VOLUME 6, ISSUE 8 | MARCH 16, 2010

Orthopedics This Week

week in review

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Spine Procedure U.S. Market Reports	Code
Spine Fusion	
Anterior cervical fusion	81.02
Posterior cervical fusion	81.03
Anterior dorsal and dorsolumbar fusion	81.04
Posterior dorsal and dorsolumbar fusion	81.05
Anterior lumbar fusion	81.06
Lateral lumbar fusion	81.07
Posterior lumbar fusion	81.08
Spine Refusion	
Posterior lumbar refusion	81.38
Other Spine Procedure	
Discectomy	80.51
Decompression	03.09

Large Joint Reconstruction	Code
Total Hip Replacement	81.51
Total Knee Replacement	81.54
Revision of Hip Replacement	81.53
Revsion of Knee Replacement	81.55
Excision of Semilunar Cartilage	80.6
Cruciate Ligament Repair	81.45
Synovectomy of the Knee	80.76
Removal of Implanted Device Tibia/Fibula	78.67
Hemiarthroplasty	81.52
Hip Resurfacing	00.85

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	81.63
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/ Fixation	79.37

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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Alphatec roars onto the Power Rankings at #7 this week as earnings forecast post-Scient'x purchase have moved up smartly. Orthofix repeats as the most attractive company in orthopedics on the strength of surprisingly strong cash flows and the lowest valuation. We love buying dollars for $0.40.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	11.00%	16.65%	Sells cardiovascular unit to Covidien, pays off more debt, cash is building, still only 1x sales.
2	4	Exactech	12.61	12.73	Off hours at AAOS, other managements were on Bourbon Street. Not these guys. They were on Royal St. Up two spots to #2.
3	6	Integra LifeSciences	15.37	9.56	Second best value in ortho with eight new products announced in eight days at three conferences. Up three spots this week.
4	8	Stryker	24.71	6.09	New mobile bearing hip previewed at AAOS. With outlook stabilizing for medical device firms, SYK should benefit.
5	5	Johnson & Johnson	27.1	3.12	We still think JNJ should break up and free DePuy. Seriously. Everyone would win.
6	3	Medtronic	31.37	3.53	AAOS exhibit floor rumor mill has MDT buying Stryker. Don't see it. ZMH + MDT makes more sense.
7	NR	Alphatec	-0.44	36.81	Call us one of the skeptics but this company under CEO Kuyper is making me a believer. Analyst estimates moving higher.
8	9	Zimmer	27.71	3.49	Strong AAOS topped off with an award for one of the best podium papers. Subject? Cost justification for TKA and THA.
9	2	Smith & Nephew	19.17	-0.58	Lots of SNN orange at AAOS but KCI wins key patent lawsuit. Down this week to #9.
10	7	Symmetry	11.48	-0.56	Management is trying to lower expectations for 2010. Down 3 spots this week.

Orthopedics This Week

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Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	NuVasive	NUVA	$44.10	$1,710	52.2%
2	Regen Biologics	RGBO.PK	$0.24	$2	38.2%
3	Alphatec Holdings	ATEC	$6.43	$334	36.8%
4	RTI Biologics Inc	RTIX	$4.28	$233	32.1%
5	Osteotech	OSTE	$4.15	$75	22.1%
6	Orthofix	OFIX	$35.38	$606	16.7%
7	TiGenix	TIG.BR	$5.61	$138	15.2%
8	TranS1	TSON	$3.63	$75	14.5%
9	Exactech	EXAC	$19.65	$252	12.7%
10	Integra LifeSciences	IART	$41.96	$1,200	9.6%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Wright Medical	WMGI	$16.25	$630	-7.8%
2	Synthes	SYST.VX	$120.63	14,316	-5.5%
3	Capstone Therapeutics	CAPS	$0.94	$38	-3.1%
4	Smith & Nephew	SNN	$51.20	$9,070	-0.6%
5	Symmetry Medical	SMA	$8.84	$317	-0.6%
6	Mako Surgical	MAKO	$13.05	$433	2.8%
7	Johnson & Johnson	JNJ	$64.18	176,620	3.1%
8	*Average*			*$11,629*	*3.1%*
9	Zimmer Holdings	ZMH	$59.24	$12,010	3.5%
10	Medtronic	MDT	$43.94	$48,550	3.5%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Kensey Nash	KNSY	$22.27	$244	12.64
2	Medtronic	MDT	$43.94	$48,550	13.55
3	Symmetry Medical	SMA	$8.84	$317	13.82
4	Johnson & Johnson	JNJ	$64.18	$176,620	13.86
5	*Average*			*$11,629*	*14.27*

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$51.20	$9,070	78.12
2	RTI Biologics Inc	RTIX	$4.28	$233	48.44
3	NuVasive	NUVA	$44.10	$1,710	42.39
4	ArthroCare	ARTC	$27.29	$732	24.01
5	CONMED	CNMD	$23.87	$695	24.00

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CryoLife	CRY	$6.62	$189	0.70
2	NuVasive	NUVA	$44.10	$1,710	0.81
3	Integra LifeSciences	IART	$41.96	$1,200	1.12
4	Alphatec Holdings	ATEC	$6.43	$334	1.20
5	Medtronic	MDT	$43.94	$48,550	1.28

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CONMED	CNMD	$23.87	$695	9.67
2	Orthovita	VITA	$3.75	$287	6.25
3	Johnson & Johnson	JNJ	$64.18	176,620	1.90
4	*Average*			*$11,629*	*1.72*
5	RTI Biologics Inc	RTIX	$4.28	$233	1.70

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$4.15	$75	0.78
2	Symmetry Medical	SMA	$8.84	$317	0.88
3	CONMED	CNMD	$23.87	$695	1.00
4	Orthofix	OFIX	$35.38	$606	1.12
5	Wright Medical	WMGI	$16.25	$630	1.28

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$5.61	$138	192.84
2	Mako Surgical	MAKO	$13.05	$433	12.74
3	NuVasive	NUVA	$44.10	$1,710	4.74
4	Synthes	SYST.VX	$120.63	$14,316	4.22
5	Stryker	SYK	$55.23	$21,980	3.30

