

Orthopedics This Week

week in review

05 The Best Spine Technologies of 2009 ♦ The Best Spine Technologies of 2009 were officially christened November 9 in San Francisco. Under the soaring chandeliers 200 attendees celebrated innovation, engineering and a relentless drive to improve spine care. Here are the winners!

08 Satisfied Surgeon, Depressed Patient ♦ Dr. Robert O'Toole, Assistant Professor of Orthopaedics at the R Adams Cowley Shock Trauma Center, along with Renan Castillo, Associate Professor at the Johns Hopkins Bloomberg School of Public Health, weigh in on patient satisfaction after lower extremity injury.

11 "No" ♦ The FDA Ortho panel said no to another spine device in November. A "fog of data" left panel members in a state of inconclusiveness and led them to believe that the Zimmer PMA application may have done a disservice to the Dynasys dynamic stabilization system. What happened? Read it here.

16 Large Joints: Revenues Increase, Pulse Strengthens ♦ After two quarters of revenue decline for the large joint reconstruction industry as a whole, third-quarter reports finally show signs of revenue growth and a stronger pulse within the industry. Read here for the details.



the picture of success

36 Dr. Elad Levy ♦ He performed the first surgery in the U.S. to use Axial LIF. And, Dr. Elad Levy, Associate Professor of Neurosurgery at the University of Buffalo, envisions a future where neurosurgery and orthopedics come closer together.



breaking news

- 20 Orthofix's Spine Recovers**
- Hip Fracture Rate Could Drop 25%**
- AMA, Surgeons Split on Reform**
- Alphatec Sustains Double-Digit Growth**
- Study: Childhood Abuse and Arthritis are Linked**
- Shock Waves Heal Fractured Bones**
- Biofilms Causing Non-Union and Device Failure?**

For all the news that is Ortho, read on.

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Spine Procedure U.S. Market Reports	Code	Large Joint Reconstruction	Code
<i>Spine Fusion</i>		Total Hip Replacement	81.51
Anterior cervical fusion	81.02	Total Knee Replacement	81.54
Posterior cervical fusion	81.03	Revision of Hip Replacement	81.53
Anterior dorsal and dorsolumbar fusion	81.04	Revision of Knee Replacement	81.55
Posterior dorsal and dorsolumbar fusion	81.05	Excision of Semilunar Cartilage	80.6
Anterior lumbar fusion	81.06	Cruciate Ligament Repair	81.45
Lateral lumbar fusion	81.07	Synovectomy of the Knee	80.76
Posterior lumbar fusion	81.08	Removal of Implanted Device Tibia/Fibula	78.67
<i>Spine Refusion</i>		Hemiarthroplasty	81.52
Posterior lumbar refusion	81.38	Hip Resurfacing	00.85
<i>Other Spine Procedure</i>			
Discectomy	80.51		
Decompression	03.09		

Extremity Market Reports	Code
Ankle Fusion	81.11
Triple Arthrodesis	81.12
Subtalar Fusion	81.13
Total Shoulder Replacement	81.80
Partial Shoulder Replacement	81.81
Rotator Cuff Repair	83.63
Total Ankle Replacement	81.56
Open Reduction of Fracture Radius & Ulna w/ Internal Fixation	79.32
Open Reduction of Fracture Humerus w/ Internal Fixation	79.31
Open Reduction of Fracture Tarsals & Metatarsals w/ Internal Fixation	79.37

(2004-2008 U.S. Procedure, Sales, Charging and Demographic Data as derived from Medicare AND Private Payer datasets)



Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Alphatec reported great results at NASS and gets crunched. Sales up 27%. Cash flows up 31% sequentially. Two years ago this was a meat and potatoes spine company. Today it is a leading innovator of spine implants. Last week was voted Best Spine Technology of 2009 TWICE. Under no circumstances should Alphatec's value be down. Up four spots.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Stryker	23.50%	8.43%	On a buying spree. Three companies since mid-year. Not blockbusters, but solid bolt ons.
2	6	Alphatec	(2.01)	(13.40)	Liked it at \$5.00. Like it even more at \$4.40. Very strong NASS meeting. Winner of TWO Best Spine Technology Awards for 2009.
3	4	Smith & Nephew	22.42	13.39	Hello buyers. Stock is up 13% in a month and SNN buys Nucryst for \$21 million.
4	3	Zimmer	28.10	6.43	\$1 billion raised in sale of Notes. Piled on top of \$443 million in existing cash. What's the War Chest for?
5	2	Orthofix	10.33	(0.92)	Rating Agencies raise OFIX credit rating. Smart, smart financial management is setting the stage for upside results across the board.
6	5	CONMED	6.92	8.08	Buying interest has cooled for now, but CNMD remains one of the most intriguing value stories in Orthopedics.
7	8	Exactech	12.61	9.43	Baird upgrades EXAC on the strength of 3rd quarter's 12% sales increase and even stronger earnings gains.
8	7	Medtronic	31.09	6.65	NASS meeting was so-so for MDT. New technology action was elsewhere. Down one spot.
9	9	Integra LifeSciences	15.37	0.22	2nd least expensive stock in Orthopedics. Orthopedic revenues up 19% in most recent quarter.
10	NR	Johnson & Johnson	26.94	0.69	Reorganization is tough and the troops are working through it. Operating margins up. Valuation, as always, is compelling.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Smith & Nephew	SNN	\$47.94	\$8,470	13.4%
2	Exactech	EXAC	\$17.64	\$226	9.4%
3	Synthes	SYST.VX	\$129.02	\$15,311	8.5%
4	Stryker	SYK	\$49.16	\$19,550	8.4%
5	CONMED	CNMD	\$21.81	\$635	8.1%
6	Medtronic	MDT	\$39.46	\$43,670	6.6%
7	Zimmer Holdings	ZMH	\$55.59	\$11,840	6.4%
8	Wright Medical	WMGI	\$18.09	\$699	5.4%
9	Average			\$10,604	3.0%
10	Mako Surgical	MAKO	\$9.23	\$306	1.8%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGOB.OB	\$0.50	\$5	-44.4%
2	Osteotech	OSTE	\$3.10	\$56	-31.9%
3	CryoLife	CRY	\$5.58	\$159	-29.4%
4	Symmetry Medical	SMA	\$8.05	\$288	-22.6%
5	Capstone Therapeutics	CAPS	\$0.67	\$27	-20.0%
6	Kensey Nash	KNSY	\$23.45	\$261	-18.6%
7	TranS1	TSO1	\$3.80	\$78	-15.9%
8	Alphatec Holdings	ATEC	\$4.33	\$227	-13.4%
9	Orthovita	VITA	\$3.71	\$283	-13.3%
10	ArthroCare	ARTC	\$19.85	\$519	-5.5%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Symmetry Medical	SMA	\$8.05	\$288	7.93
2	ArthroCare	ARTC	\$19.85	\$519	11.44
3	Medtronic	MDT	\$39.46	\$43,670	13.12
4	Johnson & Johnson	JNJ	\$61.43	\$169,490	13.48
5	Kensey Nash	KNSY	\$23.45	\$261	13.65

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	I Flow Corp	IFLO	\$12.63	\$309	292.10
2	Smith & Nephew	SNN	\$47.94	\$8,470	77.56
3	RTI Biologics Inc	RTIX	\$3.83	\$208	46.92
4	Synthes	SYST.VX	\$129.02	\$15,311	40.12
5	NuVasive	NUVA	\$39.41	\$1,510	36.08

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	ArthroCare	ARTC	\$19.85	\$519	0.46
2	CryoLife	CRY	\$5.58	\$159	0.74
3	Orthofix	OFIX	\$30.00	\$514	0.97
4	Symmetry Medical	SMA	\$8.05	\$288	0.98
5	Integra LifeSciences	IART	\$31.95	\$910	1.11

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	\$39.41	\$1,510	3.49
2	CONMED	CNMD	\$21.81	\$635	3.06
3	RTI Biologics Inc	RTIX	\$3.83	\$208	2.06
4	Johnson & Johnson	JNJ	\$61.43	\$169,490	1.82
5	Zimmer Holdings	ZMH	\$55.59	\$11,840	1.72

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	\$3.10	\$56	0.60
2	Symmetry Medical	SMA	\$8.05	\$288	0.74
3	CONMED	CNMD	\$21.81	\$635	0.92
4	Orthofix	OFIX	\$30.00	\$514	0.95
5	RTI Biologics Inc	RTIX	\$3.83	\$208	1.28

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	\$6.37	\$157	218.76
2	Mako Surgical	MAKO	\$9.23	\$306	11.65
3	Synthes	SYST.VX	\$129.02	\$15,311	9.36
4	NuVasive	NUVA	\$39.41	\$1,510	4.43
5	Orthovita	VITA	\$3.71	\$283	3.30

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The Best Spine Technologies of 2009

By Robin Young

The Best Spine Technologies of 2009 were officially christened November 9 at a spectacular gala banquet at the Palace Hotel in San Francisco. The spine industries big event under the soaring chandeliers celebrated innovation, engineering and a relentless drive to improve spine care for patients and those who care for them.

Eighty-three technologies were submitted in 8 categories and 26 inventors took home the massive crystal award. The voting by 34 surgeon judges was live and when the dust settled, a weary but elated group of 200 had participated in the selection and celebration of this year's winners.

Three companies were dual winners. Pioneer Surgical Technology won for both nanOSS Cervical and for NuNec Artificial Cervical Disc. Alphatec Spine won for both the OsseoScrew Expandable Screw and for the GLIF-Guided Lateral Interbody Fusion device. NuVasive won for the XLIF and the PCM.

There were several surprising picks. The judges chose to recognize three obscure technologies—the Bionic Spacer from the Israeli firm Spine21; the as yet un-named biomaterial from a consortium of the Aston, Oxford and Keele Universities in the UK and the “bone welding” technology from the Swiss firm WW [WoodWelding] Technology.

Spine 21's Bionic Spacer is a POST OPERATIVE adjustable interspinous process device which distracts via radio



control. Imagine real-time distraction with patient feedback regarding pain relief. The three UK universities, Aston, Oxford and Keele, collaborated on a new biomimetic hydrogel nucleus prosthesis to restore intervertebral disc height after surgery for patients with severe disc degeneration. The material has matching properties to those of the patient's native tissue. The Swiss firm, WW Technology, submitted bonewelding for the spine. Bonewelding technology anchors implants into bone using ultrasonic energy. During implantation, the energy liquefies the polymer coating and creates an immediate and extremely strong bonding with the bone.

Then on the other end of the spectrum, the surgeon judges selected technologies that are so widely used, that, frankly, we

thought they wouldn't be judged as innovative.

The judges were asked to evaluate each technology according to six criteria:

1. Is the technology creative and innovative?
2. Does the technology have long term significance?
3. Does the technology solve a current clinical problem?
4. Does the technology have the potential to improve standard of care?
5. Would you use it?
6. Is it cost effective?

Based on those criteria, the judges selected the following widely used and, yes, creative and significant technologies:



- Invibio's PEEK-OPTIMA material
- L.I.T.'s ONE HEADLIT
- NuVasive's XLIF
- K2M's SERENGETI MIS system

Invibio's material was used in a fair number of the submitted technologies and a high percentage of the winning technologies. No question about it, surgeons like PEEK-OPTIMA. L.I.T.'s cordless, battery powered head lamp for surgeons may not require a PMA, but it clearly struck a responsive chord among surgeons. The fact that a head lamp would share the stage with such high-end products as the Stabilimax, the M6, or Facet Solution's ACADIA is testament to the importance of basic tools. Finally, NuVasive and K2M have been wildly successful innovators in the market place with such MIS (minimally invasive surgery) systems as the XLIF and SERENGETI. But commercial success did not prevent the Spine Award judges from recognizing true clinical problem solving when they saw it.

