a link connecting a degenerative biomarker, MCP-1, with pain behavior in a rat OA model (***Eureka! Rush Researchers Find Breakthrough in OA***; *OTW*, Jan. 3). This paper, presented at the National Academy of Sciences in December with a summary broadly distributed to outlets nationwide, repeats and reinforces observations made by Scuderi's group over several years in *clinical* settings.

Cytonics first identified elevated MCP-1 (monocyte chemotactic protein 1) and other proteins in the synovial fluid of the knees of patients with cartilage damage and knee pain, when compared to normal volunteers, and presented the results to the Orthopedic Research Society in 2008[1]. They further showed that the levels of these molecules performed as well as MRI in the prediction of intraoperative findings. This study, along with subsequent human studies that were published in peer reviewed journals demonstrated elevated MCP-1 in meniscal injury in the knee[2], anterior cruciate ligament injury in the knee[3],

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articular trauma to the ankle[4], and disc pathology in the cervical spine[5]. In fact, these insights into the relationship of MCP-1 with painful states in cartilage injury lead to a utility patent that was granted in May 2010.

Naturally Scuderi is a big fan of Rush's research: "This is great! Their efforts should be applauded for the rigorous scientific endeavor and results in developing an animal model for pain in cartilage injury. Indeed, Malfait's et al. results in a mouse model of arthritis appear consistent with what we have observed in humans with cartilage injury and further validate our observations and conclusions."

In Cytonics' research, MCP-1 was only one of several molecules that correlated with cartilage damage pain, and, in fact, the best correlation was with the fibronectin-aggrecan complex[6],which may also play a role in the pathogenesis of joint pain. The Cytonics FACT (Fibronectin-Aggrecan Complex Test) diagnostic assay is now making its way to the market.

Has Scuderi Found a Holy Grail?

The possibility that a physician could diagnosis and treat effectively, routinely and cheaply one of the most common scourges of mankind—chronic musculoskeletal pain—may not be out of this world. Indeed, Cytonics may well represent the next generation of successful musculoskeletal companies—one that is based on biologic solutions. In Cytonics' case, the solution led to both a revolutionary diagnostic test and an equally disruptive treatment plan.

Meantime, Scuderi and his team are shaking the various money trees to fund their evolution from start-up to clinical commercialization.

In retrospect, the old saw "that which doesn't kill you makes you stronger" proved uncannily accurate for this extraordinarily talented physician, entrepreneur, provocateur and one time motorcycle enthusiast.

For more information:

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2. Cuellar, J., Scuderi, G.J. Golish, R., Gabrovsky, V., Yeomans, D., Diagnostic utility of cytokine biomarkers in the evaluation of knee pain. JBJS 2009. 91. 2313-20.
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5. San Giovanni, T, Palanca, A., Golish, SR, Hanna, LS, Scuderi, G.J. Ankle intra-articular pathology correlation with inflammatory markers and degradation products. Foot Ankle International. 2012 33:8 627-31.
6. Scuderi GJ, Golish SR, Cook FF, Cuellar, J., Hanna, L. Identification of a Novel Fibronectin-Aggrecan Complex in the Synovial Fluid of Knees with Painful Meniscal Injury. J Bone Joint Surg Am. 2011;93:336-340 ♦

Cappuccino, NuVasive, Lanx and the Defectors

By Walter Eisner

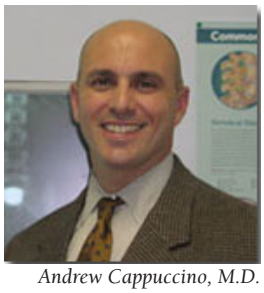
NuVasive, Inc., employees approached the dinner table at the China Poblano restaurant in Las Vegas on December 28, 2011. At the table sat Andrew Cappuccino, M.D., his partner Ryan DenHaese, M.D., and three former NuVasive reps now working for a new competitor named Lanx, Inc.

"Lanx is going after all [NUVA's] guys," Dr. Cappuccino allegedly said to the NuVasive reps.

This all happened after Dr. Cappuccino had a very public break up with NuVasive and the reps defected from NuVasive to join the competitor.

NuVasive Charges Breach of Duty

In an August 12, 2012 lawsuit filed by NuVasive against its former reps Michelle Kirby, Blake Bednarz and Jason Gotham, the company claims Kirby was observed competing with NuVasive while working as a Lanx rep at the Lanx Lateral Lab in Las Vegas on January 27-28. On the 27th, Kirby allegedly accompanied Dr. Cappuccino to a Cirque de Soleil performance. NuVasive claims this was a violation of Kirby's previous employment contract with them.



Andrew Cappuccino, M.D.

Smallwon and Morguefile/RRY Publications LLC

The company accuses the trio of breach of "intentional and malicious violations of their duties of loyalty to NuVasive, misappropriation of NuVasive's trade secrets, and violations of their post-employment obligations," according to documents filed with the U.S. District Court for Western New York.

The Cappuccino/NuVasive Split

This encounter is symbolic of the multiple lawsuits resulting from Dr. Cappuccino's 2011 departure from NuVasive as a consulting surgeon to join the new rival.

Dr. Cappuccino is a spine surgeon with Buffalo Spine Surgery in Lockport, New York, and has served on the medical staff of the Buffalo Bills for many years. In addition to his work on the artificial cervical disc, he has been one of the leaders in bringing minimally invasive and lateral spine surgery, disc replacement and spine motion preservation to the field of spine surgery.

Dr. Cappuccino attracted international attention as the orthopedic surgeon who treated Buffalo Bills football player Kevin Everett for his cervical spine injury suffered in a game in 2007. Cappuccino's use of induced hypothermia garnered world-wide headlines for the technique may have staved off paralysis in the player.

NuVasive engaged Dr. Cappuccino to serve as an exclusive consultant and clinical advisor in 2003. The parties entered into various general consulting and services agreements which imposed confidentiality requirements regarding

his work for NuVasive and assigned any rights he had to the intellectual property developed to the company.

Kirby, Bednarz and Gotham

Kirby was primarily responsible for working with Drs. Cappuccino and DenHaese. She was given confidential and proprietary NuVasive information which she allegedly failed to return to the company after Cappuccino allegedly lured her away from NuVasive to work with him at Lanx.

Gotham and Bednarz were her supervisors who also, allegedly, failed to return proprietary information.

NuVasive's complaint said the employees lied to the company about Cappuccino's plans to join Lanx and then followed him to work for Lanx, taking confidential and proprietary information with them.

Cappuccino Sues NuVasive Over Cervitech

While that lawsuit plays out in New York, Cappuccino recently filed a lawsuit against NuVasive accusing the company of failing to pay him a $660,000 "milestone payment" tied to FDA approval of the cervical disc replacement device which NuVasive acquired when it bought Cervitech, Inc. in 2009 for $80 million.

NuVasive agreed to pay $47 million upfront and another $33 million when approval was granted. Dr. Cappuccino and his fellow Cervitech inventors were to receive payments within 30 days of FDA approval of the device. That approval was granted on October 26, 2012. All other former Cervitech shareholders were paid with the exception of Dr. Cappuccino. He is seeking the payment that he says was promised him under the share purchase agreement, as well as interest from the day of the breach and attorneys' fees and costs.

Alan Bozer, Cappuccino's lawyer told us that NuVasive has admitted that it owes Cappuccino the money, "but is withholding payment for reasons unrelated to the Cervitech matter." Bozer wouldn't elaborate about those "unrelated" matters when we called him. He encouraged us to ask NuVasive why the company wasn't paying his client, "who has fulfilled every obligation of his contract with NuVasive."

NuVasive Claims IP Violation

The company did not comment directly on Cappuccino's lawsuit, but gave us a statement that said: "NuVasive has strong justification for its actions; Dr. Cappuccino violated intellectual property agreements with NuVasive and owes the company far more than the amounts reflected in his lawsuit."

Might those "unrelated" matters noted by Bozer stem from Dr. Cappuccino leaving NuVasive to join Lanx and allegedly "going after" [NUVA] guys? The answer may lie in the lawsuit filed by NuVasive against their three former employees, Kirby, Bednarz and Gotham.

According to the lawsuit, the defendants were key members of NuVasive's sales force in Western New York before "abruptly" resigning on October 2011 to work for Lanx, Inc.

Kirby started working for NuVasive as a senior spine specialist in Buffalo, New York, in March 2006. Bednarz started working for NuVasive as a spine specialist in New York in March 2008. From July 2010 until his resignation, he was the area business manager for upstate New York.

Gotham started at NuVasive as a spine specialist in Detroit in May 2007. He was divisional sales director east covering upstate New York, Maine, Vermont, New Hampshire, Massachusetts, and Michigan.

Cappuccino Joins Lanx

Unbeknownst to NuVasive, states the suit, Dr. Cappuccino decided to unilaterally end his relationship with NuVa-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Lanx Launches Patient Education Website on Minimally Invasive Spinal Fusion

MinimallyInvasiveSpineFusion.com *Serves as Resource on Back & Leg Pain and Less Invasive Surgical Options*

20, 2012 - Lanx, Inc., a privately held medical device company focused on de
devices for spinal surgery, today announced the launch of a new e
back and leg pain, www.MinimallyInvasiveSpineFusion
of pain, available treatment options, and ne
elieve symptoms and that may he

Lanx

sive and entered into a similar agreement with Lanx with a contract dated September 15, 2011. "The defendants knew of this and failed to report it to NuVasive. They also actively concealed Dr. Cappuccino's new relationship with Lanx from NuVasive, and misrepresented their efforts to maintain Dr. Cappuccino's business to NuVasive," states the lawsuit.