Orthopedics This Week

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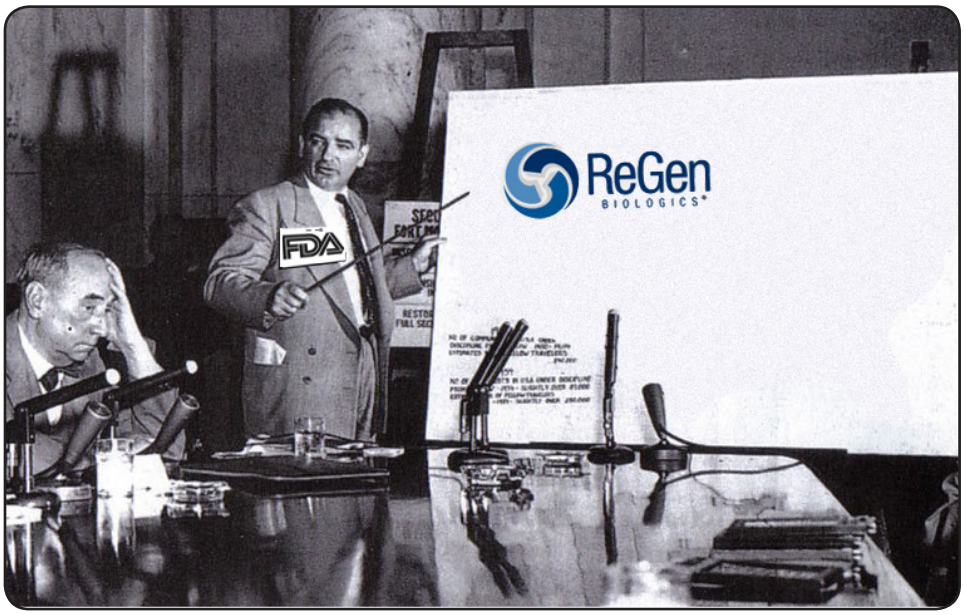
FDA Abuse of Power?

By Walter Eisner



The upcoming March 23 meeting of the FDA's orthopedic panel to "discuss and make recommendations on issues relevant" to the agency's reevaluation of its previous clearance of ReGen Biologics' Menaflex, raises significant and troubling questions for the device industry.

Does a "redo" of a previously cleared device in the absence of any adverse event reports constitutes a dangerous precedent for industry and violate one company's equal protection under the law?

Warning to Industry

Twin Cities attorney Mark DuVal, a well known and respected legal expert who has guided many devices through the FDA's Clearance and PMA processes, offers a sobering warning. DuVal, incidentally, has no financial or professional ties to ReGen Biologics.

Mark DuVal

DuVal told *OTW,* "This hearing borders on being vindictive and the whole matter is a very dangerous precedent for the industry and should not go without comment." The FDA's review of ReGen, says DuVal, is "unprecedented and unfortunate."

"The Agency has no legal basis for rescinding this 510(k). But it may not make a difference because the FDA is doing indirectly what it cannot do directly. By holding this hearing it is making a statement of some sort to the medical community and medical device industry and it is using adverse publicity to do it."

To those members of the broader medical community who may not understand these proceedings, said DuVal, it will scare them. Surgeons, hospitals and payers may well shy away from using a perfectly good product because the specter of an FDA review and the potential added risk of being second-guessed by product liability lawyers. Added DuVal,

"Physicians have already been worried about using this product given all the adverse publicity and now FDA is piling on by holding this hearing—to what end?"

FDA's Deafening Silence

OTW tried repeatedly to ask the FDA about its hearing and to specifically find out what the panel will be asked to review, consider and, frankly, do. What is the purpose of the meeting? The usually responsive agency public affairs officers declined to answer *OTW*'s repeated inquiries.

"At a time when the Agency is trying to become, or at least appear to be more consistent, predictable and rational, they convene this panel to reconsider a good decision once made after an exceedingly long and thorough deliberation. As a CEO or investor you now not only face the difficulty of trying to run FDA's gauntlet to obtain approval or clearance, you now also face the prospect of FDA attempting to reconsider its decision," added DuVal.

Device Background

ReGen's device has been in use in Europe for seven years and has been implanted in more than 2,500 patients. The FDA cleared the device after a tumultuous review process, which included soliciting the help of a congressional delegation and a meeting with the agency's orthopedic panel at the end of 2009.

A multicenter, prospective clinical trial was started at the end of 1996 and became one of the largest controlled, randomized clinical studies ever organized and conducted to test a product used for arthroscopic knee repair.

The company submitted its first module of a PMA in 2004. Independent of ReGen's submissions, other firms submitted comparable surgical meshes for FDA review and when the FDA cleared those device under 510(k), ReGen then decided to change its approach from PMA to 510(k). That submission occurred in December 2005 and the FDA granted 510(k) clearance on December 18, 2008.

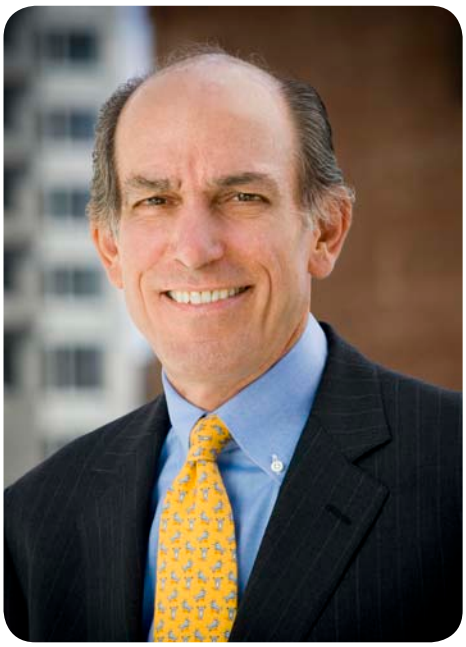
ReGen's Menaflex

"Maybe the message," says DuVal "is that industry had better not enlist the support of its congressional delegations when it doesn't like how things are going at FDA. But we should be not be dissuaded as an industry, nor as citizens, from calling upon our elected representatives to help us when an agency is dysfunctional and unaccountable."