In the Biomaterials category, Covidien's recently approved DuraSeal spine sealant system received the judge's award. In Diagnostics and Imaging, two technologies stood out—Nemaris' Surgimap software system and Ortho Kinematics Vertebral Motion Analyzer (VMA). Both offer spine surgeons important new tools. Importantly,

Nemaris' system is free. It is an imaging processing software that handles all types of files and even

goes so far as to simulate procedures. Ortho Kinematics' VMA system delivers motion diagnostics, which outperforms the current end-stage X-ray methodologies.

Every one of the Best Spine Technologies of 2009 were the result of thousands of hours of intense effort and achievement. No hyperbole—it was an honor to highlight all 83 of the submitted technologies and the hundreds of engineers, inventors and surgeons who contribute to what is the best in the spinal implant and instrument industry.

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Here are the BEST SPINE TECHNOLOGIES OF 2009!

Biomaterials

Covidien BioSurgery	DuraSeal Spine Sealant System
Invibio Ltd.	PEEK-OPTIMA Polymers
WW Technology	Bonewelding for Spine

Cervical Care

Aspen Medical	Symmetrically Adjustable Cervical Collar
Pioneer Surgical Technology	nanOSS Cervical
Pioneer Surgical Technology	NuNec Artificial Cervical Disc

Diagnostic & Imaging

L.I.T. Surgical	ONE HEADLIT
Nemaris	Surgimap Spine
Ortho Kinematics	KineGraph VMA (Vertebral Motion Analyzer)

Lumbar Care

Alphatec Spine	OsseoScrew Expandable Screw
Ouroboros Medical, Inc.	Ouroboros Spinal System (OSS)
Spine21	Bionic Spacer

Minimally Invasive Care

Alphatec Spine	GLIF - Guided Lateral Interbody Fusion
K2M, Inc.	SERENGETI Minimally Invasive Retractor System
NuVasive, Inc.	XLIF (eXtreme Lateral Interbody Fusion)

Motion Preservation:

Facet Solutions, Inc.	ACADIA
Spinal Kinetics, Inc.	M6 Artificial Disc (M6-C Cervical and M6-L Lumbar)
NuVasive, Inc.	PCM
Paradigm Spine, LLC	DSS Spine Stabilization System
Applied Spine Technologies	STABILIMAX

Pain Management

Alpha Orthopaedics, Inc.	ReleF Technology
Vexim	SpineJack
Spine21	Bionic Spacer

Regenerative Technologies

Advanced Biologics, LLC	OsteoAMP
Aston-Oxford-Keele	Intervertebral Disc Biomaterial
Bacterin International, Inc.	OsteoSponge Demineralized Bone Matrix



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Satisfied Surgeon, Depressed Patient

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

Dr. Jones is pleased with his work on that open tibia fracture. It was messy, but he salvaged the leg. Mrs. Smith, now hobbling down the hall, has a less positive opinion of the situation.

Dr. Robert O'Toole, Assistant Professor of Orthopaedics at the R Adams Cowley Shock Trauma Center, University of Maryland School of Medicine, thinks surgeons should pay attention to this discrepancy.

Detailing the background on his work in this area, Dr. O'Toole says, "This study on patient satisfaction after lower extremity trauma emanated from the LEAP (Lower Extremity Amputation Prevention) project, work done by numerous dedicated individuals. The team, led by Dr. Michael Bosse and Ellen MacKenzie, Ph.D., looked at 463 patients treated at eight level-I centers for limb-threatening lower-extremity injuries.



Source: <http://commons.wikimedia.org>

Along with these and other authors, we looked at the data in an attempt to answer new questions."

Proving that research abhors a vacuum, Dr. O'Toole and his colleagues found a niche. "Using the original LEAP paper, I worked with a team that included Renan Castillo, Associate Professor at the Johns Hopkins Bloomberg School of Public Health, to examine the data comparing patient and surgeon perception of outcomes. We found wide disagreements between these two parties. For example, patients and surgeons disagreed on the cosmetic appearance of the limb. Various entities are increasingly interested in patient satisfaction, but there

has been virtually no work done in this area regarding high energy, lower extremity trauma."

The researchers then set out to determine which factors go into patients' overall satisfaction with the outcomes of their surgeries. Dr. O'Toole: "What was the clinical picture, how was the person functioning, what was their level of physical and psychological impairment, what was their pain level...we wanted answers to all of these questions. In addition, we looked at the sociodemographic characteristics of the patient, the nature of the injury, and the treatment decisions that were made."

With a nod to his colleagues, Dr. O'Toole notes, "The original LEAP designers had considered these questions, and pertinent information



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had been sitting in the database since 1994. The central idea was to examine factors related to negative outcomes. One such measure was performance on the Sickness Impact Profile (SIP) scale, which ranges from 0 to 100. A normal score is 2 or 3, whereas these patients averaged 12. The factors involved in a bad SIP score were high school level education, being poor, nonwhite, lack of insurance, Medicaid, little or no social support, and a low level of self sufficiency.”

“Interestingly,” says Dr. O’Toole, “We didn’t find that these things mattered when it came to patient satisfaction. The real issues were more along the lines of, ‘Was the person in pain?’ and ‘How fast could he or she walk?’ This was not only surprising, but encouraging because unlike the socio-demographic variables, we might actually be able to help with these outcome variables. Theoretically, we could do something about their pain whereas we couldn’t change the fact they never completed high school.”

Leader or follower, emotional or rational...things of this nature were found to be inconsequential. Dr. O’Toole explains, “We looked at personality profiles, none of which had an effect on patient satisfaction. What did come into play at the two year mark was whether or not someone could return to work, and whether or not they become depressed. Overall, however, it was the physical functioning of the SIP that was relevant.”

“Nothing about the injury mattered, nor did the treatment. There was quite a mixed bag of injuries so it was shocking that the injury type didn’t matter, although all of the injuries were high energy in nature. I would say that these patients are not typical. Anyone can have trauma but it has been shown that these patients seem to have a high rates of substance abuse and some atypical personality tendencies. There was something about them that was more homogenous in that way...they were predominantly low income, with not much education, evidence of more neuroses, and less ‘agreeable’ than the average patient.”

The Underlying Issues

There remains a controversy about how much to emphasize patient satisfaction, says Dr. O’Toole. “Some people argue against using patient satisfaction to measure quality

of care, saying, ‘Well, people are just responding to how much they like the doctor.’ Others say that using patient satisfaction as a marker of quality of care is reasonably accurate, but this might depend on the disease process and the nature of the care. For example, it might be very difficult for a patient to determine the technical competence of a surgeon. Generally speaking, patients choose a treatment facility based on satisfaction, so hospitals—and insurers—are very interested in these data.

Renan Castillo, Ph.D., who, among other things, did the data analysis for this study, likes understanding



the underlying issues. He says, “What exactly is patient satisfaction measuring? Patients may not always be aware of all the clinical implications of the care they are receiving. For example, they might have unrealistic expectations or may be focused only on the acute care they received. It seems, however, that surgeons are focused on how they are doing *following* the injury. We actually need better measures of patient satisfaction for trauma. When you use standard measures of functional outcomes such as return to work and physical pain, you are not specifically measuring patient satisfaction.”

The divergence of surgeon and patient opinions on satisfaction is significant, says Dr. Castillo. “It seems that patients evaluate things differently and that patients consider different sort of information. For example,

surgeons seemed to value return to work and complications more than patients. The surgeons were more dissatisfied with recovery than the patients if the patient did not get back to work within a given amount of time. Similarly, if there was a clinical complication, the surgeons were less satisfied, even though the patients were not. On the other hand, the patients were dramatically less likely to be satisfied than the surgeon if they were unhappy about the care they received.”

What's Next?

Going forward, adds Dr. Castillo, the team will not only focus on research, but try to assist patients with education. “We are now looking more deeply into the discrepancies between patient and surgeon opinions. Specifically, we want to look more at

pain as a predictor of satisfaction. In these studies, pain and satisfaction with care were the strongest predictors of patient satisfaction with recovery. Additionally, we are working with the Trauma Survivors Network at the University of Maryland in an effort to improve patient satisfaction. Using observations from the LEAP study, we have helped to create an online community to encourage peer support, and will soon be creating a family handbook.”

Renan Castillo concludes, “We presented these and other findings at the American Academy of Orthopaedic Surgeons and the Orthopaedic Trauma Association. Because there is a paucity of literature on patient satisfaction after trauma, we are hoping that our work will encourage others to get involved in this arena.”



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“No”

By Walter Eisner



Rejected; <http://commons.wikimedia.org/wiki/File:Inkvisisjonen.jpg>

The FDA Orthopaedic and Rehabilitation Devices Panel said “No” to Zimmer on November 4 and did not recommend FDA approval for Zimmer’s Dynesys Spinal System. It was the second panel “No” vote for a spine device in the past year. Earlier in 2009 the panel also declined to recommend approval for Stryker’s OP-1 bone growth product.

The panel’s proceedings came to a stunning, if not also awkward, halt

when panel member Edward Hanley, M.D., moved at the end of the long day that the panel recommend approval of the device with conditions. His motion was met with silence. **No other panelists seconded the motion.**

Panel member and spine surgeon John Kirkpatrick, M.D., then looked around the table at his colleagues and said, “I’ll be the heavy.” He then moved that the panel vote that the system is “not approvable” by the FDA.

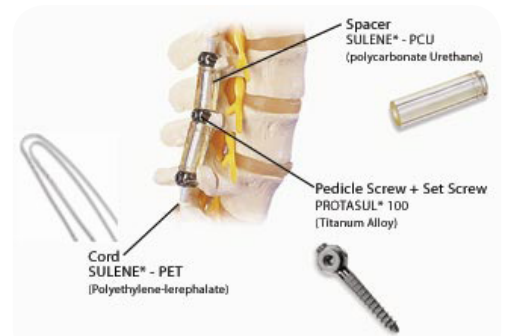
Brent Blumenstein, Ph.D., the panel member who famously pointed out OP-1’s “Abuse of the Alpha”, seconded the motion. The panel then voted 5 to 1, with one abstention, in favor of Kirkpatrick’s motion.

Just like that, another spine device was shot down by the FDA’s independent group of surgeons and scientists.

Don’t Blame the FDA

Don’t blame the FDA staff for this recommendation. FDA reviewers said they thought the device was safe and effective in documents released before the panel meeting.

The reviewers said a Zimmer study of the device met its goals, showing results at least as good as the company’s older Silhouette Spinal Fixation System used as an adjunct to fusion. Patients implanted with Dynesys showed a 52% treatment success rate, compared with 40% for Silhouette.



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“Zimmer Spine has developed a clinical option that is an alternative to fusion for stabilizing the lumbar spine. The data from this trial demonstrate that this device has been shown to be safe and effective for the treatment of patients with leg pain resulting from spondylolisthesis and/or stenosis,” said the FDA summary.

“The patient outcome and radiographic data in the Dynesys Spinal System prospective, randomized, multi-center clinical trial support the conclusions that this device is safe and effective in this context and the results generated are not-inferior to those of posterior lateral fusion. The trial was designed and executed to ensure that the results can be generalized to the population with lumbar spinal instability from degenerative spondylolisthesis/retrolisthesis and/or independently, lateral or central stenosis.”

Flawed PMA?

So what happened?

“The [Dynesys] PMA (premarket approval) application may have done a disservice to the device,” said panel member and a NASS (North American Spine Society) leader, Raj Rao, M.D., of the Medical College of Wisconsin in Milwaukee.

“The Dynesys is an intriguing concept that utilizes a well-established posterior pedicle screw platform. It intends to stabilize the motion segment, while preserving some degree of motion. The device is an attempt at addressing many of

the questions that spine surgeons grapple with on a daily basis—what is the ideal pattern and range of motion at a spine segment, how much motion does a spine segment need following decompression procedures, and what motion at a spine segment is good for the adjacent segments,” Rao told *OTW* after the meeting.

“The proposal submitted did not have a clear premise behind the workings of the device and this, in my opinion, led to a study design that did not allow these questions to be clearly answered. In addition, there were questions regarding the longer-term viability of the screw/construct within the body,” added Rao.