Defendants Follow

On August 22, 2011, Bednarz and Gotham allegedly travelled to Lanx's headquarters in Colorado and presented a business plan to Lanx's CEO, chief financial officer, senior vice president of sales and the company's general counsel.

The alleged plan called for them to form a company named Empire Medical Systems, Inc. which would distribute Lanx's products in New York and move a substantial amount of NuVasive's business in their sales region to Lanx. They also would solicit and convert NuVasive's sales force to Lanx so that the surgeons in their sales regions would not see an interruption in their service. "They knew Dr. Cappuccino's intended to sever his relationship with NuVasive and sign a new agreement with Lanx at the time they presented their business plan to Lanx," says the suit.

By September, Lanx's director of recruitment and Gotham allegedly exchanged emails which address materials he and Bednarz needed to submit in order for Lanx to offer employment to them.

On September 16, 2011, one day after Cappuccino signed his agreement with Lanx, Lanx's then senior vice president of sales directed his colleagues to prepare written employment offers for Bednarz and Gotham.

Four days later, Kirby allegedly emailed Bednarz and Gotham to inform them that Dr. Cappuccino was using Lanx's products for surgery rather than the NuVasive products he historically used.

Bednarz and Gotham forwarded this email up the chain to senior NuVasive executives, and along with Kirby, "feigned surprise" that Dr. Cappuccino would utilize Lanx products. "They were trying to induce NuVasive into believing that they were still acting in NuVasive's best interests, when in fact, they were keenly aware of Dr. Cappuccino's intent to join Lanx."

Lanx Offers Employment Contracts

Lanx allegedly emailed employment offers to Bednarz and Gotham the same day Kirby made her "discovery." Lanx emailed similar offers to Kirby and two other members of NuVasive's Buffalo-area sales force the next day. The offers were allegedly for "significantly" more money than NuVasive paid the recipients, and are "grossly excessive" of industry standard.

Cappuccino's "Inducement"

Documents submitted by Kirby and the others to Lanx before September 21, 2011, "prove" that Dr. Cappuccino "encouraged them to leave NuVasive for Lanx," claims the lawsuit.

On October 3, 2011, Kirby allegedly emailed Bednarz and Gotham and other NuVasive managers about her inability to predict what Dr. Cappuccino would do. In response Gotham informed Kirby and various NuVasive executives that he would work to regain Dr. Cappuccino's business.

"This was, at best, intentionally misleading because they knew Dr. Cappuccino's intentions and were dedicated to joining [him] at Lanx."

NuVasive claims Bednarz, Gotham, Dr. Cappuccino and Lanx induced Kirby to violate her non-compete by allowing her to continue to work with Dr. Cappuccino.

Kirby resigned from NuVasive on October 17, 2011. On October 18, Kirby and the other two members of the sales force entered into employment agreements with Lanx.

On October 25, her second day on the job at Lanx, she allegedly received an email from Lanx's senior project manager regarding the Lanx products required to adequately serve Dr. Cappuccino.

Defections Complete

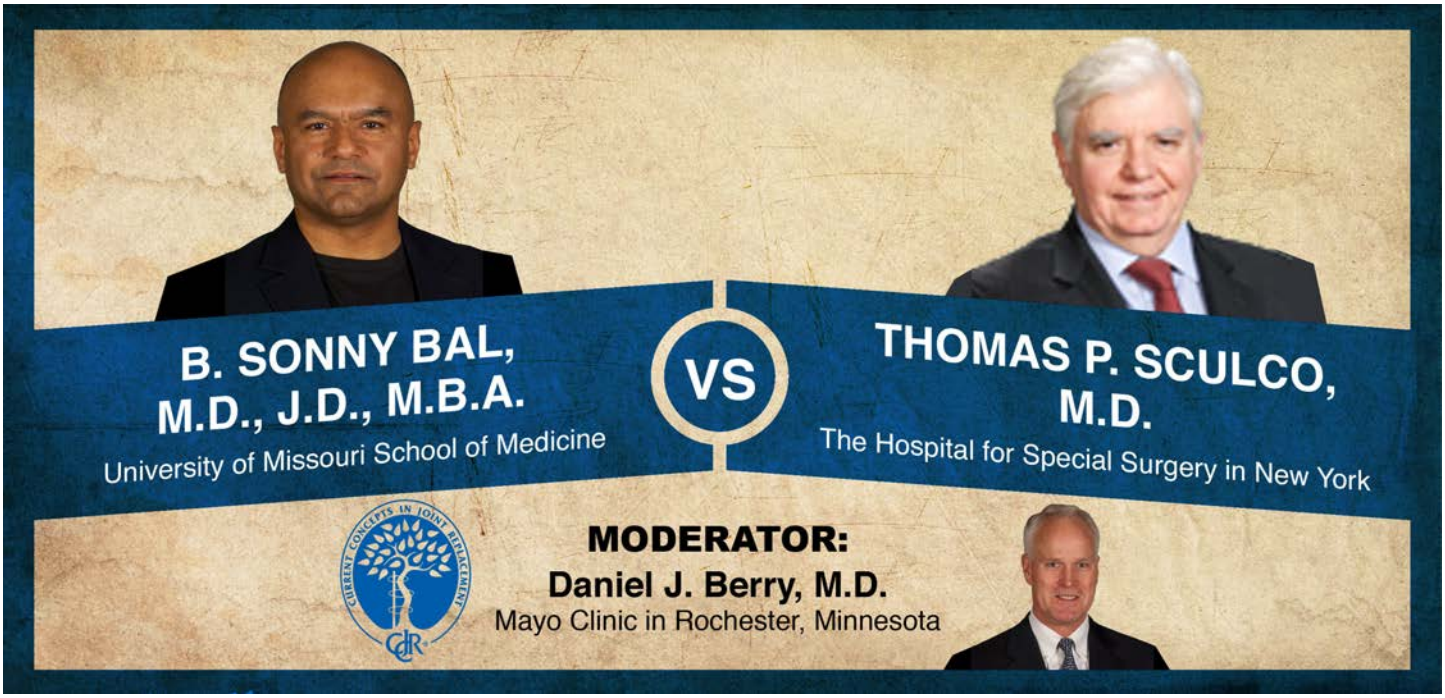
Fewer than six weeks after she left NuVasive, on December 2-3, 2011, Kirby allegedly accompanied Cappuccino to the didactic and cadaveric portion of the Cornell Weill MIS Spine Course in New York City. And then on to Vegas, dinner and Cirque de Soleil.

In addition to the case in New York, NuVasive is also in the Delaware Court of Chancery over other defection of former sales reps.

What happens next? Lawyers for the parties tell us that not much new has happened since the complaints were filed and various motions for evidence offered. No trial dates have been set. ♦

Bal v. Sculco Over Anterior THA

By Elizabeth Hofheinz, M.P.H., M.Ed.



Current Concepts in Joint Replacement/RRY Photo Creation

"Anterior THA is an efficient surgery, and it's easy on the surgeon and patient," states Sonny Bal. "But," says Tom Sculco, "You need a special operating room table, intraoperative fluoroscopy, there is a difficult femoral exposure, increased OR time, and the possibility of higher complications."

This week's Orthopaedic Crossfire® debate is "The Anterior Approach Optimizes THA Outcome." For the proposition was B. Sonny Bal, M.D., J.D., M.B.A. from the University of Missouri School of Medicine. Against the proposition was Thomas P. Sculco, M.D. of The Hospital for Special Surgery in New York. Moderating was Daniel J. Berry, M.D. from Mayo Clinic in Rochester, Minnesota.

Dr. Bal: "The anterior THA [total hip arthroplasty] technique I use involves a fracture table with simple draping; the exposure isn't compromised at all. This approach is amenable to short and long stems, ream stems, wrasp stems and hip resurfacing. The exposure is excellent with the table. There is a hook that lifts the femur up a line for easier retraction. It's definitely less traumatic to the muscle. You can do a revision through the anterior approach."

"In 2009 a study by Bhandari involving nine centers and 1,152 hips found early return to function and the same learning curve as a conventional hip. The following year Bourne did a study comparing anterior to anterolateral, and found faster return to function with the former."

"In 2010 Joel Matta reported 1,345 consecutive cases—unselected. They had reasonable blood loss, three dislocations, none of which needed surgery; patients could ambulate without support at 15 days postop. Nakata's 2009 study comparing anterior to mini-posterior showed that the anterior had faster recovery and more accurately placed implants."

"A 2010 study by Restrepo looked at anterior versus direct lateral and found that anterior had better scores and outcomes up to two years...then they equalized. In 2009 Berend compared the direct lateral to the anterior, and found that the anterior resulted in faster discharge; the complications were about the same as the direct lateral."

"My own data: 500 consecutive anterior hips. At 3.8 years there were two late resections for sepsis, two I&Ds (incision and drainage), one small femur fracture required one wire; one was a postop injury that required two wires and a new stem. There were two dislocations from trauma and six metal-metal bearings were changed; each revision surgery was done through the same approach...which is extensile distally."