"Even the FDA's own lawyers have taken the agency to task for not following the law or its own rules. The internal report already conducted by the FDA on ReGen found no wrongdoing on the part of the company, nor did it find the ultimate decision was influenced by the company's activities. In fact, FDA's Office of Chief Counsel found, as the rest of the industry is already aware, the review staff did not follow the law in its consideration of this product under the 510(k) program. The review staff asked the company to establish the clinical benefit and utility of the product and asked for comparisons to the standard of care, none of which are legitimate criteria for clearance of a 510(k)."

ReGen Appeals to Commissioner

In a letter on March 12, 2010 to FDA Commissioner Margaret Hamburg, M.D., ReGen's Chairman and CEO, Gary Bisbee, Ph.D., asks the Commissioner for relief from the agency's "undermining ReGen's ability to participate in the upcoming meeting."



Gerald Bisbee, Jr., Ph.D.

Bisbee writes that the panel questions prepared by the agency's staff, "demonstrate that the conclusions on ReGen's clearance have already been made and the panel simply represents an item on a list of items to be checked off."
"On the whole, the questions are leading, suggesting negative implications regarding ReGen's data, and unresponsive to ReGen's clinical data in its 510(k) submission and clearance."

As an example, Bisbee cites a question which asks the panel to identify whether differences between ReGen's device and the individual predicate devices raise questions about safety and effectiveness and suggests that such questions are inherent to different anatomical sites.

"However," writes Bisbee, "the agency fails to explain that surgical meshes have been cleared for numerous anatomical sites because the question in determining substantial equivalence is not whether the differences between devices raise safety and effectiveness questions, but rather whether the differences between devices raise different types of safety and effectiveness questions."
Other questions ask panel members to draw conclusions based on only part of the relevant information.

ReGen Denied Statutory Rights

Further, claims the company, the agency's administrative procedures for this panel meeting deny ReGen its statutory right granting persons whose products are reviewed by panels the "same access to data and information submitted to a classification panel…as the Secretary..."

Bisbee writes that the agency refused to inform the company of the precise questions for the panel prior to the preparation of company's written materials, although the agency's written materials are structured to respond to the questions it drafted and provided to the panel. In fact, writes Bisbee, the agency provided ReGen the panel questions only after the company's written materials were already complete and submitted to the agency.

Bisbee says the company received the questions, along with FDA's 50-page panel executive summary, only 48 hours before both were shipped to the panel and the company only had the opportunity to comment on the agency's errors in the summary and panel questions.

FDA's Unfair Advantage

FDA's "unfair advantage" of preparing its executive summary with knowledge of the questions for the panel's consideration, while denying ReGen's February 12 request for the panel questions in order to prepare their written panel submission, denies the company, according to Bisbee, the same access to data and information provided to the panel by FDA and therefore the same opportunity for the company to participate in the panel meeting.

Bisbee writes, "panel members received one set of written material that focuses on the core of the panel's deliberations—the FDA's—and another set that by comparison is an abstract effort to guess what the panel will be addressing."

It is common procedure to provide panel questions to the sponsor

48 hours prior to sending them to a panel. Because this meeting to reevaluate a 510(k) cleared device is unprecedented and threatens a property right (a cleared 510(k)), Bisbee tells Hamburg that reasonableness would dictate modified approaches to agency's non-binding guidance.

Bisbee asks that the questions provided by FDA's staff to the panel be revised to remove any bias and leading language and conform to the regulatory standard for 510(k) review that has been applied to hundreds of cleared surgical meshes. "Furthermore," writes Bisbee, "we request that the company be provided the opportunity to submit appropriate written materials responsive to the questions provided to the panel prior to the panel meeting."
Concluded DuVal:

> I know people intimately aware of this product who say it is a great product, albeit much maligned in a post-Dan Schultz Agency. Legally, it will be interesting to see what FDA intends to do with this hearing. Will ReGen be given an opportunity to defend itself and be afforded due process?

Industry has many questions and FDA is providing few answers or direction, but it is keeping industry off-balance and on edge. What can we expect next from this new FDA administration?

This whole matter is a very dangerous precedent for the industry and it should not be conducted without comment.

Put Down the Xray and Talk

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

Jan Havicksz Steen, 1625/1626, The Doctor and His Patient/Wikimedia Commons

Forget about house calls… Dr. Neel Anand, Director of Orthopaedic Spine Surgery at the Cedars-Sinai Spine Center in Los Angeles, would be happy if orthopedists would just *examine* their patients.

Dr. Anand:

> *"For a number of reasons, we have reached the point where imaging tests are ubiquitous and random. Some days it seems that all orthopedists do is look at tests."*

If you are going to be a medical detective, says Dr. Anand, you need to use all the tools available to you… even if they are seemingly basic/old fashioned/not sexy. "Just because you see something on an Xray doesn't mean it is the source of the problem. Our job as orthopedists is to put together all of the clues and correctly determine what is causing the patient's symptoms. But all the signs need to point in the same direction…the clinical exam must correlate with what the technology is telling you. You should not, once you have found something on the MRI, then try to make it match with your findings from the clinical exam."

Getting Back to the Fundamentals

Getting ahead in the field should not mean getting ahead of oneself… or getting ahead of the patient. Dr. Anand: "Orthopedists have more responsibility than ever, and I'm sure we're busier than ever. But that doesn't mean we can forget the fundamentals, including the fact that we are doctors *because of* the patients. They probably don't know their diagnosis, but they are certainly the best ones to report their symptoms. These days it is normal for residents to look at the imaging before seeing the patient, and, as they walk into the room say to themselves, 'OK, she's got stenosis at T3, T4, so I will do a decompression.' Then they find that the patient has other symptoms. If the doctor doesn't do a detailed exam, then the patient ends up being operated on at more levels than necessary."