The first warning of the day that panel members had trouble with the PMA occurred when panel member



Raj Rao, M.D./OTW

Sanjiv Naidu, M.D., Ph.D., of the Pinnacle Health System questioned discrepancies between lab and clinical outcomes for patients with leg pain.

Kirkpatrick said he didn't understand the target population for the device and there were too many conflicting results without explanation. He cited the “paradoxical” results of patients with stenosis. He questioned sponsor presenters why leg pain results were different when researchers had expected the results to be the same.

Fog, Inconclusiveness and the Altar of Randomization

Blumenstein added that the “fog” of the clinical data left him in a “state of inconclusiveness.” He later said that he worships at the altar of randomization and noted that more than 25% of patients from the initial trial group were excluded from the final analysis. Rao noted a large discrepancy at some sites of Dynesys vs. Silhouette assignments.

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When the sponsor's presenters said their belief that all patients in the study were candidates for spinal fusion because of instability in the spine, Rao commented that instability of the spine for fusion candidates was defined by the pain generator. "But where was the source of the pain for the Dynesys patients?" asked Rao.

His question went unanswered.

Road to PMA

The Dynesys Spinal System was first introduced in Europe in the mid-1990s as a nonfusion pedicle screw

system. The original technology was developed by Dr. Gilles Dubois of the Nouvelle Clinique St. Jean, France.

This technology was subsequently transferred to Zimmer GmbH (formerly Centerpulse) where the design and development continued. The product was first used in the European Union in 1994 as a pedicle screw system for non-fusion applications. It received the CE mark in 1999.

Through March 2009, there have been over 40,000 patients implanted and the device was also cleared by the FDA

for posterior fixation as an adjunct to fusion.

Zimmer Reaction

This has to hurt at Zimmer headquarters in Warsaw. Just a few weeks ago CEO Dave Dvorak told Wall Street analysts during a quarterly earnings conference call that the majority of "headwind" at the company's spine division, stemmed from Dynesys' financial performance.

"We're heading for a panel review of the Dynesys product with the broader indications coming up next month.



Dave Dvorak

So that's going to be telling to the future of that product line, but we are big believers in the clinical success of that product and believe that it's really a

product that can make a big difference for patients," said Dvorak.

After the panel's vote, the company, through its spokesperson Brad Bishop, said,

"Following today's decision, Zimmer Spine will continue to work with the FDA to determine necessary next steps. Zimmer Spine remains committed to the Dynesys system, which has a proven clinical track record over 14 years in more than 42,000 cases globally."

"The system is used in fusion applications in the United States and non-fusion applications outside of the United States. This recommendation by the FDA panel does not impact use of the product outside of the United States. The company continues to believe the Dynesys system has the potential to become a valuable treatment alternative in a non-fusion application for Americans suffering from lumbar degeneration," added Bishop.

Potholes on the Approvability Road

With the device panel once again voting against recommending approval of a device because they

believed that the clinical trials were poorly designed, we asked Mark N. Melkerson, Director, FDA's Division of Surgical, Orthopedic, and Restorative Devices immediately after the meeting if initial IDE (investigational device exemption) study designs developed collaboratively with sponsors and the FDA were out of touch with device panel standards?

The FDA works with sponsors in designing the clinical trials and identifies milestones that must be met to reach "approvability" for the device. By the time the device panel sees the results of the clinical trials, many years have passed since those milestones of approvability were defined and agreed upon by the sponsor and FDA.

Melkerson said the agency was not ready to answer that question. He said he told the company immediately after the vote that there would be a review of the transcript of the panel meeting and the agency would get back together with the company to see if there were opportunities to continue to work towards approvability. The FDA is not obligated to follow the recommendations of the panel and could grant Dynesys approval with a significant post-market study requirement.

Some long-time FDA panel observers told *OTW* that they would not find it out of the question for the FDA to approve the previously cleared device. They reminded us that the FDA pays as close attention to the answers given by panelists to the questions posed by staff members as they do to the final vote. It was also noted that St. Francis Medical went through a similar ordeal with the agency following a negative

panel vote, before receiving final approval for the X-STOP.

Investigator Bias and Financial Disclosure

While the drama of another "No" vote by the panel took center stage, there was another notable item raised by Bob Durgin, J.D., the panel's industry representative from Biomet.

Durgin asked FDA staff why their summary document was highlighting an analysis of possible bias that could have been introduced through the financial interests of investigators. Investigators are always required to disclose their levels of financial interest in devices under panel consideration.

An analysis of those interests in the Dynesys showed that "no

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statistically significant treatment-by-compensation” was found in this case. A second analysis examined the correlation between compensation and clinical success rates for the Dynesys treatment, Silhouette treatment and both cohorts combined.

The FDA summary stated, “The correlation was positive for the Dynesys treatment and negative for the Silhouette, which are the anticipated directions if there were to be an effect of compensation. Therefore, there is only a trend which suggests the possibility of bias from compensation

with no statistically significant evidence of such an effect.”

Durgin wanted to know why this was being highlighted if it was determined that it was statistically irrelevant?

After repeated inquiry from Durgin, Mark Melkerson told the panel that pressure from Congress was behind this new emphasis. Some FDA staffers told us that the experience of Synthes’ ProDisc, where allegations of investigator bias due to financial interests were made, contributed to this new focus.

Clearing the Fog

In the end the panel members could not overcome their doubts of approving this cleared device for a new indication. The fog was too thick and comparisons for indications and patient selection too unclear. Whether or not Zimmer can find its way through the fog to eventually approval of the device is unknown.



Large Joints: Revenues Increase, Pulse Strengthens

By Scott Ellison, PearlDiver Large Joint Reconstruction Senior Analyst



Radial pulse/wikimedia commons

Large joint industry suppliers sold \$2.7 billion of products in the third quarter (3Q09), exceeding our forecast by \$126.4 million, or 4.9%. We have, therefore, increased our forecast for the large joint reconstruction industry by 4.5% to \$2.9 billion for the upcoming fourth quarter. We have also increased our forecast for the year from \$10.8 billion to \$11.0 billion.

Prior quarters had been marked with declines in revenue, with decreases of 2.6% year-over-year (YOY) in the first quarter, and 4.2% in the second quarter. These positive results from the third quarter, however, show signs of a strengthening pulse within the large joint reconstruction industry.

Two reasons, we believe, caused this change toward positive revenue

increases within the large joint reconstruction industry:

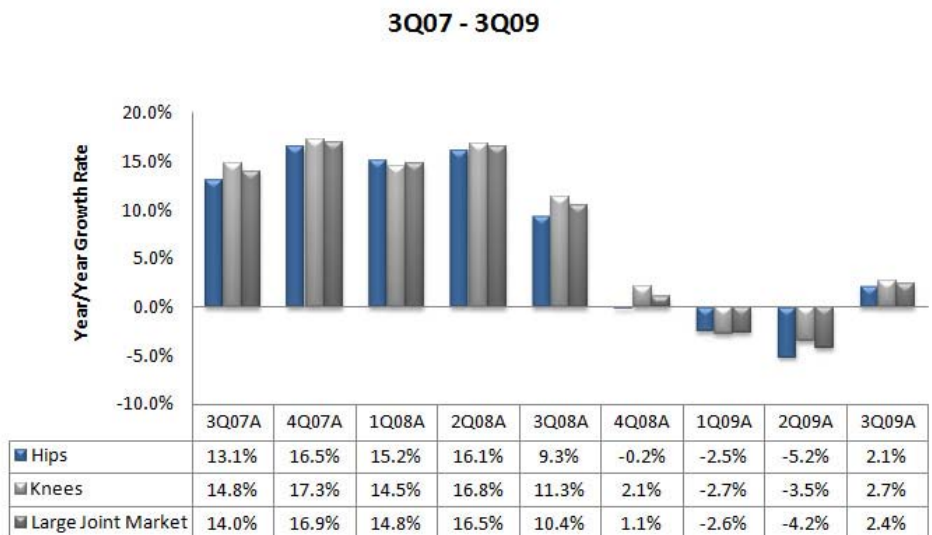
- Procedure volumes stabilized after two quarters of decline.
- European sales are recovering after steep declines in the second quarter.

Third-quarter results showed year-over-year revenue increases of 2.4% for the overall large joint reconstruction industry as shown in Chart 1. Specifically, the greatest revenue growth came from the knee implant sector, which increased 2.7% YOY, contrasting sharply with declines in growth over the previous two quarters. In addition to the progress within the knee sector, the hip sector also made progress. Prior to the third quarter, hip revenues had declined 2.5% and 5.2% YOY in the first and second quarters, respectively. Third-quarter reported earnings showed that revenues increased a modest 2.1% YOY.

A Strengthening Pulse

Whether the volume of large joint reconstruction procedures came from deferrals or an increase in patients feeling comfortable about moving forward with surgery, the numbers indicate that procedure volumes are stabilizing. When asked about knee and hip procedure volumes, Johnson

Chart 1: Large Joint Reconstruction Market Revenue Growth (Year-Over-Year)



Source: Company reports

& Johnson's Worldwide Chairman of Medical Devices and Diagnostics Alex Gorsky said, "We've seen some slight softness in price offset by some mix so overall we're seeing it about flat...we have not seen any additional deterioration."

President and CEO of Zimmer Inc. David Dvorak, also echoed this point: "Although there continues to be some uncertainty about the rate at which procedure volumes will return, we believe this quarter's results suggest the early indications of stabilization and potential trends towards more normalized growth rates."

In addition to stabilizing procedure volumes, sales of large joint reconstruction products outside the United States (OUS) improved vastly over 2Q09. As we reported in August, each of the top three large joint reconstruction manufacturers saw brutal decreases in year-over-year revenue:

- DePuy – declined 14.0%
- Stryker – declined 13.5%
- Zimmer – declined 13.1%

As of the end of 3Q09, revenues had again decreased year-over-year for each of these manufacturers, but these were only minor decreases in comparison to 2Q09:

- DePuy – declined 0.5%
- Stryker – declined 1.0%
- Zimmer – declined 0.3%

Along with the vast improvement to OUS sales overall, Stryker's hip product line actually gained ground during the third quarter with year-over-year sales increasing 1%.

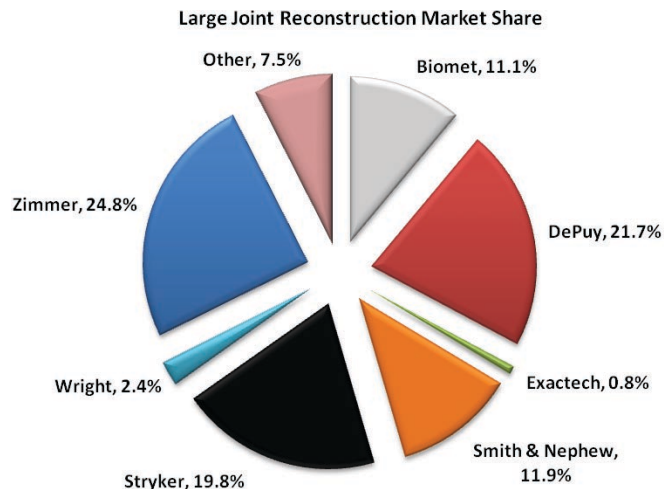
Despite these significant improvements over the quarter, pricing pressure continued to have a negative impact on implant revenues. Stryker commented during its quarterly call that hip and knee implants continued to see low-single-digit pricing declines

for both hip and knee product lines. Zimmer's hip product revenue growth was impacted by a pricing decline of 1.1% while its knee product revenue was impacted by a pricing decline of 1.2%.

Based upon Zimmer, the market leader in terms of market share, pricing pressure during the third quarter was the most pronounced within the domestic market. Specific to Zimmer, in the domestic market hip and knee products faced pricing declines of 1.7% and 1.5%, respectively. In the European market, hip pricing declined 1.4% while knees decreased 0.2%. In the Asia-Pacific market pricing actually improved in hips "about half a point, but we still have negative pricing in knees of about half a point" according to Jim Crines, EVP, Finance and CFO of Zimmer.