"The clinical outcomes were reasonable, however, at four weeks 17% had reported thigh numbness. HO (heterotopic ossification) was an issue in 15%. The trochanteric tip migrated in seven patients, but this was not clinically relevant. There were very consistent radiographic outcomes."

"It's an efficient surgery, and it's easy on the surgeon and patient. The supine approach is more physiologic, the leg lengths are very easy to measure, and the hip deltoid of the fascia is preserved. Bilateral hip replacements are very easy, there are no precautions specified for any patient, and it's the easiest total hip replacement for obese patients because the fat is in the back, not the front. If there is any doubt, you can pull in the X-ray and get a fluoroscopic view. All implant companies support it, patients prefer it, it's easy to get trained, and you have intermediate term outcomes from a number of studies."

"Disadvantages: a definite learning curve, and quick success with this technique involves training and preceptorship…but that's true of any new method."

Dr. Sculco: "There are many ways one can get into the hip with less invasive approaches: medial, anterior, anterolateral, posterolateral (my preference), and two incision. All are good approaches that should be done by people with experience."

"I like the posterolateral approach because it's the most commonly used in hip surgery, it can easily be extended, there is less blood loss, and it's expeditious. The main disadvantage is the increased dislocation rate, which has now been dealt with primarily with larger femoral heads and dual mobility cups (in older women particularly)."

"The incision is between 8-10 centimeters. This approach does vary depending on the size of the patient, but in a thin woman the incision is two-thirds below the tip of the trochanter, one-third above. Note that you must see—circumferentially—the upper portion of femur so that fracture does not occur."

"We have an ongoing study with 1,465 patients that we've followed for nearly nine years, with an average incision of 8.4 centimeters. Our radiographic evaluations have been the same as with our more dramatic approaches. Cement technique in the cemented ones has been excellent, as has the stem position."

"We've had complications. The dislocation rate was 1.2%, the femoral fracture rate was 0.3%, and the neuropraxia rate was 0.3%, particularly in our earlier patients when we were a bit too aggressive with trying to make the incision too small. Three of those five patients recovered, but two did not. There were few wound complications."

"The Internet has over 62,000 websites dealing with the anterior approach… and patients come to me daily asking for this approach because of the media blitz. The claims made are that it is tissue sparing, involves less pain and faster recovery, but there is little evidence in the literature to document these claims."

"The disadvantages are that you need a special operating room table, intraoperative fluoroscopy, a difficult femoral exposure, increased OR time, and the possibility of higher complications."

"Menghini did a study looking at whether this approach is really muscle sparing. He found significant injury to muscle about the hip—tensor fascia as well as the external rotators. Another study, done by Pilot, looked at IL-6 and an enzyme followed in muscle to evaluate tissue injury using a posterior and an anterior approach. There was no difference found in these markers of tissue injury in the two series."

"Looking at dislocation rates reported in large series of the anterior approach: Siguier had 1,037 THA with a 0.96% dislocation rate; Matta had 437 THA with 0.61%; Kennon had 2,132 THA with 1.3%; Sariali had 1,374 THA with 1.5%. I would put that up against the 1.2% incidence in 1,465 THA that I've reported. And I don't think there's really any difference in the two operative approaches."

"In another study by Dr. Matta, who's a developer of the technique, there were 494 THA-anterior with a 2.4% fracture rate…as opposed to my 0.3% (posterior). And note that there were three ankle fractures when you externally torque the limb in order to expose the anterior part of the femur."

"My opinion is: keep it simple. Disaster is always a threat."

Moderator Berry: "Sonny, rebuttal?"

Dr. Bal: "A surgeon of Dr. Sculco's stature is used to the posterior approach.

The anterior approach is not only a shortened incision, but is a brand new approach. So the surgical data that Joel Matta had, I've had early on with a two incision approach, which is very similar. The supine position is new for most of us, the acetabular positioning is different, and the femoral exposure requires certain techniques (which if you don't know can make for a long day in the OR). So I don't think we're comparing apples to apples."

Moderator Berry: "Tom?"

Dr. Sculco: "Use any approach…these are all very useful. This one requires a special table and techniques and takes time to learn; and you're going to have problems when you do it. When you weigh that against the posterior approach I don't see a lot of advantages. In Sonny's hands I'm sure the results are very good. In my hands the posterolateral approach has been very good. I just think it's easier for the erstwhile joint replacement surgeon out there doing 25-30 joints a year. Sonny, HO…I've seen reports that it may be higher in this approach. You had a 15% incidence. Were those Brooker ones and twos?"

Dr. Bal: "My data is at least twice the size I showed you and I've never seen more than a Brooker two. Partly because it's not a simple approach. The table is useful in the sense that the assistant who is holding the foot has to make subtle moves during the case to increase abduction and relieve pressure on the muscle. It's not a matter of forcing; it's splitting the muscles and trying to see what you want to see. To your earlier point, the learning involved here includes a mentorship and cadaver dissection, as well as courses where you learn the subtle tips and techniques."

Moderator Berry: "Sonny, what about the charge that this is a marketing game? And if you ask everyone in the room to learn a whole new approach, use a fracture table, etc., then they're all going to have to go through that learning curve. Is that really justified?"

Dr. Bal: "The marketing thing is very unfortunate. One of the advantages touted at the meetings (and by the companies) is that if you learn this approach you will increase the volume of your total hip surgery. It gives the wrong message about our profession and it misleads patients. These issues are played out in the lay press and then the scientific evidence comes to light. So I can't support the websites that say this is a new or different approach."

Moderator Berry: "Speed of recovery: Tom does a relatively small incision, posterior approach, and theoretically none of the main muscles around the hip are compromised. You do an anterior approach and theoretically none of

the main muscles around the hip are compromised. Why should there be any real difference in speed of recovery—or is there one?"

Dr. Sculco: "I don't think there is any difference. When you hear a lot about speed of recovery you've got to look at the patient population. There is a self-selection, and if you operate on very young, fit people, they can walk the next day. If you operate on an 85-year-old sedentary person then they're going to be less active. So I don't think it's the approach…I think it's the protoplasm you're dealing with."

Dr. Bal: "I think the jury is still out. In a number of the papers I showed, some by conservative authors who published in some of the best journals there is a feeling that the recovery rates are faster. Eventually the recoveries are about the same. My data is weak because I didn't do a direct comparison, but I can tell you that in one month after an anterior hip replacement the patients almost don't want to see you again. They're done and want to go on with their lives. I didn't find that with direct lateral or posterior approaches."

Moderator Berry: "Sonny, one of the things about the direct anterior approach is that it's harder to get the femoral component in. One of the solutions has been to change the type of femoral component; sometimes we've seen problems with fixation when people have switched around previously reliable femoral components to ones that are designed to just fit through a special approach. How do you counter that concern? Is it a concern?"

Dr. Bal: "It's not. If you know how to expose the femur then regardless of patient obesity safe exposure is possible such that any femoral stem, particularly the reliable ones with a track history, can be used. If you're struggling with the approach—with exposure—then you're resorting to a stem that allows unlimited exposure. Then you're playing with fire."

Moderator Berry: "What are the unique problems of the anterior approach?"

Dr. Bal: "Exposure! If you use the table to force exposure you might break the ankle or femur. Wound maceration—same thing. It's a misguided attempt to try too small an incision."

Moderator Berry: "Thank you, gentlemen." ♦

Please visit www.CCJR.com to register for the 2013 CCJR Spring Meeting, May 19 – 22 in Las Vegas, Nevada.

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Workers Comp Patients ARE Different…So Are Children—Why Pediatric Patients Are Not Adult Patients...The $$ Is There for Meaningful Use, Is Security?

By Elizabeth Hofheinz, M.P.H., M.Ed.

Workers Comp Patients ARE Different See a workers compensation patient on your schedule today? Do you form preliminary opinions about that person and his or her surgical recovery? Konrad I. Gruson, M.D., assistant professor of Orthopaedic Surgery at Albert Einstein College of Medicine, wanted to know. He shared his findings with *OTW.* "My partner Dr. Tony Wanich and I see a significant number of workers compensation patients who can't return to work because of their injuries…typically, these involve the rotator cuff and labrum. Because there can be a negative connotation attached to these patients, we decided to look back into the literature and see if there was actually evidence for these suppositions. Thus, we embarked on a comprehensive review of the outcomes for surgical treatment of upper extremity injuries in workers compensation patients."

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"The most surprising finding was that these patients who have injuries to their upper extremity seem to—at baseline—have a worse perception of their injuries than their non workers compensation counterparts. We think that this is because this population is more likely to contain blue collar patients who routinely do strenuous physical work. There are also several studies indicating that these patients have more financial constraint and more marital discord, so perhaps this inclines them to see themselves as worse off than non workers compensation patients. Then there is the most cynical take on things, which is that these patients seek financial gain from remaining out of work and eventually going on permanent disability. This means that they would have an incentive to report a worsening level of pain to begin with…and to report less of a positive outcome in the long term."

"When I begin treating a workers compensation patient I let them know that their clinical improvement is likely to take longer than a non workers compensation patient. Not only are they starting out at a worse subjective position than a non workers compensation patient, but they seemingly never achieve the same final clinical outcome as their non workers compensation counterpart…and it takes longer for them to reach a plateau. That being said, in the properly indicated workers compensation patient undergoing upper extremity surgery, reasonably good outcomes can be expected. The message is to treat workers compensation patients as a distinct population… no treating them with a cookie cutter approach."