Which, of course, sounds not just unethical, but seems like something that would interest a lawyer. "The fallback is the radiologist," says Dr. Anand. "He or she reads the films and, for example, writes 'spinal stenosis at T3, T4' in the report. Then the doctor finds something else during the clinical exam. In the event of a lawsuit, however, the defense attorney can say that stenosis was in the report. A good prosecutor, however, will essentially say, 'Well, Dr. X, didn't you go to medical school as well? This *is* your patient.'"

Thus for many reasons a touch of the old fashioned is in order. "Over time the importance of history taking and the clinical exam has been relegated to background. In the past we had grand rounds in which the doctors would go from patient to patient as a team taking the history and discussing the management and care of the patient. Today we sit in radiology rooms,

throw films up and talk about them, as opposed to discussing the whole patient."

"The value of the history and physical has also slid into the background in residency training," continues Dr. Anand.

> *"When the history is presented on the podium, in most cases the resident doing the presenting has just taken the information from the chart. This misses the fact that the patient has recently gone through a divorce, has major psychological issues, or that he had similar symptoms six years ago that resolved themselves."*

Examining Pain

Recalling a clinical situation he once encountered, Dr. Anand notes, "I know of a case where the patient presented with classic back pain accompanied by leg pain. The majority of leg pain is related to just one nerve, so any pain down the leg has to follow the pattern of that nerve (the L4 nerve). The patient had seen three orthopedists, had a block, and the MRI was reported as normal…but no one had bothered to examine him. The fact that the block had improved his pain meant that there was indeed a problem. It turned out that he had an extra foraminal disc—and yet people had written him off as histrionic."

But if it's not in the patient's head, it may be in his neck. "You may have someone with cervical myelopathy, who presents with bizarre symptoms such as dropping things, a change in handwriting, and stumbling. A well trained spine surgeon will be comfortable doing a neurological exam in order to fully assess the situation."

"Let's take another case," says Dr. Anand. "You have a 65-year-old woman with multiple levels of stenosis or degenerative changes, all of which is noted on the report. If you talk to the patient, you will find that she is active, and in fact walks five miles a day. For more than six weeks she has had pain down to her foot, to the top of her foot to the great toe. This is clearly related to the L5 nerve—she has no symptoms in her other leg and is otherwise healthy. All she needs is a block at L5, not, as some would preemptively say, a fusion or four level decompression."

Continuing with the all too frequent back pain theme, Dr. Anand notes, "Back pain is usually mechanical and comes from loading, i.e., sitting for long periods of time, lifting, etc. The patient may be fine in the mornings, but gets up from a sitting position and feels pain. The same patient now tells me that his buttocks hurts, meaning that a pinched nerve is the likely culprit. But a lot of patients don't differentiate between their back and their buttocks. Buttock pain needs to be differentiated from axial central back pain, as it usually indicates radicular pain and a pinched nerve, as compared to axial pain which is pain from the disc or facets."

Learning Good Social Skills

While you didn't go to medical school to learn how to be a good human, having a clinical practice may indeed require that you learn those skills anyway. "It may sound mundane, but you must have good social skills. We are dealing with people who are in pain, angry, and who may feel that they have been given the run around. Even though you may feel like walking out the door, you have to listen to their stories. Just accept that a full understanding of the person's situation means that you will have to give of yourself…and give your time."

Dr. David Helfet, Chief of Orthopaedic Trauma at Hospital for Special Surgery, concurs. "There is no question that a patient's history and examination are still the most important aspects of the evaluation. No matter how much people try, we are not supposed to be

treating an Xray. And Xrays are only part of the picture because while they define a bony injury, they don't define a soft tissue injury. You could actually be dealing with a nerve injury, vascular injury, a muscle or tendon injury, none of which will show up on an Xray.

"Most of my senior colleagues and I are proponents of 'old school' orthopedic education, i.e., you talk to the patient, examine the patient, and only then review the imaging. This trend in medicine to jump to the technology means that people are looking at the bloodwork, scans, etc., and are in fact spending more time reviewing this information than talking to and examining their patients. Technology has unfortunately taken over healthcare."

Laying out what could be a confounding situation, Dr. Helfet states, "Let's say a patient presents with knee pain…you take a knee Xray, find some arthritic changes and jump to the conclusion that the patient needs knee surgery. If you examine the patient, however, you learn that the knee itself doesn't have pain but that it is actually emanating from the hip."

The wavelengths on the Xray are sometimes less important than being on the same wavelength with the patient, says Dr. Helfet. "Mr. Jones comes in, says he's had an accident, and that his hip doesn't feel right. The doctor reviews the Xrays and says, 'Well, I don't see anything,' but doesn't examine the patient or doesn't adequately examine the patient. Maybe it's a case where the hip subluxes or impinges and almost pops in and out of the joint. You have to take the time to go through all of this with this patient. Sometimes I run two or three hours late, but believe it or not patients don't mind…they do mind if they wait two hours and then you spend only a few minutes with them."

To those whose starting point is a legal one, Dr. Helfet notes, "Don't practice legal defensive medicine—practice good medicine. Then you don't have to worry about litigation. You can easily justify your decisions and actions, and have a history of communicating well with patients."

"We have a noble profession that is sometimes dirtied by a few bad apples. Truth be told, we have a contract with every patient—an ethical and moral contract—one that they expect us to fulfill."

Get Thee to Duck Key

By Robin Young

Dr. Antonio Castellvi

Are there too many spine surgeon meetings? Or, are there too few **good** spine surgeon meetings? One that consistently rises to the top is the 2010 Preservation of Motion in the Spine meeting at Duck Key which starts in about three weeks (April 7 - 10).

What makes this meeting stand apart? Three reasons:

1. Intimacy and a rich schedule of hands-on work shops
2. Superior faculty from around the world. It certainly helps that the meeting is held at Hawks Cay. It's amazing how many top lecturers are ready for sea breezes after hibernating all winter in Baltimore, Philadelphia, Chicago, New York, Denver or Minneapolis.
3. State of the art information including probably the best series on biomechanics of any meeting in the U.S. But, to be precise, the lectures cover all types of spinal disorders and include a truly excellent review of complex cases covering disc replacement options, revisions and the latest techniques and technologies for tough cases.