Yet even with each of the manufacturers experiencing pricing pressure domestically and abroad,

Chart 2: Large Joint Reconstruction Implant Market Share as of 3Q09



Source: Company reports



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some are gaining ground. As shown in Chart 2, Zimmer remains the largest company by market share within the large joint reconstruction industry closely followed by DePuy and Stryker. Over the course of the last fiscal year, Zimmer has lost ground to Biomet, DePuy, Stryker, and Wright—decreasing 1.2% from 26.0% of the large joint reconstruction market at the end of 3Q08. The biggest gain from any one of Zimmer's competitors was an increase in market share by Biomet from 10.1% one year ago.

Third Quarter Breakdown

Biomet, Inc.

Biomet, Inc. reported large joint reconstruction product sales of \$342.6 million in its 1Q10 (which ends August 31, 2009), an overall YOY

increase of 4.3%. Hip repair product sales increased 2.0% YOY on the success of their press-fit stems. Knee repair product sales increased 6.0% on strong sales of the Oxford Partial Knee System and Vanguard Complete Knee System.

DePuy, Inc.

DePuy, Inc. reported large joint reconstruction sales of \$640 million, a 2.7% increase from the third quarter of 2008. The company's hip division reported sales of \$296 million, above Wall Street consensus expectations of \$280 million and PearlDiver Technologies, Inc. expectations of \$279 million. This represents a YOY revenue growth rate increase of 3.9%. DePuy reported knee repair product sales at \$344 million, an increase in revenue of 1.7% from 3Q08, above Wall Street expectations of \$330 million and PearlDiver expectations of \$337 million.

Smith & Nephew, Inc.

Smith & Nephew, Inc. reported large joint reconstruction product sales of \$334.0 million, flat by YOY comparison with 3Q08. Hip repair product sales increased YOY 0.6% to \$158.0 million, above PearlDiver estimates of \$148.0 million. Knee repair product sales decreased YOY 0.6% to \$176 million, slightly above PearlDiver estimates of \$172.0 million.

Stryker, Inc.

Stryker, Inc. reported revenue YOY revenue growth in both the hip and knee reconstruction markets. Overall, large joint repair product sales were reported to be \$591.6 million, an

increase of 4.5% over the previous year. Stryker hip repair product sales increased YOY, breaking a streak of three quarters marked by decline with a 4.0% YOY increase in 3Q09 to \$280.5 million. Revenues for hip repair products exceeded Wall Street expectations of \$265.3 million and PearlDiver expectations \$267 million. Knee repair product revenues increase 5.0% to \$311.1 million, beating Wall Street expectations of \$294.9 million and PearlDiver expectations of \$295.3 million.

Wright Medical, Inc.

Wright Medical, Inc. reported that large joint reconstruction product sales increased YOY 5.9% to \$70.2 million. Hip repair product sales increased YOY by 6.6% to \$40.1 million, above PearlDiver estimates of \$37.0 million and Wall Street estimates of \$37.2 million. Knee repair product sales increased 5.0% YOY, to \$30.1 million, slightly above Wall Street estimates and in line with PearlDiver estimates.

Zimmer, Inc.

Zimmer, Inc. reported sales well above expectations in both hip and knee reconstruction markets with revenues of \$288 million and \$417 million, respectively. In total, large joint reconstruction product sales increased 0.3% from 3Q08 to \$705 million.

Looking Forward

The third quarter showed very positive signs and better-than-expected results, and we have increased our forecasts for the large joint reconstruction industry. Finishing out 2009, we expect 1.8% YOY revenue increase in

the hip product market, 4.8% increase in the knee product market, and 3.5% overall increase for large joint reconstruction market revenues in the fourth quarter with gains on a per company basis shown in Table 1.

As we have seen during the third quarter, even with European revenues still down slightly, in comparison to the third quarter of 2008, the overall return of these revenues to near stability is a drastic improvement over the second quarter of 2009 and a key

piece of the equation for a strengthening pulse in large joint reconstruction revenues. In addition, the stabilization of procedure volumes has set the pace for a solid fourth quarter.

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Table 1: Forecasted Hip and Knee Repair Revenues

	3Q09A	4Q09E	2009E	4Q10E	2010E	2011E	2012E
<i>Biomet*</i>	\$342.6	\$333.6	\$1,340.5	\$345.6	\$1,389.2	\$1,474.2	\$1,588.6
Hips	\$143.2	\$140.5	\$560.8	\$141.5	\$580.0	\$603.2	\$631.8
Knees	\$199.4	\$193.1	\$779.6	\$204.1	\$809.2	\$871.0	\$956.8
<i>DePuy</i>	\$640.0	\$685.7	\$2,577.7	\$723.7	\$2,720.3	\$2,900.6	\$3,132.7
Hips	\$296.0	\$311.0	\$1,162.0	\$332.1	\$1,240.8	\$1,302.8	\$1,407.0
Knees	\$344.0	\$374.7	\$1,415.7	\$391.6	\$1,479.5	\$1,597.8	\$1,725.7
<i>Exactech</i>	\$24.1	\$24.1	\$98.9	\$25.0	\$102.5	\$107.5	\$112.8
Hips	\$6.8	\$6.3	\$26.4	\$6.4	\$26.9	\$27.7	\$27.7
Knees	\$17.3	\$17.8	\$72.5	\$18.6	\$75.6	\$79.7	\$85.1
<i>Smith & Nephew</i>	\$334.0	\$376.0	\$1,415.0	\$433.3	\$1,630.5	\$1,734.4	\$1,891.6
Hips	\$158.0	\$176.0	\$666.0	\$202.2	\$765.1	\$811.0	\$875.9
Knees	\$176.0	\$200.0	\$749.0	\$231.1	\$865.4	\$923.4	\$1,015.7
<i>Stryker</i>	\$591.6	\$618.0	\$2,356.8	\$618.6	\$2,359.4	\$2,455.1	\$2,590.9
Hips	\$280.5	\$282.8	\$1,107.1	\$284.7	\$1,114.5	\$1,147.9	\$1,205.3
Knees	\$311.1	\$335.1	\$1,249.6	\$333.8	\$1,244.9	\$1,307.2	\$1,385.6
<i>Wright</i>	\$70.2	\$75.5	\$289.2	\$78.8	\$302.0	\$317.6	\$339.0
Hips	\$40.1	\$44.5	\$167.5	\$46.2	\$174.2	\$182.4	\$194.3
Knees	\$30.1	\$31.0	\$121.8	\$32.6	\$127.8	\$135.2	\$144.7
<i>Zimmer</i>	\$705.0	\$760.0	\$2,940.0	\$782.0	\$3,025.2	\$3,172.5	\$3,327.2
Hips	\$288.0	\$313.0	\$1,209.0	\$321.6	\$1,242.2	\$1,318.3	\$1,371.0
Knees	\$417.0	\$447.0	\$1,731.0	\$460.4	\$1,782.9	\$1,854.2	\$1,956.2
<i>Total</i>	\$2,707.5	\$2,872.8	\$11,018.0	\$3,006.9	\$11,529.1	\$12,161.9	\$12,982.8
Hips	\$1,212.6	\$1,274.1	\$4,898.8	\$1,334.8	\$5,143.7	\$5,393.4	\$5,713.1
Knees	\$1,494.9	\$1,598.7	\$6,119.2	\$1,672.1	\$6,385.4	\$6,768.6	\$7,269.8

* adjusted to match fiscal year of Jan 1 to Dec 31 • Source: Company reports

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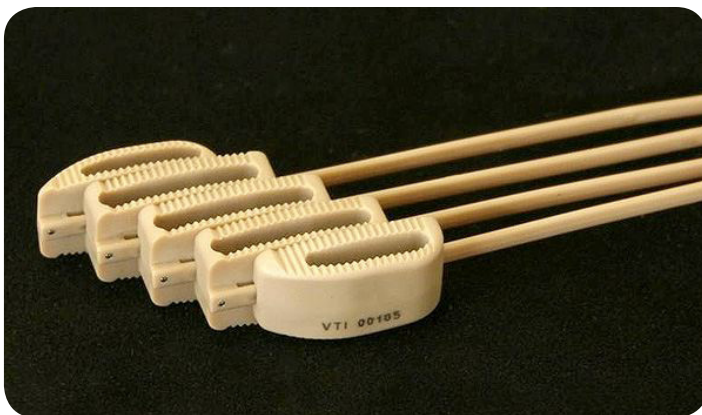
400th Implant for VTI's One-of-a-Kind IFD

This implant is truly unique. Nothing in the market is like it. This is an implant that self-assembles in the intervertebral space. Here's a picture.

The manufacturer, Vertebral Technologies, Inc. (VTI), is based in the Twin Cities and announced last week that it had sold the 400th implant of its InterFuse Interbody Fusion Device. Because the implant is modular and assembles in the intervertebral space, it can be implanted through a minimally invasive surgical approach.

Naturally, VTI has branded the approach and it is called "The Unilateral Posterior Lumbar Interbody Fusion (UPLIF). Uplif, get it? Uplifting—as in lift the vertebral bodies and, presumably, the surgeon's mood when he sees how easy this is.

Who says start-up medical engineering firms can't have clever brand names?



The UPLIF procedure was developed to allow the surgeon to access the intervertebral space with a single posterior incision and, in the process, keep tissue dissection and nerve root retraction to an absolute minimum. The approach also helps to preserve the facet joints. The company's senior management (industry veteran Jeffrey Felt, M.D. and CEO) stated that VTI has completed Phase I of the pilot launch and is currently expanding commercial distribution.

One surgeon who's used the VTI product, Manuel R. Pinto, M.D., Clinical Assistant Professor at the University of Minnesota and staff surgeon at Twin Cities Spine Center said, "The InterFuse Interbody Fusion System combines my preferred minimally invasive posterior surgical approach to the spine with a larger implant footprint than other implants. This combination provides superior anterior spinal column support while significantly reducing post-operative pain."

Finally, VTI is using its inter-operative assembling approach to improve

other fusion and even non-fusion devices including a disc nucleus replacement product—branded the InterCushion Disc Nucleus Replacement Device. The InterCushion is in clinical trials currently.

Seriously, this is a cool design and of course the company will be displaying it at the upcoming North American Spine Society meeting in San Francisco. Check it out.

—RRY (November 2, 2009) 

Allegheny General Joins Applied Spine Trial

Twenty-one down and nine to go for Applied Spine Technologies (AST).

Allegheny General Hospital in Pittsburgh, Pennsylvania, has become the 21st site enrolled in the company's FDA-approved Investigational Device Exemption (IDE) clinical trial of the Stabilimax Dynamic Spine Stabilization System.

Donald M. Whiting, M.D., performed the hospital's first surgery with the device on October 26.

AST's CEO Craig Corrance was happy to note that Allegheny General Hospital's status as "a nationally recognized comprehensive spine Center of Excellence reflects our strategy of partnering with leading U.S. spine facilities for the duration of our IDE clinical trial."

Company CFO Terry Brennan told OTW that, "We have approval to include 30 sites in our clinical study and we will selectively add key sites. Allegheny is an excellent site for AST as they have world class surgeons, including the study's Principal Investigator, Dr. Don Whiting and

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world class research led by Dr. Boyle Cheng.”

The Stabilimax Dynamic Spine Stabilization System, a posterior dynamic stabilization device, is believed to have expected benefits over current fixation products and even new artificial discs. Those benefits include a less invasive and less traumatic implant procedure, maintenance of spine motion and disc function, and the potential to prevent or slow adjacent-segment disc disease.

AST is conducting its clinical trials at a time when 16 previously cleared dynamic stabilizations systems have been required by the FDA to collect and submit post market clinical data.

—WE (November 3, 2009) 

Orthofix's Spine Recovers

Orthofix reported increased sales of 4% to \$135.1 million from the third quarter in 2008 and made another advance payment on a loan to retire their debt from the Blackstone acquisition.