ACL Injuries in Kids: What Works, What Doesn't Let's cut through the fog on ACL injuries in children. The journals are full of information on what approaches should be used. Dr. Jeremy Frank, a pediatric and adolescent sports medicine specialist and Assistant Director of [U18] Sports Medicine at Joe DiMaggio Children's Hospital in

Hollywood, Florida, recently clarified the problem in his lead article in the *Journal of the American Academy of Orthopaedic Surgeons*. He told *OTW*, "We are seeing a tremendous increase in ACL injuries in young people whose growth plates are open. With a plethora of studies and educated opinion in the orthopedic literature regarding appropriate treatment, my goal was to synthesize this large volume of data. What we concluded was that one must base their decision on whether or not to reconstruct the ACL not only on the patient's chronological age but take into account their physiologic (stage of puberty) and skeletal age (bone age based on standard wrist x-rays) as well. Once this assessment is complete, you can then accurately decide what kind of operation is appropriate for each individual patient."

"What does *not* work is applying adult principles to kids whose growth plates are still open. If you handle young patients in an adult manner you can injure their growth plate, and likely cause leg length discrepancy. Pediatricians routinely say, 'Kids are not little adults.' Pediatric orthopedists and pediatric sports medicine doctors say, 'A child athlete is not an adult athlete.'"

Pyrocarbon: Better Wear Characteristics Wear characteristics…it's a drumbeat. While pyrocarbon implants have been around for a while, they are relatively new in the realm of orthopedic surgery. Joseph Abboud, M.D., an orthopedic surgeon at the Rothman Institute in Philadelphia, is helping to change that. Dr. Abboud commented to *OTW*, "We are currently involved in an IDE [investigational device exemption] trial being conducted by Integra LifeSciences looking at the use of pyrocarbon radial head replacements in comparison to a standard chrome cobalt radial head replacements for radial head arthritis or fractures."

"Pyrocarbon's potentially improved wear characteristics may offer improved longevity and outcomes in shoulder and elbow surgery compared to standard metal heads. One of our biggest concerns in total shoulder arthroplasty is polyethylene wear and glenoid failure. In previously conducted bench top research pyrocarbon has shown favorable wear characteristics on polyethylene as compared to a standard metal head. In addition, one of the most difficult aspects of shoulder arthroplasty is implanting a glenoid component. That is why some surgeons often opt to implant a hemiarthroplasty over a total shoulder arthroplasty despite studies showing inferior midterm results for hemiarthroplasties."

"Interestingly, animal retrieval studies conducted with pyrocarbon joint implants have demonstrated that pyrocarbon implants cause minimal cartilaginous wear to the contra lateral side of the joint. The logical thought then

would be that pyrocarbon hemiarthroplasties may end up providing better pain relief then metal hemiarthroplasties due to their potential for the decreased rate of progression of glenoid arthrosis. Early European and Australian data looking at this very issue has been promising. If these findings bear out in vivo then we may have a solution for a couple of challenging surgical problems in shoulder surgery. With that in mind there is great enthusiasm for a potential shoulder replacement IDE looking at pyrocarbon hemiarthroplasties in 2014."

The $$ Is There for Meaningful Use, Is Security? What's that big thing coming down the pike? Opportunity or headache? Probably both. We are now approaching Stage 2 of CMS [Centers for Medicare and Medicaid Services] Meaningful Use and things could only get more challenging. Herb Alexander, M.D., President of the Society of Medical Consultants to the Armed Forces, has been delivering lectures on this topic for the last few years. He told *OTW*, "There are three significant changes required in Stage 2 for orthopedic surgeons. The first is the ability of the certified electronic health record (EHR) to send secure communications via email. We must work this out because private practitioners will have to do it. Next year, 2014, is 'the magic year' for us because in order to continue receiving the incentives being offered by the government, we have to comply with the program. Also coming down the pike for Stage 2 is that your EHR must be able to provide an electronic portal for patients to view their health records. Note that this will be mandatory for individual practitioners as well. The third is CPOE, or computerized physician order entry. These are but 3 of the 17 Core and 6 Menu items required for Stage 2. If you started meaningful use in 2011 then you received the maximum reimbursement from Medicare of $44,000 over five years per doctor. If you wait until this year to qualify the maximum drops down to $39,000; if you start in 2014 then the maximum is only $24,000. Those of us waiting until 2015 get nothing but a 1% penalty; those of us delaying until 2016 will be hit with a 2% penalty."

"My primary concerns with Stage 2 are related to security. How can we be certain that private information on the EHR patient portal sites is protected. What is to prevent someone who designs a patient electronic access portal from divulging a method to gain access to patient information? What will prevent a "hacker" from breaching security? All we need is one patient's information to be leaked and the system will come under intense scrutiny." ♦

company

DePuy Recalls Another Metal Hip

While a jury listens to evidence about Johnson & Johnson's DePuy Orthopaedics's failed ASR metal-on-metal hip replacement device in a Los Angeles courtroom, the company issued a field safety notice on January 15, 2013 for physicians and consumers for the Adept 12/14 Modular Head used in total hip replacement. This was done after reviewing revision rates of the device from the UK National Joint Registry Supplier Feedback data and the Australian Orthopaedic Association National Joint Replacement Registry.

The notice stated that a review of post-market surveillance data suggests a higher-than-expected revision rate for the head when used in conventional total hip arthroplasty. Analysis of UK National Joint Registry Supplier Feedback data (download 11th November 2012) indicates a cumulative revision rate of 12.1% at seven years for the head when used in conventional total hip arthroplasty.

When this combination is used with the Adept cementless stem, the data showed a cumulative revision rate of 9.7% at five years. This is based on 17 revisions in a cohort of 195 implantations.

The head was manufactured by Finsbury Orthopaedics Ltd., which was acquired by DePuy in December 2009. The devices were available commercially from Finsbury or DePuy from 2004 to September 2011. From September 2011, the heads were acquired by MatOrtho Ltd. DePuy issued the field safety notice due to its responsibility for monitoring ongoing performance of the product.


DePuy
a Johnson & Johnson company

Urgent Field Safety Notice (FSN)

Product Name: ADEPT® 12/14 Modular Head (Finsbury Orthopaedics Ltd)

FSCA-identifier: DVA-107259-HHE

Type of Action: Field Safety Corrective Action

Date: 15th January 2013

Attention: Trust Chief Executives, the Clinical Director-Orthopaedic Department, the Orthopa
Theatre Manager, the Safety Liaison Officer, General Managers – Private Sector Hospitals

Total Hip Replacement Implant

dular Head (Finsbury Orthopaedics Ltd)

www.mhra.gov.uk

Sales of the device were reportedly halted in 2011, but apparently 7,500 of the implants spread to 21 different countries including the UK, Germany, Denmark, Australia and Canada. None were sold in the U.S.

The notice involves the top part of the devices and the company notes that a similarly named product called the Adept Hip Resurfacing Femoral Components was not recalled.

Customer Directions

Customers are being told that if they have any remaining inventory to please cease further distribution or use of the product with immediate effect.

The company is asking customers to undertake the following urgent actions:

- *Quarantine/Bond any Adept 12/14 Modular Head inventory that is located at your facility or hospital*
- *Arrange with your local DePuy representative to return for credit any unused implants*
- *Please sign and return a confirmation/reconciliation letter to the specified DePuy contact*
- *Please ensure all departments and colleagues within your organization who are impacted by this Field Safety Corrective Action notification are made aware of this action*

Patient Care

Patients who have received the Adept head should be followed according to local guidance/standard of care for patients receiving metal-on-metal articulations.

—WE (February 22, 2013)

Medtronic's Core Spine Flexing Muscle

Medtronic Inc.'s core spine business continued to stabilize in the third quarter of 2013. Revenue of $639 million was flat on a constant currency basis. Total spine sales of $753 million declined by 3% on a constant currency basis (-4% reported) as Infuse and kyphoplasty continue to drag down overall sales.

The U.S. core spine business, according to a February 19 company announcement, continued to stabilize, as new products and therapies are gaining broad surgeon acceptance. The company believes it is differentiating its spine business through its focus on enabling technologies, including imaging, navigation, and powered surgical instruments.

Bone morphogenetic protein (BMP-Infuse) revenue of $114 million declined 21% on a constant currency basis.

Wells Fargo analyst Larry Biegelsen said spine revenue was above consensus' $750 million and his own $730 million estimate. Growth in spine, on a constant currency basis, accelerated to -3% from -5% in the previous quarter.

Medtronic, Inc. Spine 3Q13	Sales ($ in millions)	% Change*
Total Sales	**$753.0**	**Down 3%**
Core Spinal	$639.0	Flat
Biologics	$114.0	Down 21%

Source: Medtronic, Inc.
** In constant currency*

Ishrak: Gaining Share

Omar Ishrak, company CEO, told analysts on February 19 that core spine business gained share on both the sequential and year-over-year basis. "Our U.S. core business continues to stabilize as new products and procedures are rolling out and performing well. And our Solera system is generating strong surgeon interest."

In cervical, Ishrak said the company was beginning to seeing growth in the U.S. as surgeon training is ramped up with the recently launched Bryan ACD cervical disc. He also noted newly launched Capstone Control interbody system was contributing to the stabilization of sales.