Snowbirds take note. It is so **great** to attend these courses with the sounds of the ocean and dolphins wafting through the open windows.

The course director is the perennial podium speaker at NASS, SAS and other major conferences Dr. Antonio Castellvi. This is Tony's conference. It reflects his style which is open, comprehensive, sophisticated and a little fearless—particularly when it comes to posting up tough, challenging cases.

If you attend, and we hope you will (no, we don't have a financial stake—we pay our own way to the meeting) you will come away with an improved ability to:

- Assess and critique emerging surgical techniques and be able to compare them with current treatment options. This is an increasingly important skill.
- Assess and critique the latest implant, biologic and motion preserving technologies.
- Review clinical and biomechanical outcomes from motion sparing devices

- Assess, discuss and critique the biomechanics in both cervical and lumbar spine and how fusion and motion sparing devices affect motion
- Summarize evidence-based information and discuss current controversies in spine

Bring Your Whole Team

Calling all orthopedic surgeons, neurosurgeons, orthopedic surgical and neurosurgical assistants including physician assistants, nurse practitioners, orthopedic nurses and neurosurgical nurses. That's right. The whole team. Dr. Castellvi has designed this course to elevate the surgeon and the team. Since the morning is set aside for lectures and hands-on clinical sessions, the afternoon is a great time for your team to relax and perhaps do some planning away from the day-to-day demands back home.

The Faculty

Many of these names will be familiar—they're often authors of the peer reviewed papers you see in your journals.

Jean-Jacques Abitbol, MD, FRCSC
Orthopedic Surgeon
California Spine Group
San Diego, CA

Neel Anand, MD
Cedar Sinai Med Center
Los Angeles, CA

James Billys, MD
Orthopaedic Surgeon
Florida Orthopaedic Institute
Brandon, FL

Christopher Bono, MD
Chief of Orthopaedic Spine Service
Harvard Medical School
Co-Director Harvard MGH-BWH
Orthopaedic Spine Fellowship

Antonio Castellvi, MD
Director of Spine Fellowship
Florida Orthopaedic Institute
Tampa, FL

Boyle Cheng, PhD
Asst Professor of Neurological Surgery
Dir Welch Neurosurgical Research Lab
University of Pittsburg
Mars, PA

Anders Cohen, DO
Chief of Neurosurgery & Spine Surgery
The Brooklyn Hospital Center
Brooklyn, NY

Domagoj Coric, MD
Neurosurgeon, Carolina Neurosurgery & Spine Associates
Chief, Neurosurgery Carolinas Medical Ctr
Charlotte, NC

Reginald Davis, MD
Chief of Neurosurgery
Greater Baltimore Neurosurgical Association
Baltimore, MD

Ira Fedder, MD
Towson Orthopaedics Associates
Towson, MD

Lisa Ferrara, PhD
Biomedical Engineer
Orthokinetic Technologies LLC
Southport, NC

Rolando Garcia, MD
MPH Orthopaedic Care Center
Aventura, FL

Charley Gordon, MD
Neurological Spine Surgeon
Gordon Spine Associates
Tyler, TX

Stephen Hochschuler, MD
Orthopaedic Surgeon Texas Back Institute
Chairman of the Board. Texas Back Institute
Plano, TX

Manoj Krishna, FRCS, MCh
University Hospital of North Tees
Stockton-on-Tees, UK

Carl Lauryssen, MD
Co-director, Spine R&D
Olympia Medical Center
Beverly Hills, CA

Aniruddh Nayak,
Supervisor, Biomechanics Foundation for Orthopaedic Research and Education
Tampa, FL

Kenneth Pettine, MD
Rocky Mountain Associates
Loveland, CO

Luiz Pimenta, MD, PhD
Associate Professor UC-San Diego Hospital
S. Rita- Sao Paulo
Sao Paulo, BR

Dilip Sengupta, MD, PhD
Orthopaedic Surgeon
Dartmouth-Hitchcock Medical Center
Lebanon, NH

Jessica Shellock, MD
Orthopaedic Surgeon
Texas Back Institute
Plano, TX

Frank Vrionis, MD, MPH, PhD
Director, Complex Spine Surgery and Skull Base Surgery
Professor, University of South Florida
Tampa, FL

Scott A. Webb, DO
Florida Spine Institute
Clearwater, FL

Anthony Yeung, MD
Orthopedic and Minimally Invasive Endoscopic Spine Surgeon
Desert Institute for Spine Care.
UCSD School of Medicine
Phoenix, AZ

Hansen Yuan, MD
Professor, Orthopaedic & Neurological Surgery
State University of New York
Upstate Medical University
Syracuse, NY

And here are some of the lecture topics:

- Quality of Spine Motion
- Interpedicular Facet Travel and Center of Rotation
- Biomechanical Analysis of Motion With Stabilimax
- Bone Biomechanics
- Wear of Artificial Motion
- Preservation Implants and Wear Prediction Models
- Lumbar Total Disc Replacement Panel Discussion
- Biomechanics of Lumbar Total Disc Replacement
- State of the Art Lumbar Total Disc Replacement
- Reoperations in the 1st 1,000 patients at Texas Back Institute
- Experience With ActivL
- Total Disc Replacement From Charité to Freedom
- Total Disc Replacement With Flexicor
- Lateral Total Disc Replacement
- Prospective Evaluation of the Charité Lumbar Artificial Disc Replacement With Minimum 3-Year Follow Up
- Complications of Total Disc Replacement: Work-Up Strategies
- Dynamic Spinal Stabilization
- Do Posterior Dynamic Systems Actually Move?
- Experience With Dynesis
- Posterior Dynamic Stabilization
- Experience With the Transition System
- Biomechanics of the Total FSU Replacement – Design Criteria
- Experience With FlexuSpine Stabilization System
- Stem Cells in Spine Care

This will be my fifth year attending and frankly Tony's course improves each year. I hope to see many of our readers in Duck Key. Don't delay with your registration since openings are limited. To learn more and to register, go the this link: http://www.foreonline.org/CME/conferences/2010-Preservation-of-Motion-in-the-Spine

Slower Spine Growth Lowers Forecast

By Matt Menze, PearlDiver Spinal Market Analyst

Spine industry suppliers sold $2.2 billion of products in the fourth quarter ending December 31, 2009, 1.5% short of our forecast. Based on several factors, we are lowering our 2010 spine industry sales forecast 1.5% to $9.7 billion.