Spine implants and biologics were up 10%.

Spine stimulation products were up 12%

They also made money.

Reported third quarter net income totaled \$6.2 million compared to a reported loss of \$237.3 million in the third quarter of the prior year.

Company President and CEO Alan Milinazzo pointed out that there was growth in each of the company's core businesses on a constant currency basis for the quarter.

Milinazzo particularly praised his spinal implants division for, “another strong performance...which generated 20% sales growth from our cervical and lumbar implant devices. This increase was driven primarily by the success of recent new product introductions, including the Firebird pedicle screw system and Pillar SA interbody device,” said Milinazzo.

“During the quarter the Musculoskeletal Transplant Foundation continued to increase its production capacity of our new stem cell-based allograft, Trinity Evolution, to a point where it met, and exceeded, the production levels included in our original commercialization plans. Additionally, as a result of continued strong cash generation during the third quarter, this month we made another \$5 million debt repayment ahead of schedule.”

Outlook

The company reiterated its full-year revenue guidance of \$535 million to \$545 million and reiterated its expectations for 8% to 12% full-year revenue growth and fourth quarter operating profitability in its spinal implants division. The company also expects to incur approximately \$800,000 in fourth quarter legal costs associated with an ongoing

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investigation of the bone growth stimulation industry.

Mike Matson of Wells Fargo upgraded his recommendation for the company's stock because of the better-than-expected results in the spine business which has now had two consecutive quarters of double-digit revenue growth.

Orthofix has also successfully navigated the transition from Trinity to Trinity Evolution, noted Matson. Looking forward, he expects Orthofix's spine implant and biologics business to grow at least in line with the spine market.

—WE (November 3, 2009) 

MAKO Raises Revenues and Capital

MAKO Surgical's third quarter revenues for 2009 increased by eightfold over the same quarter in 2008.

The company reported quarterly revenues of \$6.7 million on November 3, versus \$0.8 million the previous year.

The increased revenues came from the installation of six RIO systems during the quarter and 418 MAKOplasty procedures. This brings the total number of commercial sites with the systems to 29 and the total number of procedure performed since 2006 to 1,823.

Losses Narrow

In the first nine months of this year, MAKO had a net loss of \$24.7 million on revenue of \$25.4 million. In the same period last year, the company had a net loss of \$26.3 million on revenue of \$2 million.

Company President and CEO Maurice R. Ferre, M.D., said, "The 418 MAKOplasty procedures performed by our customers and the addition of six new commercial sites represent an increase in the adoption trends we experienced in the first half of 2009. In addition, we are gratified that we have received additional capital that we believe is adequate to allow for the continued execution of our business plan."

Equity Financing Raised

The company also announced a doubling of its sales force to 16 sales people and the completion of \$58.4 million in equity financing during the quarter. The net proceeds of the financing are expected to be used to support commercialization,



MAKO RIO System/MAKO Surgical

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sales, marketing, and general administrative activities, for research and product development activities and to fund working capital and other general corporate purposes.

MAKO Surgical markets both its RIO robotic arm interactive orthopedic surgical platform and Restoris implants for minimally invasive orthopedic knee procedures known as MAKOplasty.

According to the company, the FDA-cleared system allows surgeons to provide a precise, consistently reproducible tissue-sparing, bone resurfacing procedure to a large, yet underserved patient population suffering from early to mid-stage osteoarthritic knee disease. MAKO has an intellectual property portfolio of more than 250 licensed or owned patents and patent applications relating to the areas of robotics, haptics, computer assisted surgery and implants.

—WE (November 6, 2009) 

Alphatec Sustains Double-Digit Growth

In the third quarter of 2009, Alphatec Spine reported \$32.7 million in consolidated revenue which represents the ninth consecutive quarter of revenue growth and the sixth straight quarter of year-over-year growth exceeding 25%.

Alphatec Holdings, Inc., the parent company of Alphatec Spine, Inc.,



posted significant growth in revenues for the ninth consecutive quarter. On November 9, the company announced the financial results for the third quarter of 2009 (3Q09), which ended on September 30, 2009. Alphatec reported \$32.7 million in consolidated revenue, a 27% growth over the 3Q08. That makes 3Q09 the sixth straight quarter of year-over-year (YOY) revenue growth exceeding 25%.

Alphatec may only have a small share of the entire market for spinal implants and devices (1.4% in 2Q09), but the company has found success, and plenty of room for growth, within their niche of treating the aging spine.

In addition to sustaining strong growth in the U.S., Alphatec has also found much potential for growth abroad in European markets. The company reported \$6.6 million in international revenue for 3Q09, which represents a 52% increase over international revenue in 3Q08. Part of this growth is based on the strong start of OsseoFix, Alphatec's device for treating vertebral compression fractures. In Europe, the company has trained over 150 surgeons in the use of OsseoFix, and 300 European patients have received treatment with this device. During 3Q09, Alphatec began the patient enrollment process for a clinical study of OsseoFix in the

U.S. The company also submitted OsseoScrew to the FDA for 510k approval.

In the company's press release, Dirk Kuyper, Alphatec Spine's President and Chief Executive Officer, summed up the quarter's successes by saying, "I am pleased to announce that our revenue continues to grow at a record pace. We have had nine consecutive quarters of revenue growth, which is outpacing the growth of the overall spine market. We continue to gain market share through our strengthening U.S. and international distribution network, expanded core product offerings, and our aging spine product portfolio. In addition, we continue to acquire key intellectual property by strategically entering into licensing and assignment agreements."

Alphatec Spine company officials are currently showcasing new products at the North American Spine Society (NASS) meeting in San Francisco, which began on November 11 and will continue into the weekend until November 14. They also hosted an investor breakfast on November 11 which included hands-on demonstrations of several products in the company's development pipeline. For those on the east coast who missed NASS, Alphatec will be at the Lazard Capital Markets 6th Annual Healthcare Conference next week on Tuesday, November 17, at The St. Regis Hotel in New York City.

—DK (November 12, 2009) 

legal & regulatory

AMA, Surgeons Split on Reform

Physicians are an unwieldy political bunch.

Look no further than the health care reform debate. The same week the American Medical Association (AMA) voiced its support for the House of Representative's version of the Affordable Health Care for America Act, America's 20 surgeon societies warned the Senate that they would oppose their bill without revisions.

The AMA's support was linked to support for a separate piece of legislation that would repeal the current physician payment formula. While saying the bill wasn't perfect, the AMA said the bill would increase coverage for citizens, begin market reforms, and address the shortage of primary care physicians.

Perhaps not surprisingly, the surgeon societies disagreed.

The surgeon group led by the American College of Surgeons,



represents more than 240,000 members of various medical groups, including the American Association of Orthopaedic Surgeons, the sister organization of the American Academy of Orthopaedic Surgeons (AAOS) and the American Association of Neurological Surgeons.

The North American Spine Society (NASS) was not a signatory to the letter but sent their own letter to House leaders expressing concern for a number of provisions in their bill. The primary concern of NASS is that elements within the overall package will fail to control costs, fail to improve quality and fail to increase access to care.

The surgeon coalition noted the same thing about the Senate bill, which, they said, would limit patients' access to specialty care and could impede quality care.

"The AAOS has called for meaningful health care reform for decades," AAOS President Joseph Zuckerman, M.D., said in a press release.

"We, along with other surgical associations, are committed to working for health care reform that makes surgical care more accessible to Americans. The AAOS cannot lend its support to any legislation that does not expand Americans' access to quality care."

Specific problems noted by the surgeons, was that the bill fails to permanently fix the Medicare Physician Payment Formula

and lacks medical liability reforms. They also oppose likely mandatory participation in the Physician Quality Reporting Initiative, reimbursement changes and shifting the authority of making Medicare payment and coverage decisions to an unelected executive commission.

Zuckerman noted that AAOS has proposed several programs, such as the American Joint Replacement Registry, aimed at improving quality, decreasing costs, and improving patient access to care. The surgeons estimate that the national registry project could save more than \$1.3 billion over 20 years.

"After examining specific aspects of the Senate's health care proposals, we believe that the bill will not address these concerns," Zuckerman said in the press release. "We remain ready, willing and able to be a helpful participant in improving this legislation." Should the deficiencies of the bill not be addressed, "must announce our opposition."

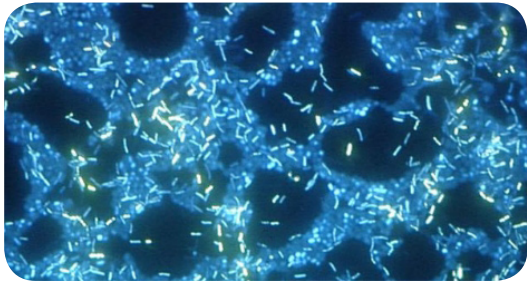
No plan for a peace conference between the AMA and the surgeon coalition was announced.

—WE (November 6, 2009) 

biologics

Biofilms Causing Non-Union and Device Failure?

In the first study of its kind, researchers at the Allegheny General Hospital are investigating how biofilms affect orthopedic procedures. Their findings could save money and lives.



Polymicrobial biofilm epifluorescence/Wikimedia Commons

Bacterial infections are elusive enemies. And when bacteria work together to form a protective community, called a biofilm, they can be almost impossible to treat. In the realm of orthopedics, these biofilms are particularly troubling when they form post-surgery around implants and devices or when they invade the site of a bone fracture.

These issues are at the heart of two new studies recently launched by researchers in Pittsburgh from the Allegheny General Hospital's (AGH) Department of Orthopaedic Surgery and Center for Genomic Sciences. Two of the world's foremost experts on biofilms, Drs. J. William Costerton and Garth Ehrlich, lead the Center for Genomic Sciences. According to their press release on October 23, "the AGH team is the first in the country to explore the impact of

biofilm infections on the success of orthopaedic procedures."

The first study will follow AGH patients with open fractures of the femur or tibia/fibula to see what kinds of bacteria lurk at the site of a fracture. The researchers know that if bacteria enter a trauma site, it can delay or stop the natural process of bone healing and sometimes result in non-union. Physicians can treat floating bacteria with antibiotics, but if the bacteria form more resistant biofilms, then physicians often need to surgically remove the biofilm and damaged tissue. The researchers will investigate whether or not biofilms are present at the site of non-union, and if so, they will also look into more effective methods of treatment.

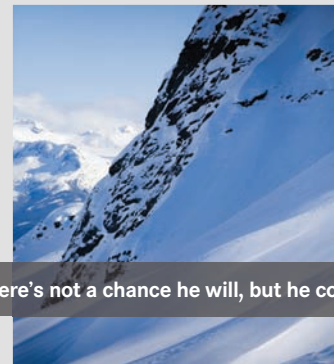
The second study will attempt to uncover the source of chronic infection in joint replacement procedures. In the press release, Dr. Costerton explains, "A small but growing body of evidence points to biofilm involvement in orthopedic implant infections. Our goal is to establish definitively what role biofilms play in complications associated with artificial joint implants and hopefully take an important step towards improving our ability to prevent this vexing problem in the future."

Biofilms on implanted devices are certainly vexing for surgeons and patients alike. These infections may cause a joint replacement to loosen,

and when antibiotics fail to treat the problem, physicians may be forced to remove the device altogether. The additional tests and surgery time translate to a higher cost for the hospital and a greater risk of complications for the patient. The AGH researchers will investigate the problem by examining aspirated fluid from patients who have received a joint replacement procedure and are experiencing complications, patients who are receiving surgery to remove a prosthesis, and patients who are having their first joint replacement surgeries (as a control group).

According to the press release, "infections occur in an estimated 2%

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of primary total joint replacements and as many as 15% of revision total joint replacements. The costs of treating such infections range from \$15,000 to \$100,000 per case.”

This research will become increasingly necessary as the population ages and the annual number of joint replacement procedures for patients rises. In addition to causing great pain to patients, these biofilm infections result in higher costs and greater burdens on Medicare.