O-Arm Pull-Through

He also noted that other biologic products, Grafton and MagniFuse DVMs, continue to perform well. "We're also differentiating our aspiring business from the competition to enabling technologies such as O-arm Imaging, StealthStation Navigation and powered surgical instruments. Hospitals are investing in our capital equipment for spine surgery as they see clear value from better outcomes and more efficient procedures. This is also resulting in significant pull through for navigation in powered and enabled spinal implants. In fact in accounts that have O-arms we're seeing core spine revenues grow 10 points higher than non O-arm accounts this fiscal year."

"There is a general stabilization in spine of volume and implants [that] has reached a level of stability that we haven't seen for years I think with the practitioners getting comfortable with qualities in place. Now we expect to continue to work with them to drive further growth in that market," said Ishrak.

Changing Customer Base

Following on the theme of his predecessor who pronounced the end of the "Surgeon Champion Era," Ishrak talked about the company's "transformational opportunity" to deliver economic value to customers supported by market leading technologies. "Healthcare payment models are becoming more complex with new paper value models becoming more important. In addition our customers are evolving and now include hospital system, suite executives, payers and governments. Within this changing environment we're transforming our business to not only deliver clinical value but also deliver economic value. This transformation will include not only our existing products but also developing and piloting new economy value programs. We're in the early stages of this transformation and Medtronic has specific competitive advantages to win in the new value oriented environment."

Medtronic, Inc.

—WE (February 24, 2013)

DePuy Synthes' "Next-Generation" Shoulder System

DePuy Synthes Joint Reconstruction has introduced the Global Unite Platform Shoulder Arthroplasty System.

According to a February 19, 2013 press release, the system enables surgeons to anatomically treat proximal humeral fractures and easily convert to a reverse total shoulder without compromising recognized biomechanical principles.

The system is a modular system that allows 72 different sizing configurations. A suture collar allows secure anatomic reconstruction of the tuberosities and helps return the shoulder to a natural anatomical position. The FDA granted 510(k) clearance of the system and is indicated for press-fit or cemented fixation and offers the only modular system to provide a suture collar, which helps with anatomical reconstruction.

The company describes the Global Unite as a next-generation platform shoulder arthroplasty system which offers:

- Modular proximal bodies available in four sizes and three heights to promote anatomic restoration of humeral head height and tuberosity placement in a press-fit application
- Modular suture collar that allows additional suture fixation and anatomic reconstruction of the tuberosities
- Humeral heads that are available in sizes 40-56mm in both standard and eccentric configurations
- Option to convert to the DELTA XTENDTM Reverse Shoulder Arthroplasty System without the use of a stack on adaptor, which may compromise biomechanics
- Similar stem geometry to the clinically successful DELTA XTEND
- Revision without removal of a well-fixed humeral stem

Joseph Ianotti, M.D., Ph.D., Chairman, Orthopaedic and Rheumatologic Institute, Cleveland Clinic, said that, "Shoulder pathology is exceptionally varied, and with the Global Unite system surgeons have a comprehensive and fully interchangeable system that affords flexibility and versatility designed to address patients' needs. My personal experience with the system has been very positive. Having a system where the implant is easily convertible gives you confidence that you can restore your patient's shoulder to a natural anatomical position."

The system is available worldwide and is also compatible with the following DePuy Synthes Joint Reconstruction glenoid components:

- Global Anchor Peg Glenoid
- Global Steptech, Anchor Peg Glenoid

The company cautioned that the performance of shoulder replacements depends on age, weight, activity level and other factors. There are potential risks and recovery takes time. People with conditions limiting rehabilitation should not have this surgery. Only an orthopedic surgeon can determine if shoulder replacement is indicated based on an individual patient's condition.

DePuy Synthes Joint Reconstruction is part of DePuy Synthes Companies of Johnson & Johnson.

—WE (February 24, 2013)

Global United Shoulder System/DePuy Synthes

Bacterin Subpoenaed Over Possible False Claims

Bacterin International Holdings, Inc. announced on February 11, 2013, that the company has received a subpoena from the Office of the Inspector General of the U.S. Department of Health and Human Services ("OIG") in connection with an investigation into possible false or otherwise improper claims submitted to Medicare.

In an SEC 8K filing, the company statement said the subpoena requests documents related to physician referral programs operated by the company. The company believes the investigation refers to a prior practice of compensating physicians for performing certain educational and promotional services on behalf of the company. Those programs, according to the SEC filing, were discontinued in 2010 and involved payments to only a small number of physicians.

"We believe [the payments] were made in accordance with all applicable laws. We intend to cooperate with the OIG's investigation," said company Founder, President and CEO, Guy Cook.

In addition to this subpoena from the OIG, the company also received two warning letters from the FDA on January 29, 2013, related to company procedures for, among other things, implementing corrective actions and evaluating complaints.

Bacterin was founded in 1998 as a sole proprietorship by Cook as a spinout of the Center for Biofilm Engineering at Montana State University.

Revenues were historically derived from testing services and milestone

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payments from collaborative product development agreements with various blue chip medical manufacturers. Today, the company generates revenue from a number of sources including: sales from products developed and manufactured by the company, sales of products manufactured by a third party and sold and distributed by the company, and contract revenue from analytical testing and development services provided to medical device manufacturer clients, which tailor Bacterin's coating process to the client's specific product/medical application.

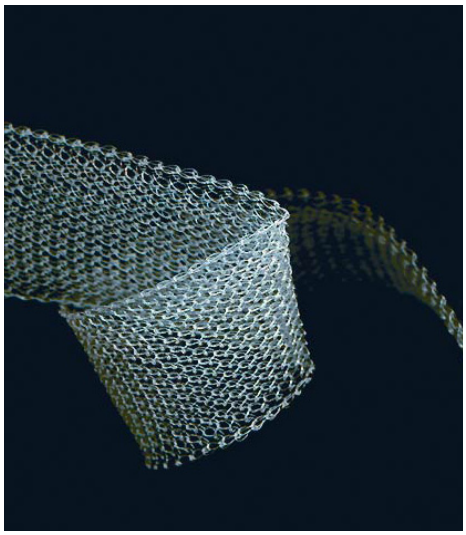
Bacterin has developed and currently manufactures and sells several human tissue-based products, primarily allografts, through the company's biologics division. In addition, the company also manufactures and sells, directly under its own name and indirectly through distributors, various coating and surgical drain products through its medical devices division.

The biologics products include: OsteoSponge, OsteoSpongeSC, OsteoWrap, OsteoLock, BacFast and hMatrix as well as certain other allograft products.

—WE (February 18, 2013)

TissueGen and Biomedical Structures Advance Drug Delivery

TissueGen Inc., makers of absorbable polymer technology for implantable drug delivery, has announced that its patented extrusion technology now enables absorbable fibers to be loaded with more drugs and biologically based entities than ever before. They are working with Biomedical Structures LLC (BMS) to develop a finished textile platform for drug-eluting medical device applications using TissueGen's patented drug delivery technology.



TissueGen, Inc.

TissueGen's core technology includes fiber extrusion at room temperature, which preserves the biological activity of incorporated drugs and therapeutic agents. This enables drug delivery through biodegradable fibers, a "groundbreaking" format that drastically expands the types of agents that can be directly incorporated into implantable medical devices. Drugs are incorporated into the fiber according to device performance requirements using a combination of commercially available polymer components.

BMS will utilize the TissueGen polymer extrusion platform to develop biomedical textile structures designed for drug delivery within the body. TissueGen indicates that because its technology allows for the engineering of both chemical composition and mechanical properties such as size, shape, and porosity to each specific application, a single structure can satisfy both physical and pharmaceutical performance requirements without requiring additional material support for implantation. Ideal for tissue engineering and regenerative medicine applications, the polymer platform is bio-absorbable and can control therapeutic release over time in accordance with its designed degradation profile as device performance requires.

"TissueGen's polymer technology is exactly the drug delivery solution that can help to overcome many of the constraints of current polymer-based systems," said BMS CEO Dean Tulumaris in the February 12, 2013 news release. "As BMS works to provide our customers with an increasingly robust suite of solutions for every device design challenge, we believe the TissueGen absorbable delivery platform will provide a tremendous addition to our biomedical textile development capabilities for cardiovascular, tissue engineering, and other applications."

"We look forward to working with BMS and its customers to bring this important technology to market," added Christopher Knowles, CEO of TissueGen. "With its extensive expertise and leadership in the medical textiles market, Biomedical Structures is ideally suited to offer our proven drug delivery platform as a viable choice for medical device and pharma companies."

—EH (February 13, 2012)

2012 – The Numbers Are In. No Reason to Celebrate.

Smith & Nephew, plc (S&N) reported fourth-quarter sales declined 3% to $1.08 billion from $1.11 billion the previous year. The revenue decline was partially attributed to the absence of the company's biologics and clinical therapies business, spun out last May as Bioventus LLC. In November the company announced the acquisition of Healthpoint Biotherapeutics for $782 million in cash. Underlying revenue growth was 2%.

S&N hip sales declined 2.0% on a constant currency basis. The company's share of the hip market declined to 12.1% from 12.6%, according to BMO Capital Market analyst Joanne Wuensch, with continued headwinds in its Birmingham hip replacement franchise.

The company's knee sales increased by 2%, while trauma growth was 7%. Advanced wound management grew by 4%.

Finding Something Positive to Say

With S&N's results, all the large orthopedic companies have reported for the fourth quarter. "It looks like it was a good quarter for the market," said Wuensch, "but let's not get too carried away," she added.