Six months ago, reported spine product revenues appeared to be rebounding from the late 2008, early 2009 slowdown. For 2Q09 and 3Q09 overall spine industry sales increased 11% and 10%, respectively. Then came the 4Q09. Year-over-year (YOY) spine product sales growth in 4Q09 was 8.6%. Three major trends, we believe, affected the fourth quarter and support lowered sales growth expectations:

- Pricing Pressure Is Increasing: As Stryker's CFO Curt Hartman noted in a recent conference call, the spine industry is an "increasingly price sensitive" market. Michel Orsinger, President and CEO of Synthes Inc., agreed stating that he had even seen capitated pricing from some of his hospital customers.
- Private Payer Pushback: Private payers are stingier with reimbursement. "Medical necessity" is driving reimbursement—for example, payers may be more inclined to reimburse for spinal stenosis and spondylolisthesis cases than discogenic back pain.
- Consolidations and Closings: Late last year Facet Solutions acquired the assets of Archus Orthopedics. On December 17, Alphatec Spine started the process to acquire the assets of Scient'x. IST, Vertebron and Disc Dynamics Inc. all closed.

Large Suppliers Set the Tone

Fourth quarter sales growth rates at Medtronic, Inc., DePuy Spine, Inc., and Synthes Inc. (collectively 60% of the industry) were 1%, 8%, and 9%, respectively, and anchored overall industry growth rates. In Table 1 we list and rank the quarterly sales for each major spinal implant company.

As the table shows, overall industry sales rose 8.6% in 4Q09. Full-year 2009 spinal implant, instrument and biologic sales increased 9.4% to $8.8 billion. We would also note that the fourth quarter is normally a seasonally strong quarter. For all of 2010, we estimate that spine revenues will rise by 10% to $9.7 billion.

Table 1: Quarterly and Annual Sales Revenue for Spine Product Companies

Revenue ($ millions)	4Q09	2009	1Q10E	2Q10E	3Q10E	4Q10E	2010E
Medtronic	842	3,500	924	914	882	885	3,605
Synthes	246	955	256	264	259	271	1,050
DePuy	240	1,002	281	295	258	267	1,101
Stryker	152	558	141	155	152	168	616
NuVasive	107	370	101	113	130	147	490
Orthofix/Blackstone	74	279	74	78	77	82	311
Globus	72	256	76	85	85	102	348
Zimmer	63	254	63	65	63	69	259
Biomet	59	234	59	66	64	67	255
Alphatec	37	132	38	61	57	66	222
Pioneer Surgical	29	112	32	34	33	35	134
Orthovita	25	93	26	30	29	31	117
K2M	22	83	27	28	28	29	112
SeaSpine	16	60	18	19	18	20	75
Scient'X	13	50	15	-	-	-	-
Osteotech	12	48	12	13	13	13	50
Integra Spine	11	41	11	12	12	12	47
U.S. Spine	10	39	12	12	12	13	50
RTI Biologics	10	41	9	10	11	12	42
LDR	9	35	13	13	13	14	53
Spinal Elements	7	25	8	8	8	9	33
Trans1	6	30	6	7	7	7	26
ArthroCare	6	21	5	6	5	6	22
Exactech (Altiva)	2	7	2	2	2	2	8
Other	148	568	156	163	161	173	653
Total Revenues	$2,216	$8,794	$2,366	$2,451	$2,377	$2,500	$9,678
Total Growth	8.6%	9.4%	10.3%	8.3%	9.5%	12.8%	10.1%

Source: PearlDiver Technologies estimates, Wall Street reports, SEC filings;Synthes, Globus, and DePuy are estimated revenues; Osteotech spine-related revenue assumes 70% DBM revenue is spine related; Abbott Spine revenues reported as part of Zimmer 4Q08

Table 2 displays market share gains and losses for the quarter. NuVasive, Inc. and Globus Medical, Inc., we estimate, gained 1.1% and 0.78% share. Medtronic's growth continues to lag and we do not expect that the company will be able to return to market growth rates in 2010.

Table 2: Market Share Changes

Company	4Q08	4Q09	Est. Market Share Δ
NuVasive	**3.7%**	**4.8%**	**1.15%**
Globus	2.4%	3.2%	0.78%
Alphatec	**1.4%**	**1.7%**	**0.26%**
Orthofix	3.2%	3.4%	0.14%
Stryker	**6.8%**	**6.8%**	**0.02%**
Synthes*	11.1%	11.1%	0.00%
DePuy	**10.9%**	**10.8%**	**-0.05%**
Biomet	2.7%	2.7%	-0.05%
Trans1	*0.4%*	*0.3%*	*-0.08%*
Zimmer	*3.5%*	*2.8%*	*-0.67%*
Medtronic	*40.8%*	*38.0%*	*-2.78%*

Source: PearlDiver Technologies estimates, Wall Street reports, SEC filings

Individual Company Commentary

Alphatec Spine, Inc.

The big news, of course, is Alphatec's bid to acquire Scient'x Group SAS, which we estimate had $50 million in revenues in 2009. The buy-out is scheduled to close 1Q10 and would significantly expand ATEC's global reach.

For 4Q09, Alphatec reported that spine product sales popped 28.9% to $36.6 million (up from $28.4 million in 4Q08). U.S. 4Q09 revenues increased 29% $28 million. This is the tenth consecutive quarter of record revenues and the seventh straight quarter in which YOY revenue growth exceeded 25%. Alphatec now has 95 distributors in the U.S. representing 280 sales reps with a goal of having over 85% exclusivity in 2010.

For 1Q10, we are forecasting that sales will rise to $38 million and for the full year, with three quarters of Scient'x added in, that sales will rise 68% to $222 million.

Biomet, Inc.