—DK (November 2, 2009) 

BioMimetic: Canadian Marketing Approval for Augment

Just in case anyone's thought of it, this will definitely be better for grafting bone than maple syrup. BioMimetic Therapeutics, Inc. has announced that it has received approval from Health Canada to begin the marketing of its lead orthopedic product, Augment Bone Graft. The product is meant to be an alternative to the use of autograft in midfoot, hindfoot and ankle fusion indications in Canada.

“After rigorous pre-clinical and clinical evaluation of the product, BioMimetic is now ready to introduce this novel, implantable biologic to the marketplace,” commented Dr. Samuel E. Lynch, President and CEO of BioMimetic, in the news release. “In the Canadian clinical study, we observed 90% clinical success without the morbidity and



extra operating room time required to harvest autograft. We are proud to offer this safe and effective product to Canadian surgeons, who will now be able to offer their patients an alternative to the previous method of cutting bone out of one site of their body and transplanting it to another site.”

Steven Hirsch, COO and Executive VP of Orthopedics for BioMimetic Therapeutics, commented to *OTW* on future sales and marketing efforts. He noted, “Joint Solutions Alliance Corporation [JSAC] is the exclusive distributor of BioMimetic's Augment Bone Graft product in Canada. [JSAC is a sales and distribution company for orthopedic products headquartered in Burlington, Ontario,

Canada.] Joint Solutions is excited about the opportunity to make this product available to the many patients suffering from pain associated with foot and ankle injuries in Canada. BioMimetic will also deploy product specialists in the Canadian market to work collaboratively with the Joint Solutions Team. The company expects the product will be available to customers in Canada within 30 days.”

Augment, the company's second product to achieve Canadian marketing approval, is a completely synthetic grafting system for bone regeneration. It is composed of a purified recombinant growth factor, recombinant human platelet derived growth factor (rhPDGF-BB), and a

biologics

synthetic calcium phosphate matrix, beta-tricalcium phosphate (β -TCP). According to BioMimetic, it is the combination of the two components of Augment that is key to the overall effectiveness of the product. The rhPDGF-BB provides the biological stimulus for tissue repair by stimulating the recruitment and proliferation of new bone forming cells and blood vessels, while the β -TCP provides the framework or scaffold for new bone growth to occur.

With a nod to local knowledge, BioMimetic will also have product specialists in the Canadian market to work collaboratively with the Joint Solutions Team.

Health Canada based its Augment approval on a three-center, 60-patient open label trial. All participants were treated with Augment, and then monitored for healing over a nine-month period. Patients requiring fusions involving the midfoot, hindfoot and ankle were all eligible for enrollment in the study.

A full 90% of the patients, which included a large percentage of high-risk individuals, achieved a successful outcome based upon return to full weight-bearing and lack of need for revision surgery. The radiographic fusion rate was 87% at nine months after surgery. Based on a literature meta-analysis, the high level of success achieved in the study is consistent with results expected using autograft, the current gold standard for bone grafting materials,

but without the morbidity and extra operating room time required to harvest autograft. The data from GEM 21S, a BioMimetic grafting material, was also included in order to show that the product does re-grow bone. Regarding the approval process, Russ Pagano, VP Clinical and Regulatory Affairs for BioMimetic Therapeutics, told OTW, “We submitted a DLA (Device License Application) to Health Canada in mid 2008. The process is based on a submission of a comprehensive package of pre-clinical data, data from our GEM 21S study, our dental product that was approved in the U.S. and Canada in 2005 and 2006, respectively, and the 60-patient open-label registration study in Canada evaluating Augment Bone Graft. The data in the 60 patient study are consistent with success rates in literature reporting autograft rates. This is the basis for Augment being approved as an alternative to autograft.”

—EH (November 4, 2009) 

large joints

UNC Wins Awards at ACR

They don't stay late at the lab for the accolades...they do it for the people of North Carolina. Those at the Thurston Arthritis Research Center at the University of North Carolina at Chapel Hill School of Medicine have learned that their institution has garnered numerous research and teaching awards at the recent meeting



Rheumatoid Arthritis/Wikimedia Commons

of the American College of Rheumatology annual scientific conference.

Working under the “more data, more definitive answers theory,” those at Thurston have managed to collect large amounts of data from ongoing longitudinal studies, including the Johnston County Arthritis Project. According to the university, this attract top researchers, and makes it possible for faculty to investigate novel areas, including tai chi and the effects of selenium on arthritis.

To address clinical needs, and facilitate the translation of research to patient care, the center recently opened a new infusion clinic for rheumatology patients and joined a statewide family practice network to extend its reach and amplify its expertise.

“We take our role as the arthritis research center for the people of North Carolina very seriously,” said Joanne Jordan, M.D., the center director, in the news release. “That is why we are always looking for ways to bring our research findings to the

large joints



Joanne Jordan, MD

community and to learn from the community. Additionally, we have placed a high priority on working with medical and graduate students and being open to collaborating." Dr. Jordan, the Herman and Louise Smith Distinguished Professor of Medicine at UNC's School of Medicine, received the ACR's Award of Distinction for Excellence in Investigative Mentoring.

The Thurston Arthritis Research Center faculty presented their work in 25 sessions at ACR. "This is testament to the fact that UNC is a great place to train," Jordan added. "In the end, we're helping propel the field of arthritis research, which helps patients everywhere."

Regarding their training program, Dr. Jordan told OTW, "We make special efforts to attract students and trainees at all phases of their education, and we have been fortunate to have many receive awards and recognition for the high caliber of the work they have done with us. Because arthritis is becoming more common, it will become ever more important to attract more people to help us meet this growing challenge."

Others who received awards include Lauren Abbate, a third-year medical student at UNC, and Joshua Knight, a second-year UNC medical student, who won the Research Education Foundation's Abbott Medical Student Research Preceptorship. This award provided support for summer work under Leigh Callahan at the Thurston Arthritis Research Center to study how social determinants act as predictors of arthritis disability as part of the Johnston County Osteoarthritis Project.

Also on the stage receiving an award was Shelby Addison, a third-year medical student at UNC, who won the REF/Abbott Medical/Graduate Student Achievement Award in recognition of significant work in the field of rheumatology. Her poster on the selenium and joint metabolism biomarkers, using data from the Johnston County Osteoarthritis Project, was selected to be highlighted on the Osteoarthritis Poster Tour.

Amanda Nelson, M.D., won the Distinguished Fellow Award, given to clinical and research fellows in rheumatology in recognition of their meritorious performance throughout their training

Dr. Jordan also told OTW, "We know that being overweight or obese increases one's risk of knee OA, but that losing weight can be difficult. We were very interested to find out if maintaining one's weight instead of gaining weight would be good enough to decrease the risk. Unfortunately, merely maintaining weight was no better than gaining weight for decreasing the risk. The good news is though, that it may not require a huge amount of weight loss to see a benefit."

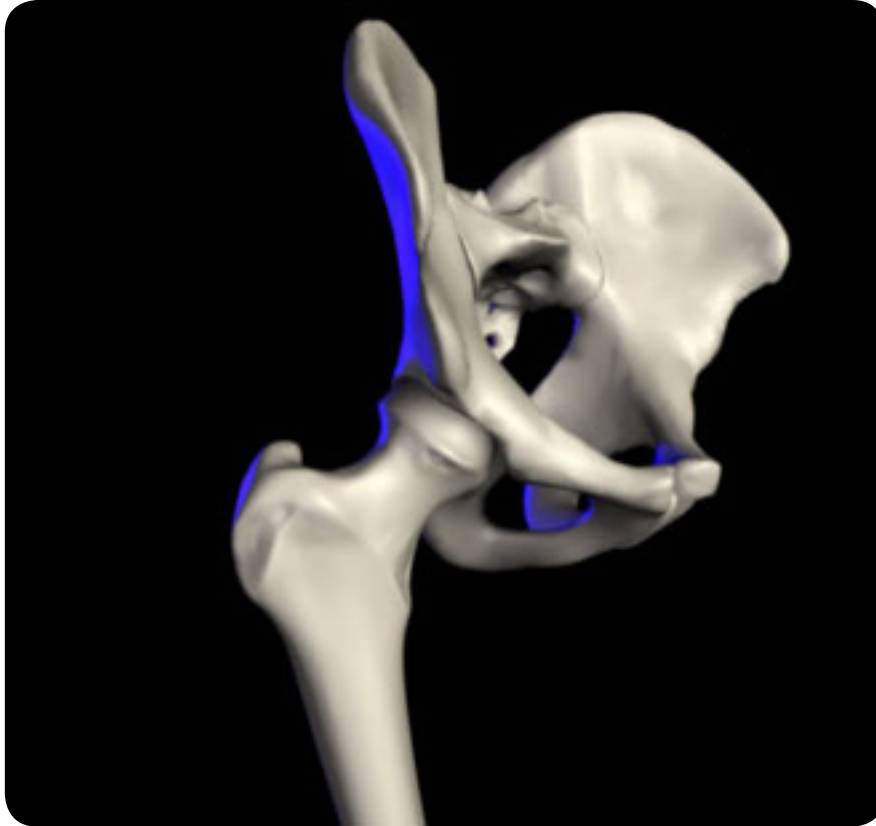
—EH (November 2, 2009) 

Hip Fracture Rate Could Drop 25%

Prevention is rather the other end of the OR...the latter being where most orthopedists like to spend a majority of their time. But, says a new study from Kaiser Permanente, the country's hip fracture rate could be reduced by 25% if at risk patients are managed aggressively.

The research, published in the November issue of the *Journal of Bone & Joint Surgery*, indicates that the first step must be a more active role by orthopedic surgeons in osteoporosis disease management. It is the largest

large joints



Hip bones. Image by Stephen Woods

study to date to examine osteoporosis management in men and women over 50 years old—650,000 men and women in Kaiser Permanente's osteoporosis management program were included. The researchers found that hip fractures dropped by 38%, preventing 970 hip fractures in 2007.

The prospective observational study examined the effectiveness of the Kaiser Permanente Southern California's Healthy Bones Program from 2002 to 2007. Kaiser Permanente indicates that its HealthConnect, the world's largest civilian electronic health record database, was used to collect

data on patients that included anti-osteoporosis medication usage, bone density scans and fragility fractures.

"Currently in the United States, the rate of treatment after a fragility fracture is only 20%. Treatment after a fragility fracture at Kaiser Permanente in Southern California is now 68%. Health care would be drastically improved if this model of osteoporosis care were adapted for the rest of America, said the study's lead author. Richard M. Dell, M.D., in the news release. Dr. Dell is an orthopedic surgeon at Kaiser Permanente in Downey, California.

When asked about the U.S. rate of treatment after a fragility fracture, Dr. Dell told *OTW* that it was previously noted by, "Several articles over the last few years and the HEDIS (Healthcare Effectiveness Data and Information Set) average treatment score."

In this study, the Kaiser researchers found that annual bone density screening rates increased by 263% from 2002 to 2007. The number of people on anti-osteoporosis medications increased by 153% from 33,208 in 2002 to 84,155 a year in 2007.

"The most important thing an orthopedic surgeon should know about osteoporosis/fracture prevention is that we can take action that helps to prevent hip and other fragility fractures," Dr. Dell said in the news release. "Simple steps like suggesting calcium and vitamin D for all your patients and bone mineral density testing in patients at higher risk for osteoporosis should be considered part of your daily practice."

"After a fracture, you need treatment, and in America, most people are not getting the treatment they need," Dr. Dell added. "The lesson here is if you are over 50 years old and have a fragility fracture, ask your doctor about getting a bone density scan, and if needed, osteoporosis treatment."

Dr. Dell also mentioned that understanding the pathophysiology of osteoporosis and fragility fractures helps to develop a treatment strategy.

large joints

To this point, Dr. Dell told *OTW*, “Knowing who gets osteoporosis and why is crucial in determining who gets the correct treatment, when to treat, for how long to treat, and all your treatment options. These treatment decision points were the main focus of the article and that by treating correctly you can see a huge drop in the fracture rate.”