DePuy Synthes, Stryker and Biomet Gainers

According to Wuensch, the hip market, on a constant currency basis, was up 1.8%, including a 3.8% rise in the U.S., and knee sales were up 3.0%, with a 4.0% increase in the U.S. Wuensch said DePuySynthes Companies regained the No. 1 share position, with its share increasing to 24.3% in the quarter from 23.4% the previous year, "After battling years of metal-on-metal concerns." Other share gainers were Stryker Corporation (22.7%; up 60 basis points) and Biomet, Inc. (11.6%; up 10 basis points). Zimmer Holdings, Inc. was the primary share contributor, with its share declining to 24.4% from 25.2%.

In knees, said Wuensch, Stryker gained the most share, benefiting from the company's direct-to-consumer GetAround-Knee marketing campaign, and increasing its market share to 20.5% from 19.9%. DePuySynthes saw its share improve slightly to 22.7% from 22.5%, given its strongest U.S. growth rate (up 7.1%) since the first quarter of 2010. Zimmer yielded ground as its Persona Knee system begins to ramp along with two fewer selling days in Europe, the Middle East and Africa, with its share declining to 27.1% from 27.7%.

Wells Fargo analyst Larry Biegelsen said global reconstructive (hips + knees) growth of 2.0% constant currency in

morguefile and hotblack

the quarter was stronger than the third quarter (+1.2%) driven by strong U.S. growth, offset by weak outside-of-the-U.S. (OUS) sales.

Worldwide spine growth, according to Biegelsen, improved slightly on a constant currency basis to -0.9% in the quarter, up from -1.9% in the third quarter. Extremities growth accelerated 60bps to +8.4% in the fourth quarter.

2012 Ortho Market Up 1.8%

On a full-year basis for 2012, Biegelsen estimates that the overall worldwide orthopedic market grew 1.8% on a constant currency basis, better than 2011 growth of 1.0%. He said the acceleration was largely driven by the rebound in the U.S. hip and knee market, which benefited from improved economic conditions in the U.S. in 2012.

Biegelsen's five key observations for the orthopedic market in 2012, included:

1. The U.S. recon market improved in 2012 likely due to improving macroeconomic conditions;
2. Knee growth accelerated more than hip growth as knee procedures tend to be more elective and correlate more with the economic environment;
3. The spine market is slowly improving but contracted in 2012 and still faces challenges;
4. Extremities is the highest growth ortho segment, with consistent growth in the high single digits;
5. Overall ortho growth in 2012 was encouraging, but off of very weak 2011 comps.

There should have been smiles all around for orthopedic device makers as the year ended.

—WE (February 24, 2013)

S&N Boss Says Device Tax Not Reason for Layoffs

Woops.

Just a week after a Smith and Nephew (S&N) public statement attributed the cut of 63 company jobs in Memphis to the 2.3% medical device excise tax, the company's CEO Olivier Bohoun told analysts during a telephone conference call on February 7 that the Memphis media reports were "just wrong."

Bohoun was asked about comments made by S&N management attributing the job cuts to the device tax.

According to a written transcript from *seekingalpha.com*, Bohoun replied: "Okay. It's a mix of a lot of things. We announced 100 layoffs last week, 63 in Memphis, about 20 in Boston and something like 12 in Europe. This is just the follow-up of the value plan. So there is nothing new on this. This has nothing to do with Obamacare. This has to do with us willing to be fit and effective for the future. So this is nothing new. I mean, this is just a plan. So what folks, TV in Memphis or the *Memphis Times* have written is just wrong. It's just a mix of things in the environment that we have seen a year ago, having driven us to make the changes we are making. And this is why it is what it is. So I mean, the 63 people have nothing to do with Obamacare per se."

Image created by RRY Publications, LLC. Source: abtforassembly.com

Analysts asked Bohoun if the device tax has forced the company to raise prices.

"No," said Bohoun, "and I double checked that yesterday night...I've seen a paper yesterday morning…saying that many companies have raised prices or have transferred the price on customers... we have not done that."

Memphis media were not happy to be accused of directly quoting a company statement and then being told they had it wrong. So *bizjournals.com* reposted the January 31, 2013 S&N statement which read:

"The nearly $30 billion tax on medical devices that took effect Jan. 1, 2013 has impacted a number of companies across the U.S. Smith & Nephew is not immune from this added expense burden. Unfortunately, and in order to absorb this cost burden into our business, this has meant less than 100 positions have been made redundant across various departmental functions in our Tennessee and Massachusetts sites. The company is providing the affected employees with a comprehensive severance package and outplacement support."

Numerous medical device companies have attributed layoffs to the new tax because of the added cost of doing business. But this was the first time we heard a company blame the tax for making jobs "redundant."

This exchange between Bohoun and the Memphis media reminds us of former Zimmer Holdings, Inc.'s colorful and combative CEO Ray Elliot's advice to his colleagues; "Never get into a fight with someone who buys ink by the barrel."

—WE (February 11, 2013)

Amedica Significantly Beefs Up Executive Team

Amedica Corporation, a spinal and reconstructive medical device manufacturer located in Salt Lake City, Utah, has added three new executives to its leadership team and reassigned a fourth.

Vytas Rupinskas is joining Amedica as Vice President of Marketing. He brings over 25 years of marketing experience in the orthopedic, spinal and neuromodulation medical device markets and previously held senior positions at St Jude Medical, DePuy Orthopedics, DePuy International and DePuy Spine.

Joining Amedica as the new Senior Vice President of Sales is Jim Abraham. He brings over 25 years of experience in the orthopedic, trauma, spine, biologics and dental markets. Formerly with Stryker Orthopedics Abraham also previously held a number of executive positions at companies such as IsoTis Orthobiologics, Regeneration Technologies, Encore Orthopedics and Sulzermedica.

The third named is Kevin Ontiveros who joins Amedica as Chief Legal and Compliance Officer. Ontiveros has more than 20 years of experience serving as in-house and outside corporate counsel for publicly traded and privately held medical device and biotechnology/pharmaceutical companies such as ImaRx Therapeutics, Inc. and NPS Pharmaceuticals, Inc..

Paul Sendro, who was formerly Senior Vice President of Sales for Amedica, will now be leading the company's strategic market development initiatives. He, too, has over 20 years of experience in the orthopedic, trauma and spine medical device industries, having held leadership positions at numerous companies such as US Spine, Vertebron, Blackstone Medical, Stryker Inc. and Synthes USA.

—BY (February 11, 2013)

Courtesy of Amedica Corporation

trauma

Ultrasound Blast Speeds Bone Healing

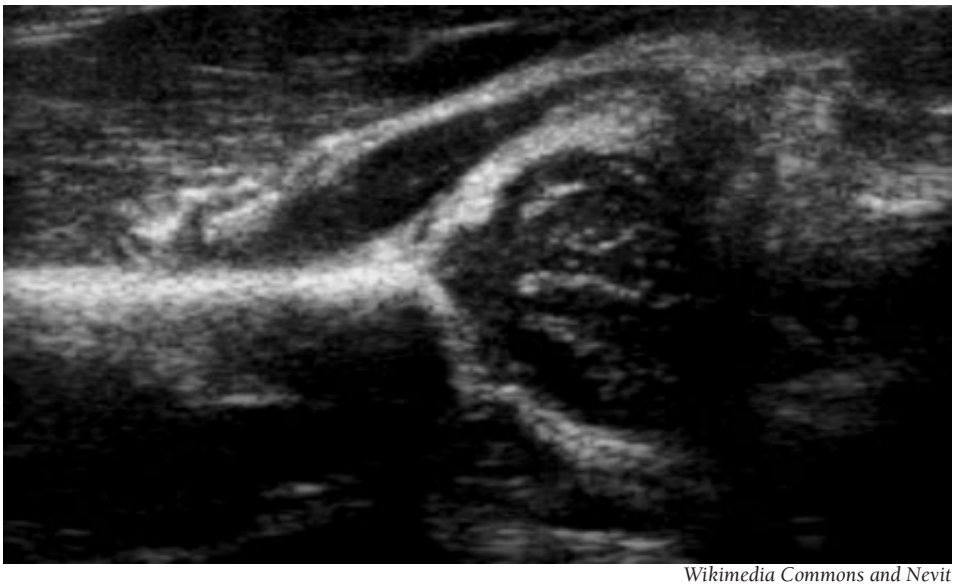
A blast of sound from a palm-sized device helps fractures heal faster according to a report by Carol Davis, writing in *Mail Online* in the UK. The battery-powered item sends pulses of ultrasound into the bone which appears to start the body's natural healing mechanisms. The British government body NICE (National Institute for Health and Clinical Excellence) has approved the device for hard-to-heal fractures and says it could be a major cost-saver.

According to Davis, about 8% of the 650,000 fractures suffered by people in Great Britain fail to heal or fail to heal properly. Especially vulnerable are injured people with other health problems such as diabetes or chronic lung disease. Why fractures in these patients fail to heal is not clear but is thought to be due to poor blood supply and suppressed healing mechanisms.