Biomet's calendar 4Q09 spine sales (fiscal 2Q10) rose 6.5% YOY to $58.9 million—which was under our $61 million estimate. U.S. sales rose 7%, marking Biomet's eighth consecutive quarter of domestic revenue growth. During January's conference call with analysts, management said that spine hardware sales increased by double-digit rates but that both spinal stimulation and biologic product sales fell. Biomet's Solitaire Anterior Spine and Polaris Deformity Systems were two notable bright spots in 2009.

Biomet launched the MaxAn Anterior Cervical Plate System during the first quarter which also helped reported sales growth rates.

This quarter's sales (1Q10), we estimate will rise 8.7% to $58.5 million. Full-year sales, we estimate, will rise 9.4% to $255.4 million.

DePuy Spine, Inc.

DePuy Spine reported worldwide spinal product sales increased YOY 11%, 11%, and 9% for the last 3 quarters, respectively. For 4Q09 specifically spinal product sales, we estimate, rose to $240 million. An extra selling week in 4Q helped U.S product revenues increase 9% and international revenues grow 10%.

Overall for 2009, we estimate spine product sales rose 9.8% to $1.0 billion from $913 million in 2008. While pricing pressures also affected DePuy Spine, unlike other firms, management was able to offset that with improved procedure mix.

The company launched Healos Fx Injectable Bone Graft Replacement for minimally invasive spine procedures in 2009 and announced new deals to test genetically engineered proteins for degenerative disc disease (DDD). We are projecting that DePuy Spine can increase sales in 2010 9.9% to $1.1 billion.

NuVasive, Inc.

NuVasive's 4Q09 performance was clearly the industry's top performer as sales rose 43% to $107 million (versus

$74.6 million in 4Q08) exceeding all expectations. CEO Lukianov set $1 billion as the company's long-term sales objective during his quarterly analyst call. Despite concerns over reimbursement, the company posted $370 million in 2009 sales, up 48%.

We have increased our forecast for NuVasive in 2010 and now expect the company will report sales of $490 million, up 32%. For 1Q10, we estimate that NuVasive's sales for minimally disruptive surgical instruments, implants and biologics will reach $101 million.

Orthofix International

Orthofix's 4Q09 spinal product sales rose an impressive 13% to $74.4 million (up from $65.7 million in 4Q08) and beating both our estimates and those of Wall Street's analysts. For all of 2009, Orthofix reported that spine product revenues reached $279 million, up 11% from $252 million in 2008. Spine stimulation sales rose 12% to $42 million while implant and biologic revenues increased 15% to $32.5 million. Thoracolumbar and cervical spine implant revenues increased a very strong 31%. Furthermore Orthofix gained share in the spine stimulation market. Fourth quarter 2009 was the ninth consecutive quarter of double-digit sales growth.

Trinity Evolution, we expect, will add $28 million to $30 million to overall spine product sales in 2010. In 4Q09, Orthofix shipped $5.3 million of Trinity Evolution 4Q09. For 1Q10, we estimate, Orthofix's spine sales will rise 11.6% to $73.6 million, reaching $310.5 million for all of 2010, up 11.2%.

Stryker Corporation

Stryker's 4Q09 spinal product sales grew 9% from $139.2 million to $151.7 million. Domestic spine sales rose just 4% YOY (versus13% in 3Q09), which surprised us and other analysts. OUS spine product revenues jumped 26% for 4Q09 (14% constant currency). Stryker's interbody and lumbar products contributed significantly to reported sales growth rates. In its quarterly call with analysts, management attributed the slower than expected growth rates to new product delays and an "increasingly price sensitive market." Full year 2009 spine product revenues rose 10.1% to $558.5 million from $507.5 million in 2008.

Assuming better top-line growth in the second half of 2010, when new products will be available, we are forecasting that full-year 2010 sales will rise 10.3% to $616 million.

TranS1, Inc.

Reimbursement challenges hurt TranS1's 2009 performance. Fourth quarter 2009 sales did not reach management's earlier $6.7 million–$7.7 million estimate and that's the second time management missed their mark in as many quarters. TranS1's 4Q09 sales were $6.3 million, down 15% from $7.4 million in 4Q08. Surgeons performed 674 AxiaLIF procedures worldwide (550 domestic) in the quarter, down 12% from 768 in 4Q08.

Category III CPT reimbursement problems are the reason. Physicians are encountering problems being

reimbursed for AxiaLIF 360° lumbar spine fusion procedures. The same is not true, however, of the use of TranS1's products in such complex spine procedures as scoliosis or deformity cases since the access code in question is not as critical for reimbursement. In 4Q09 Trans1 partnered with Life Spine, Inc. to distribute a minimally invasive pedicle screw system called Avatar, which broadens TranS1's product line.

AxiaLIF's ASP fell $300 from 4Q08 to $10,300. TranS1 also reduced its direct sales force count to 45. Based on the reimbursement issue and slowing domestic procedure volumes, we are lowering estimates for 1Q10 to $6.1 million, down 30% from 1Q09.

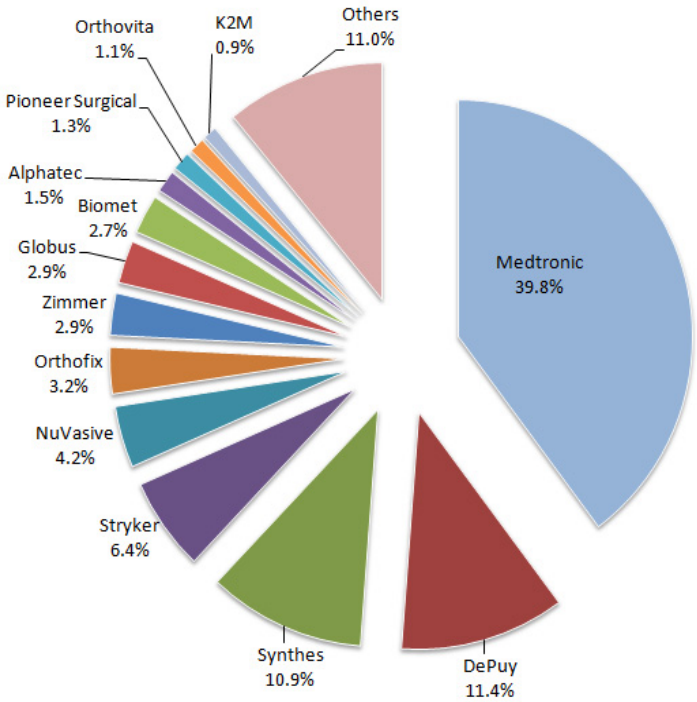
Zimmer Inc.