—EH (November 9, 2009) 

Childhood Abuse and Arthritis are Linked

A long-lasting, bone deep, horror... Researchers from the University of Toronto have just published their findings that adults who experienced physical abuse as children have 56% higher odds of osteoarthritis (OA) compared to those who have not been abused.

The researchers, using self-reports of childhood physical abuse, as well as reports of a diagnosis of osteoarthritis, determined that there was indeed a significant association between childhood physical abuse and osteoarthritis in adulthood. The study is published in the November issue of the journal *Arthritis Care & Research*.



Source: <http://commons.wikimedia.org>

“We found that 10.2% of those with osteoarthritis reported they had been physically abused as children in comparison to 6.5% of those without osteoarthritis,” said lead author Esme Fuller-Thomson, Ph.D., in the news release. Dr. Fuller-Thomson, who is with the University of Toronto’s Factor-Inwentash Faculty of Social Work and Department of Family and Community Medicine, also noted, “This study provides further support for the need to investigate the possible role that childhood abuse plays in the development of chronic illness.”


When asked what led to this research, Dr. Fuller-Thomson told *OTW*, “We thought it plausible that substantial trauma, such as one would experience in childhood abuse, may result in long-term health outcomes. There is substantial literature documenting the links between childhood abuse and mental health outcomes such as depression, anxiety and suicidal ideation but less attention has been paid to physical health outcomes. Since arthritis is the leading cause of pain and long-term disability, it seemed logical to examine the association between abuse and arthritis, particularly in light of the fact that recent U.S. studies indicated there may be a link.”

Co-author Sarah Brennenstuhl, a doctoral student at the University of Toronto, added, “We were surprised that the significant association between childhood physical abuse and osteoarthritis persisted even after controlling for major potentially confounding factors such as obesity,

physical activity levels as well as age, gender, income and race.”

According to Fuller-Thomson, one important avenue for future research is to investigate the pathways through which arthritis may develop as a consequence of childhood physical abuse.

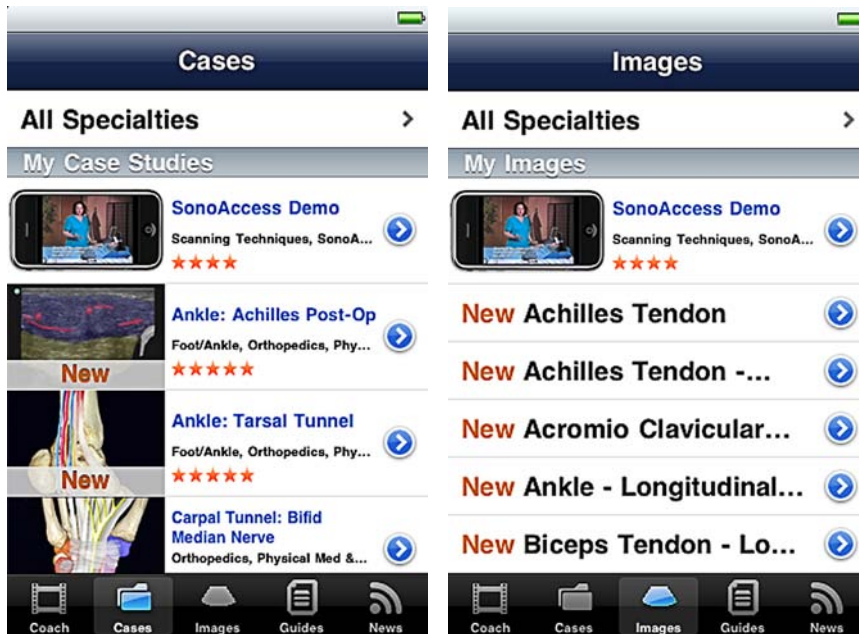
Detailing the possibility of such work, Dr. Fuller-Thomson told *OTW*, “Our cross-sectional study was not designed to determine causality. Further research should examine whether the stress of childhood abuse results in chronic dysfunctions in the Hypothalamus-pituitary-adrenal axis (HPA) which may, in turn, impact arthritis. The HPA axis is responsible for the secretion of cortisol in response to stress-inducing events. Cortisol is the ‘fight or flight’ hormone. We hope to conduct some longitudinal studies and see if these replicate our findings from this cross-sectional research.”

—EH (November 11, 2009) 

SonoSite’s App to Include MSK

Bad back? Yep, there’s an app for that. The techno wizards at SonoSite, Inc., creators of hand-carried ultrasound for point-of-care medicine, have announced the expansion of the SonoAccess iPhone application to include musculoskeletal (MSK) specialties. According to SonoSite, theirs is the first iPhone application to provide physicians with a comprehensive multimedia database of ultrasound resource materials.

large joints



SonoAccess screen shot/SonoSite, Inc.


“As technology advancements emerge all around us and physicians become increasingly ‘tech’ savvy, SonoSite is staying ahead of the curve with the SonoAccess application,” said Steven Sampson, Doctor of Osteopathy, in the news release. Dr. Sampson, who is affiliated with Orthohealing Center in Los Angeles, added, “SonoAccess is an excellent point of reference and is a quick and easy to use application that is accelerating the learning process for novice ultrasound users by changing the way physicians obtain information. In addition to formal training, SonoAccess can be used as a personal coaching tool, with tips and video demonstrations for medical treatments. Literally, SonoSite is placing a free resource for ultrasound guidance at a physician’s fingertips.”

Detailing SonoAccess for MSK specialists was the Director of SonoSite’s digital community,

Gina Kelly M.Ed., RDMS, RVT, RDCS, who told *OTW*, “We believe that musculoskeletal specialists, particularly orthopedic surgeons, rheumatologists, sports medicine specialists, and rehabilitation specialists, will most greatly benefit from the content contained within the image galleries and video libraries. The images and videos will provide MSK specialists with comprehensive scanning techniques and images that will enable them to accurately scan and diagnose their patients, as well as remain on the cutting edge of ultrasound imaging and technology. These features are also an ideal tool for clinicians within teaching environments. Because SonoAccess is loaded on an iPhone device, it is incredibly portable accessible and usually within a clinician’s grasp, unlike textbooks and many other medical resources. The comprehensive nature of SonoAccess gives clinicians

the information they want in a timely manner that they require.”

Regarding the development process, Kelly told *OTW*, “Slalom Consulting, a national management consulting and technology solutions firm with mobility expertise, worked with SonoSite on the design and development of SonoAccess to deliver the industry’s first interactive mobile learning application from an ultrasound company.”

—EH (November 12, 2009) 

people

Michael Lambert: NuVasive’s New CFO

Michael Lambert became NuVasive’s new Chief Financial Officer on November 9.

Alex Lukianov, NuVasive’s Chairman and CEO, told analysts on a recent conference call that Lambert’s “track record of guiding the finance and accounting functions at larger companies and generating operating leverage will provide in valuable to us as we continue to grow. We are grateful to Kevin, [departing CFO Kevin O’Boyle] for his countless contributions and for his continued effort to insure a seamless transition with Michael.” Lukianov said that Lambert’s starting date would coincide with the annual North American Spine Society meeting in San Francisco the week of November 9, 2009.

people

The 47-year-old Lambert joins NuVasive at a time when the company just met or exceeded Wall Street revenue expectations for practically all 22 quarters they've been a public company.


From October 2007 until May 2009, Lambert was Executive Vice President and Chief Financial Officer at Advanced Medical Optics, a publicly traded company with over \$1 billion in revenues until it was acquired by Abbott Laboratories in 2009.

Before that he was Senior Vice President and Chief Financial Officer for three years with Quest Software, Inc.

Lambert's prior work experience includes the following: Executive Vice President, Finance and Chief Financial Officer at Quantum Corporation; Senior Vice President and Chief Financial Officer at NerveWire Inc.; and various positions at Lucent Technologies, International Business Machines (IBM), Marakon Associates and Data General Corporation. Lambert received a B.S. in Business Administration from Stonehill College and an M.B.A. from Harvard Graduate School of Business Administration.

According to an October 19, 2009, SEC filing by NuVasive, Lambert's initial annual base salary is \$450,000 and he will receive a grant of 20,000 options upon his start date and 50,000 restricted stock units representing the company's stock in January 2010. Beginning in 2010, Lambert will be eligible for a performance bonus of

up to 100% of his annual base salary under the Executive Management Bonus Plan.

—WE (November 5, 2009) 

spine

Heavy Bags Causing Ortho Problems

Drugging the kitchen sink around can hurt. As children scramble onto school buses and workers lug around heavy computers, they are setting the stage for future orthopedic problems. "We're seeing an increasing number of injuries to the shoulder area, neck and upper back musculature, and the

low back, in both children and adults as the result of carrying bags that are too heavy or too large," said Jeffrey M. Cole, M.D., in the news release.

Providing details, Dr. Cole told *OTW*, "The pain presentations are due to (1) soft-tissue irritation and/or strain injuries and (2) the nerve damage generally is due to neuritis of the brachial plexus and other terminal (motor and/or sensory) nerves in the distal parts of the upper shoulder girdle areas. The possible causes for an increase of their presentation would be (1) carrying more books/electronic devices (i.e., computers) for a net weight increase, (2) carrying these same weight or heavier items for a greater time or distance, and/or (3) not maintaining proper shoulder girdle alignment and posture and



spine

generally being in worse physical shape, producing shoulder upper muscle atrophy, so that the same or increased weight carried over the same or increased duration could produce a higher frequency of injury to the nerves and soft-tissue.”

Dr. Cole, the Director of Electrodiagnostic Medicine and Musculoskeletal Rehabilitation at Kessler Institute for Rehabilitation in West Orange, New Jersey, also said, “Strains and sprains of the muscles and ligaments are the most common injuries and can be extremely painful, even causing permanent damage in some cases. While most injuries can be treated with medication, rest and occupational therapy, the best ‘cure’ is avoiding injury in the first place.”

Kim Hreha, an occupational therapist at Kessler, added, “Students of all ages load books, computers and other paraphernalia into their backpacks without thinking about how much they are carrying. The same holds true for workers who pack their computers, files and more into briefcases. Women who choose to carry fashionable, but oversized and stuffed, handbags are also at significant risk of injury. Even travelers face possible injury when they overpack their luggage, carry it incorrectly and lift it improperly.”

Some of Kessler’s recommendations include:


- Choose a bag that is proportionate in size (10% to 15% of body weight) and no larger than what is needed

- Look for lighter materials and durable construction in a briefcase
- Adjust the shoulder straps on a backpack so it fits snugly across the back and weight is evenly distributed
- If the bag has a waist strap, use it
- Switch shoulders or hands frequently to avoid muscle fatigue
- When traveling, plan in advance what you will wear and pack only those items
- Consider using two small suitcases as opposed to one large one.

Dr. Cole also told *OTW*, “Furthermore, people are generally not keeping the necessary upper trunk and shoulder muscles strong enough to protect the underlying fascia and neuromuscular structures, such as the upper trapezius muscles and the levator scapular muscles. These muscles, along with the rhomboideus muscles, need to be strengthened to protect the underlying fascia, brachial plexi, and other nerves.”

As for educating individuals on these issues, Dr. Cole told *OTW*, “There are a number of organizations, including Kessler Institute for Rehabilitation (www.kessler-rehab.com), as well as the American Occupational Therapy Association (AOTA) (www.aota.org), that offer information and materials on injury prevention to schools in an effort to help educate students, parents and teachers. But it’s important to keep in mind, that this is not just a ‘school’ issue. Men and women toting computers, heavy work bags, carry-on luggage and backpacks,

and oversized handbags are also increasing their risk for injury.”

—EH (November 3, 2009) 

Kineflex PMA Submitted

The first premarket approval (PMA) application comparing an artificial lumbar disc to an FDA-approved lumbar disc has been submitted to the FDA.

On November 12, SpinalMotion, Inc. announced that it has submitted a PMA application for its investigational Kineflex lumbar disc.