Studies show that ultrasound therapy can boost bone repair. One review of more than 500 patients showed a 34% reduction in healing time compared to a placebo. Doctors in Great Britain have used ultrasound to treat non-union fractures for a decade or more but patients have had to travel to a clinic or hospital to receive it. The manufacturers of the new device, called Exogen, say patients will now be able to treat themselves at home. The gadget is a portable device with a circular probe, around the size of a quarter, which is placed against the skin. If a patient is wearing a cast, a small hole is cut into it. Patients use the device for an average of five months.

Davis quotes Angus Maclean, M.D., senior orthopedic consultant at Glasgow Royal Infirmary, as saying about the device, "By accelerating healing, there is significant potential for this technology to save money for the NHS, by reducing the need for surgery and returning patients to work more quickly than before. Cost savings and clinical effectiveness therefore make it a win-win situation for both the NHS and the patient."

—BY (February 18, 2013)



Wikimedia Commons and Nevit

iPhone App Detects Possible Concussions

Out of Kansas has come an app on an iPod or iPhone that can instantly help detect a possible concussion. Roy Wenzl, writing for the *Wichita Eagle*, reports that inventor Chase Curtiss, of Tulsa, Oklahoma, has received FDA approval for the app called SWAY Balance.

Courtesy of Sway Balance and Chase Curtis

Curtis explains that his app does not diagnose concussions, as such, but measures balance as a significant symptom of a possible head injury. The trainer testing an athlete for possible injury instructs him or her to hold the iPhone or iPad containing the app against the chest. Then she instructs him to take a brief test. The athlete is told to, with eyes closed, put his feet together and then move the dominant foot in front of the other, heel to toe. The athlete then is to lift the dominant foot and stand on the non-dominant foot. The app gives an immediate reading, by numbers, as to whether an athlete has developed a problem with balance.

Before gaining approval, Curtiss tested his app for two years at Wichita State University (WSU) and among hundreds of athletes at Wichita East and Andover Central high schools, as well as in schools in Oklahoma and California.

Jennifer Hudson, the head athletic trainer for the Wichita school district who helped test the app with East High athletes calls it a "very cool tool." Jeremy Patterson, a staff member at WSU who was involved in studying and testing the app, said it is an inexpensive tool that can gather evidence in a matter of minutes indicating if an athlete may have suffered a concussion. What Curtiss did, said Patterson, was develop a cheap, fast, accurate tool that trainers and other health care specialists have never had before. It gathers measurable evidence in moments, indicating whether or not a person has probably suffered a concussion.

Ideally, athletes will be tested at the beginning of a season, when they are healthy and un-injured, Wenzl noted. That gives the trainer a recorded baseline of how much balance the athlete has when healthy. That baseline can then be compared with whatever the app shows if the athlete is injured in a practice or competition.

Wenzl quoted Hudson, who teaches in the athletic training program at WSU, as saying, "A lot of the initial assessments by trainers on the sidelines have had to be much more subjective, much of them based on how the athlete is feeling," she said. "A concussion until now has not necessarily been an injury that you can see, like a swollen ankle. But this app shows real numbers and gives you a better assessment."

She added that the app does not "prove" a person has a concussion because some concussions don't affect the area of the brain that controls balance. But it gives a better assessment than she's seen before.

—BY (February 12, 2013)

large joints

TKR Incidence Data in U.S.

How prevalent is total knee replacement (TKR) in the United States? A team led by Elena Losina, of Brigham and Women's Hospital in Boston, Massachusetts, used a computer simulation of the history of knee osteoarthritis, together with data from two national surveys to estimate the incidence of TKR among U.S. patients with end-stage knee osteoarthritis.

As reported by Liam Davenport, *medwireNews* reporter, they estimated that the prevalence of TKR in adults aged 50 years and over was 4.2%. Women had a higher incidence, at 4.8%, and men had a lower one, at 3.4%. Total knee replacements increased with each additional decade in age for both males and females. Doctors diagnosed symptomatic knee osteoarthritis in 11.5% of adults aged 50 years and over. Women still led, at 13.3%, with men following at 9.4%.

Using U.S. Census data, the researchers estimate that 4,007,400 U.S. adults have had a TKR, and 536,100 of that number now live with a revised TKR. Nearly 1.5 million of these primary TKRs were implanted in patients who were from 50 to 59 years old.

Losina and her team estimate that 11,059,800 adults in the United States have symptomatic knee osteoarthritis. The percentage of these individuals who have an intact TKR implanted in their bodies is about equally divided between men at 31.6% and women at 31.3%. More women, 5.1%, have had a revised TKR than men at 4.4%.

The researchers put the lifetime risk of having a TKR at 7% from the age of 25 in men and 9.5% in women. They put the life time risk of contracting knee osteoarthritis at 13.3% for men and 18.8% in women.

Davenport , in her article, quotes the authors in the *Journal of Bone and Joint Surgery* as writing, "While total knee replacement is a remarkably successful treatment for individuals with end-stage knee osteoarthritis, our findings emphasize the large public health burden posed by the millions of adults in the U.S. living with total knee replacement."

—BY (February 18, 2013)

Wikimedia Commons and Robert F. LaPrade and RRY Pub

Plastics + Stem Cells Regrow Bone

The faculties of two universities, the Department of Musculoskeletal Science at the University of Southampton and the University of Edinburgh's School of Chemistry, both in the UK, joined forces to develop a polymer implant using stem cells. The research was intended to find ways to extend the time an implant, such a hip replacement joint, can survive. The researchers found that their material promoted effective bone regrowth around an implant and they published their findings in the journal *Advanced Functional Materials*.

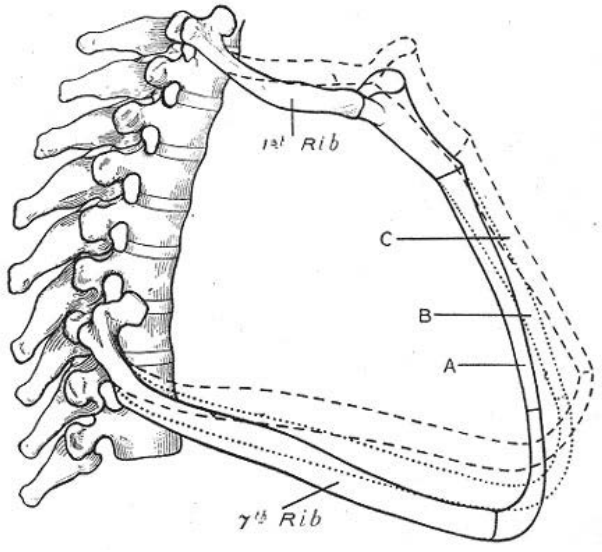
"Several of the blend materials were found to be excellent supports for human bone marrow-derived skeletal cells and foetal skeletal cells, with the optimized blend exhibiting in vivo osteogenic potential," the authors wrote, "suggesting that these polymer blends could act as suitable matrices for bioengineering of hard tissues".

The material they used, made from three different plastics, was built into a 3D honeycomb pattern to act as scaffolding for the bone stem cells. Tiny holes in the material permitted blood flow, feeding the stem cells which attached themselves all around the structure to form new bone.

"Fractures and bone loss due to trauma or disease are a significant clinical and socioeconomic problem," said Richard Oreffo of the University of Southampton. "This collaboration between chemistry and medicine has identified unique candidate materials that support human bone stem cell growth and allow bone formation."

In 2010 Paul Wooley of the Centre of Innovation for Biomaterials in Orthopaedic Research regrew bone inside a mammal's leg using a porous composite material similar to the honeycomb now being used. According to Wooley, bone and blood vessels grew around and through the material in six weeks. It could, he claimed, mean the prevention of countless amputations.

—BY (February 18, 2013)



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First NavioPRS Sale Made in U.S.

Six weeks after receiving FDA clearance for its NavioPFS system, Blue Belt Technologies, Inc., of Pittsburgh, Pennsylvania, has made its first U.S. system sale to Community Regional Medical Center in Fresno, California. In a release from PR Newswire, Blue Belt officials said they expect "that Community Regional will establish itself as the first U.S.-based center for Blue Belt and begin performing Navio partial knee surgeries in February 2013 led by Dr. D. Kevin Lester."

BLUE BELT TECHNOLOGIES, INC

Courtesy of Blue Belt Technologies Inc.

Lester said, "The Navio technology allows me to precisely plan and prepare the bone for partial knee replacements, making available a surgery that can positively impact a patient with mild to mid stage osteoarthritis and knee pain. The NavioPFS hand piece provides me precise control in a form factor that lends itself to easy integration into my operating room's traditional workflow."

Officials of Blue Belt Technologies, Inc. report that the firm is developing the next generation of "smart" surgical instruments with precision robotics for use initially in orthopedic procedures. The NavioPFS System provides the surgeon with a layer of safety and enhanced accuracy while performing bone-shaping tasks through minimally invasive incisions.

—BY (February 12, 2013)

extremities

New Scanner Reveals Extremity Fractures

The first CT system that can image seated, supine and standing patients has received FDA 510(k) clearance. Called the Planmed Verity extremity scanner, the device is designed to be used for pre- and post-operative imaging with better resolution, patient adaptability, and significantly lower dose than full-body CTs. Unlike other 3D imaging devices, Planmed Verity also allows weight-bearing imaging of the extremities. Planmed Verity is designed to find subtle extremity fractures at the first visit to the clinic—the sort of fractures that have been the most commonly missed using only 2D radiographs.