The PMA clinical study, involving 21 U.S. sites and a two-year patient follow-up period, compares the Kineflex to DePuy Spine’s Charité lumbar disc.



Kineflex Lumbar Disc/SpinalMotion

“Submitting our lumbar PMA caps more than six years of work in product development, clinical studies, and patient follow up,” David Hovda, SpinalMotion’s President and CEO told *OTW* at the recent NASS meeting in San Francisco.

The company also announced that it has secured \$27.4 million in Series

spine

D funding. Hovda said the company plans to use the additional funds for completing its Kineflex|C cervical disc PMA application and developing its next-generation artificial discs. In total, the company has enrolled and completed two-year follow up on over 750 patients in its U.S. clinical trials. Hovda also said that SpinalMotion continues to make progress on its lateral lumbar disc study, with approximately 20% enrollment completed.

SpinalMotion obtained FDA approval to conduct lumbar and cervical artificial disc clinical trials in the United States in 2005.

The company is privately held and was founded in 2004 by Southern

Medical, a spinal implant company in South Africa, and Thomas Weisel Healthcare partners. Three Arch Partners became an investor in 2005, and in 2006 Skyline Ventures and MedVenture Associates joined the company's investor group.

It's not a given that the FDA will convene its Orthopaedic Device Panel to make a recommendation of approval of the device. It can take anywhere from one to two years for the FDA to reach a decision on PMA applications.

—WE (November 13, 2009) 

trauma

Shock Waves Heal Fractured Bones

A new study by Italian researchers shows that shock-wave therapy is as effective as surgery in healing fractures which have resulted in nonunion. This treatment method could become a more economical and less painful option for patients.

According to a new study published in the November 2009 issue of *The Journal of Bone and Joint Surgery*, shock-wave therapy is as effective as surgery in healing fractures which have resulted in nonunion. This treatment method could become a more economical and less painful option for patients.

The Study

Dr. Angelo Cacchio led the research with colleagues from the Division of Orthopaedic Surgery and the Department of Physical Medicine and Rehabilitation at San Salvatore Hospital in LAquila, Italy. The study, titled "Extracorporeal Shock-Wave Therapy Compared with Surgery for Hypertrophic Long-Bone Nonunions" followed 126 patients from 2001 to 2004 who suffered from fractures which resulted in nonunion. The research centered on the treatment of femur, tibia, ulna, and radius fractures.

Researchers randomly placed the patients into one of three groups. The first two groups of patients received shock-wave therapy constituting four treatments of 4000 impulses



shockwave/prpinjection.blogspot.com



trauma

of shock waves with an energy flux density of 0.40 mJ/mm² (Group 1) or 0.70 mJ/mm² (Group 2). Group 3 patients received surgery for their fractures. According to the study, “at both twelve- and twenty-four months after treatment, there were no differences among the three groups.” Earlier in the healing process, at the six-month mark, radiographic results showed that nonunions healed in 70% of Group 1 patients, 71% of Group 2 patients, and 73% of Group 3 patients.

Shock-wave therapy may also have the advantage of providing more immediate positive results. In the November 2 press release for the study, Dr. Cacchio explains, “When we examined patients and compared their outcomes at three and six months, initially those who received the shock-wave therapy actually felt better than those who had surgery.

When we examined patients at 12 and 24 months, there were no significant differences in terms of healing. Scans of the bones proved non-invasive shock-wave therapy worked just as effectively as surgery.”

How Does it Work?

Researchers believe that shock-wave therapy stimulates certain growth factors which encourage the bone tissue to regenerate. The treatment elicits a metabolic reaction similar to what occurs during the natural process of bone healing. Shock waves also help reduce pain so that patients feel better sooner than if they received surgical treatment.

Shock-wave therapy may be less painful for patients than surgery, but is it also easy on their wallets? Dr. Cacchio told *OTW* that “in Europe (and especially in Italy and

Germany), shock-wave therapy is more economical than surgery, and above all, it carries less risk of adverse events. Much more will be done to make shock-wave therapy for nonunions even more economical.”

In the U.S., physicians have used shock-wave therapy for years to dissolve kidney stones, and orthopedists have used shock waves to treat conditions such as jumper’s knee and tennis elbow. While using shock-wave therapy to treat bone fractures is still a relatively new procedure, studies such as this will hopefully encourage more research into the effectiveness of this treatment.

—DK (November 6, 2009) 

The Picture of Success: Dr. Elad Levy

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



After essentially stumbling into medical school, Dr. Elad Levy, Associate Professor of Neurosurgery at the University of Buffalo, wasted no time distinguishing himself as an expert in the field of spine care. And he hasn't yet reached his 38th birthday.

Born in Israel, Elad Levy followed the peregrinations of his father as he pursued his studies to become an OB/GYN. "After my father's studies, we settled in rural northern New York, a lovely area, but one that lacked a stellar primary educational system. After switching to boarding school for my last two years of high school, I entered Dartmouth College and proceeded to spend my time out on the water rowing, as well as playing a lot of guitar. As for a career strategy, most parents say, 'Get a college

education...you can always fall back on that.' My parents said, 'Go to medical school...you can always fall back on that.' So, for lack of a better plan, in my junior year of college, I knuckled down, focused on my science courses and set my sights on medical school."

While Elad Levy was still rather focused on crew, his family crew reigned him back into academia. "My parents were so concerned about my education that the year my team won the NCAA rowing competition they didn't allow me to go to spring training so that I could study for the MCATs. I began medical school in 1993 at George Washington University in Washington, D.C., in part because I wanted to join their rowing team. Two years into medical school, however, I got tired of eating beans for breakfast, running into class dripping wet, and falling asleep while taking notes in lecture. I had to drop rowing. I still maintain that it was one of the best things I could have done for my career, though, because it gave me focus and discipline."

Medical Training

Making his way through medical school, a pensive Dr. Levy perched on the fence between orthopedics and neurosurgery. "The chair of neurosurgery at George Washington, Dr. Lalgam Sekhar, was a renowned physician who offered me the opportunity to do a summer research project after my freshman year of medical school. I was leaning toward orthopedics at the time because it

was more congruent with my love of sports. I applied for an internship in orthopedics that would involve work on bone cancer; my backup choice was a project on neurosurgery for brain tumors. Destiny spoke... and I didn't get the orthopedic internship. I came to discover a love of neurosurgery, in part because it allows you to move back and forth between spine and microsurgery. On the same day you can do macro 3D surgery involving fusion, and then go and perform a delicate operation on the nerves."

Dr. Levy then entered a world of minimally invasive innovation. "I chose the University of Pittsburgh for my neurosurgical residency because it was one of the highest volume programs in the country. There was a strong culture of innovation at 'Pitt' where it was expected that you would help push the field forward. The Chair, Dr. Peter Janneta, was the father of microvascular decompression, a surgery that doesn't damage the nerve and cures the clinical problem. His successor was Dr. Dade Lunsford, who brought the Gamma Knife to the University of Pittsburgh. I was intrigued by his work, and decided that I wanted to do minimally invasive endovascular surgery. At that point, however, the technology was insufficient to reach the brain."

So Dr. Levy's cerebrum began to churn...where could he learn the next level of vascular skills? "Pitt allowed me to take a two year leave of absence to go to Buffalo and work with the father of neurointerventional surgery,

Dr. L. Nelson Hopkins. While the hours were horrific, on a monthly basis we were seeing many new technologies and ways of approaching things. Upon my return to Pittsburgh I shared those things with my mentors and colleagues.”

Research and Advice

In 2004 the University of Buffalo welcomed Dr. Levy back as partner in the neurosurgery group. Two years later he joined those advancing spine care by performing the first surgery in the U.S. to use axial lumbar interbody fusion (Axial LIF). “There are no silver bullets in medicine; having a large toolkit minimizes complications and maximizes good outcomes. The bottom line is: don’t force the patient to fit the technology.”

Spine care can be thrilling, yes. But know when to put the brakes on, advises Dr. Levy. “Sometimes doctors get so enamored of technology that they make a minor subtle compromise—multiple times—and these all add up to a significant compromise which not infrequently leads to device failure.”

“I encourage residents and fellows to resist the temptation to be first, and ask them, ‘At the end of the day, would you do this surgery if patient X was a member of your family?’ If they are not 100% sure, then I have them draw up a new treatment plan. It is incumbent upon surgeons to stay current and thoroughly evaluate new technologies—not just take a sales rep’s word that XYZ product is the latest, greatest thing. In the end, we are the last line of defense for patients. I try to make sure

residents understand that patients trust us and ask them to keep in mind that patients usually have no in depth understanding of the underlying pathology or treatment options.”

Some of those patients only know about hospitals from TV; others have appeared on TV. “I have done a fair amount of work with patients who have scoliosis due to spinal tumors. In those cases I would call in an orthopedic surgeon who reconstructs the spine. One of our neurosurgeons, Dr. Kevin Gibbons, treated a player from the Buffalo Bills who had a traumatic cervical spine injury. The treatment began with an orthopedist who was at the game and who indicated that the player may have a spinal cord injury.”

One of the lingering post-surgical issues is infection control, an area where Dr. Levy and his colleagues are making headway. “We are finding that stroke patients with poor glucose control have worse outcomes. And, we think that the same is true in infection management. If so, better glucose control could lead to a lower incidence of infection and faster patient recovery with fewer complications. But, as is often the case, we need more data in order to make any definitive statements.”

Matching Patients With the Right Treatment

Of the five ‘W’s, Dr. Levy just may think that ‘Who’ is the most

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important. When asked what challenges he sees down the spine pike, Dr. Levy said, “A major issue continues to be patient selection... who should be operated on and who should be treated conservatively. Elderly patients with spine fractures are a complex demographic requiring thoughtful treatment plans. Also, once the decision is made to proceed with surgery, we need to know which approach is the most appropriate—maximum, minimally invasive, hybrid...side, front, back. Then once the surgery is complete, we need to have an appropriate way of assessing its success.”

“What we’re talking about here is, of course, evidence based medicine (EBM). Not only is EBM best for patients, the fact is that going forward reimbursement will be tied to being able to prove what works. Unfortunately, the culture outside of academic centers tends to be resistant toward evidence based medicine. The reality is that the majority of

physicians practice medicine the way they were trained—instead of evolving. We must, however, know if we should operate and how. And, fundamentally, are we indeed making a difference.”


Detailing the importance of patient selection, Dr. Levy notes, “Let’s say you have a patient with L5S1 spondylolisthesis who has experienced loss of disc height and mechanical back pain. You might do an Axial LIF, use percutaneous pedicle screws, or do an ALIF or TLIF. In order to decide which approach to take you must understand the implications of the patient’s physiology, body type, and age, among other things. So, if the patient is morbidly obese you would not do an anterior approach and may do things minimally invasively and percutaneously so that you don’t have

to retract the muscles and tissue. As for the age factor, in a younger person you want to get longevity out of the hardware so you would do everything possible to achieve a true fusion. In an older or frail person you might sacrifice longevity for a less traumatic surgery.”

What’s Next for Spine Care?

Although he fell in love with neurosurgery, Dr. Levy never forgot the appeal and the need for orthopedics in spine care. Dr. Levy: “I think we are going to continue to see a blurring of the lines between neurosurgery and orthopedics with regard to spine care. There are an increasing number of combined orthopedic/neurosurgery fellowships, and more and more of both ‘camps’ attending meetings in both specialties.”

Dr. Elad Levy can be found at many meetings around the country and globe. One day, he may just head out for one of these gatherings in his running shoes. “I have discovered the wonder of triathlons,” says Dr. Levy. “They are an amazing way to relieve stress. I did two last summer, and am planning on doing another half ironman next May. These events are a real testament to preparation, just as with surgery. The family sports time involves going to Buffalo Sabers hockey games with my wife and three children. They are 11, 8, and 4 and have decided that they want to work with dad when they grow up so that we can have lunch together.”

Dr. Elad Levy...making residents think and patients thank. 



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