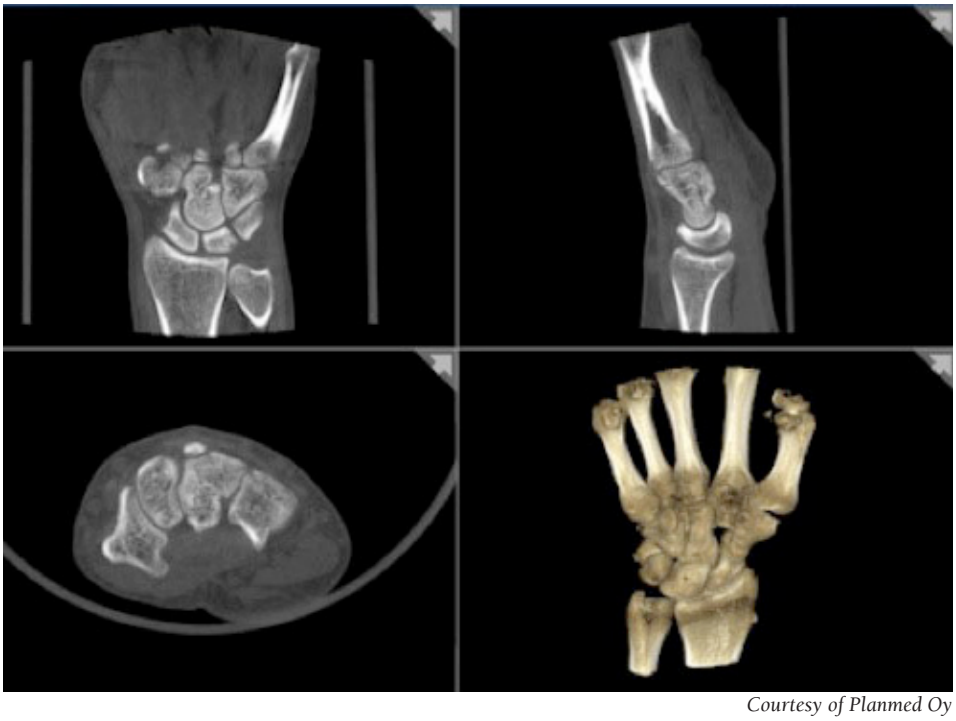
According to the manufacturer, the Planmed Verity adapts to the patient's body with anatomy-specific imaging programs, movements, and carbon-fiber positioning trays.

The device's easily adjustable, soft surfaced gantry and motorized positioning help in finding a comfortable position for various examination procedures.

"We are excited that this innovative, low dose orthopedic imaging system is now available also in the U.S. We are confident that it will be well received," said Vesa Mattila, vice president of Planmed Oy. The company is part of the Finland-based Planmeca Group which manufactures and markets advanced equipment for medical and dental fields. The U.S. subsidiary, Planmed USA, Inc., is located in Roselle, Illinois.

The Planmed Verity has the CE mark and is available for sale in the EU and other countries where the CE certificate permits sales. In the U.S., Planmed Verity has been in clinical test use at the Massachusetts General Hospital in Boston

—BY (February 17, 2013)



Courtesy of Planmed Oy

spine

Collaborative Spine Secures Medtronic Funding

Collaborative Spine RESEARCH FOUNDATION
Partnering to advance clinical spine research

Collaborative Spine Research Foundation

The Collaborative Spine Research Foundation was formed in 2011 by neurosurgeons and orthopedic surgeons to advance the science and practice of spine care. Most importantly, it would be a group that made decisions about research independent of industry influence.

The foundation was founded by the Neurosurgery Research and Education Foundation and the Orthopaedic Research and Education Foundation.

On Valentine's Day, Collaborative Spine announced the foundation is going to receive up to $7 million from Medtronic Inc.'s Spine business over the next three years to fund cross-disciplinary spinal research.

The total amount will be contingent on the foundation's ability to secure additional industry funding for its research agenda. The funds will be used to award competitive, multi-year grants for independent, investigator-driven clinical spine research studies. That's shorthand for: Not industry driven.

Medtronic's senior vice president and president of the company's Spine business, Doug King, said, "Clinical research in spine care is vital to our ability to advance patient care and improve access to needed technologies and therapies." King said Medtronic has always

demonstrated a commitment to clinical research over the years. "This grant is an evolution of that commitment. Collaborative Spine is uniquely positioned at the intersection of orthopedic and neuroscience spine care. All professional societies affiliated with spine care will have the opportunity to benefit from this research grant."

The research agenda was developed with key neurosurgery and orthopedic surgery stakeholders. The goal, according to the February 14 announcement, "is to answer the most important research questions and ensure that all funded projects are conducted in a valid, meaningful and rigorous fashion."

James Heckman, M.D., chair of Collaborative Spine, said Medtronic has demonstrated leadership with this grant. He said the group looks forward to other corporations and funding agencies joining this effort. "Together, we can broaden the reach of our research agenda and ultimately improve patients' lives."

"Collaborative Spine is plowing new ground as a multispecialty organization," said Charles Branch, Jr., M.D., the group's secretary and treasurer. "While we bridge two major specialties, we represent a united pathway for industry and other interested parties to contribute to the development of the science that will transform patient care. What's more, we're not relying only on government or NIH (National Institute of Health) funding to move our fields forward."

The Collaborative Spine board of directors consists of equal numbers of orthopedic surgeons and neurosurgeons, as well as a physician from a third medical specialty. The members are:

- Ray Baker, M.D.
- Charles Branch, Jr., M.D., FAANS
- Zoher Ghogawala, M.D., FAANS
- Richard J. Haynes, M.D.
- James D. Heckman, M.D.
- Paul McCormick, M.D., MPH, FAANS, FACS
- Peter S. Rose, M.D.
- Christopher Shaffrey, M.D., FAANS
- Jeffrey C. Wang, M.D.

As a result of the grant, Collaborative Spine made a funding opportunity announcement on February 11, 2013 of its intent to provide up to $10 million for original research projects that address its research agenda. Grants will be made for projects of one to three years in duration, at an amount up to $300,000 per year. The organization will have full and sole discretion in selecting research and awarding grants, and anticipates a solicitation for research grant applications to be published by May 1, 2013, with funding to commence by September 1, 2013. More information is available at the Collaborative Spine website, www.csr-foundation.net.

—WE (February 24, 2013)

AxioMed's Freedom Cervical Disc Tested in Europe

The AxioMed Spine Corporation, of Garfield Heights, Ohio, has introduced its Freedom Cervical Disc in Europe and successful implanted its first such device in Switzerland. The firm, which received the CA Mark for it in 2012, developed the total disc replacement device for the treatment of cervical degenerative disc disease.

AxioMed's Chief Operating Officer Jim Kuras described the disc, saying, "The Freedom Cervical Disc's unique asymmetrical design and resulting biomechanics represent advancement beyond the first generation total disc technologies, and better accommodates the cervical anatomy and spinal function. The differentiated design, with multiple footprints and heights combined with a wedge angle, provide the surgeon with an array of implants to address patient specific surgical requirements."

He continued, "The Freedom Lumbar and Cervical Disc technology is a second generation, viscoelastic polymer one-piece spinal disc replacement prosthesis that provides a combination of stability, compressibility and controlled motion that closely replicates the natural function of the native disc. The surgical procedure requires a limited number of instruments, is simple and reproducible, and requires no bone-milling or excess sculpting of the intervertebral body endplates to implant the device."

Neal Defibaugh, AxioMed's vice president of clinical and regulatory affairs said: "AxioMed is committed to conduct a Freedom Cervical Disc study in Europe that supports our goal of post-market surveillance. The clinical study

AxioMed SPINE CORPORATION

AxioMed

will provide additional data that complements the current, extensive biomechanical and biocompatibility test data that has been completed for the Freedom Cervical Disc."

The study's clinical results will be used to support a future Investigational Device Exemption (IDE) application to the U.S. FDA and to support regulatory approval in other markets outside of the EU.

—BY (February 18, 2013)

FDA Clears Innovative Spine PEEK Implant

The spinal implant device, called K7C Cervical Spacer, which uses Evonik Corporation's Vestakeep PEEK (polyether ether ketone), has received the FDA's 510(k) clearance for use as an intervertebral body fusion (IBF) device.

Michael Smith, founder and CEO of K7 LLC, attributed Vestakeep PEEK's durability as a key component in gaining FDA 510(k) clearance. "We could not be more pleased with the test results and material durability of Vestakeep PEEK," said Smith. "The inherent strength and added ductility have created new possibilities for our PEEK implant designs."

He noted that this is the first time a Vestakeep PEEK-based spinal fusion medical device has received 510(k) clearance from the FDA. The K7C Cervical Spacer is one of several PEEK-based spinal implant devices being developed by K7 LLC.

"Creating innovative solutions for our customers is a core component of Evonik," said Sanjeev Taneja, vice president of Evonik's High Temperature Polymers business. "The FDA approval is a testament to the product quality of Vestakeep PEEK and an example of the long-term commitment Evonik has to the medical device and orthopedic industries. This approval validates Evonik as a true player in the implant PEEK market."

Courtesy of Evonik Corporation

Taneja said that Evonik's customers are welcome to reference the Vestakeep PEEK product line Masterfiles (MAF). These are documents containing comprehensive test data on the product's mechanical and biocompatible properties that meet FDA regulatory requirements, which could be helpful in guiding future registration processes for implant medical devices.

—BY (February 12, 2013)

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