Zimmer Spine's 4Q09 sales fell 12% to $63.1 (-15% constant currency) from $71.8 million in 4Q08. Zimmer's sales decline breaks down to 14% drop in YOY procedure volume/mix, a 1% pricing reduction which was counterbalanced by a 3% currency exchange rate gain. Overall, sales in 2009 rose 10.2% to $253.6 million—virtually all of which is due to the Abbott Spine acquisition. Zimmer's innovative dynamic stabilization device, Dynesis, ran into competitive and reimbursement pressures and that, said management, was one of last year's greatest challenges. Zimmer CEO David Dvorak said in his quarterly call that spine sales will remain slow for the next couple of quarters but could start rebounding in 4Q10. For 2010, we estimate, Zimmer spine sales will rise 2.3% to $259 million. First quarter 2010 sales, we estimate, will fall 2.5% YOY to $63 million.

Looking Forward

In Chart 1 we display the current market share for spine product companies. The underlying fundamentals of the spine market are solid, but there are critical challenges ahead. On the plus side, procedure volumes and favorable demographics will continue to fuel demand. On the negative side, pricing pressures show no signs of diminishing. Innovation has clearly slowed and reimbursement is not keeping up. Lastly, a sluggish Medtronic will continue to pull down overall industry growth rates.

Chart 1: Company Market Share



For more articles by this author, please select the following link: http://www.pearldiverinc.com/pdi/spine.jsp

company news

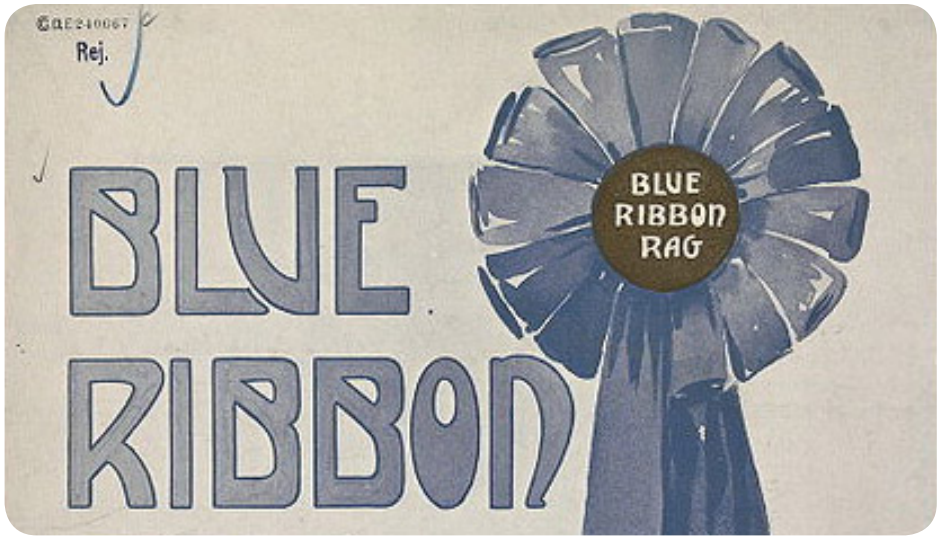
Abington Hospital Earns Blue Distinction

Those bestowing the honor know that it's for anything but independence…more like for teamwork. Independence Blue Cross of Philadelphia has designated Abington Memorial Hospital in Abington, Pennsylvania, as a Blue Distinction Center for Spine Surgery and as a Blue Distinction Center for Knee and Hip Replacement. The Blue Distinction designation is awarded by the Blue Cross and Blue Shield companies to medical facilities that have demonstrated expertise in delivering quality healthcare in the areas of bariatric surgery, cardiac care, complex and rare cancers, knee and hip replacement, spine surgery, and transplants.

"This designation is a tribute to more than a decade of hard work by our nurses, doctors, physical therapists, and support staff, virtually everyone involved in our program, who have focused on developing the most advanced musculoskeletal program for our patients," said Andrew M. Star, M.D., in the news release. Dr. Star is Chief of Orthopaedic Surgery at Abington Memorial Hospital and Director of the Human Motion Institute.

The Human Motion Institute was the first teaching hospital in Pennsylvania to have received the prestigious Gold Seal of Approval and Disease Specific Certification from the Joint Commission for the hip and knee replacement program.

"Blue Distinction puts a high value on research and evidence-based health and medical information," said Allan Korn, M.D., Blue Cross and Blue Shield Association Chief Medical Officer in the news release. "Blue Distinction Centers show our commitment to working with doctors and hospitals in communities across the country to identify leading institutions that meet clinically validated quality standards and deliver better overall outcomes in patient care."



May Aufderheide/Wikimedia Commons

Commenting to *OTW* on how they are pursuing evidence-based medicine was June Weise, RN, MHA, Program Coordinator for the Human Motion Institute, who said, "One example is that we benchmark length of stay for hip, knee and spine against the GMLOS (Geometric Mean Length of Stay). Clinically, we utilize evidence based Clinical Practice Guidelines that drive nursing care for these specific patient populations."

The selection criteria used to evaluate facilities were developed with input from a panel of expert physicians. To be designated as a Blue Distinction Center for Spine Surgery and a Blue Distinction Center for Knee and Hip Replacement, some of the criteria were as follows:

- Established acute care inpatient facility, including intensive care, emergency care, and a full range of patient support services with full accreditation by a CMS-deemed national accreditation organization
- Multi-disciplinary clinical pathways and teams to coordinate and streamline care, including transitions of care
- Quality management programs, including surgical checklists as well as tracking and evaluation of clinical outcomes and process of care

company news

The additional Blue Distinction Centers for Spine Surgery and Blue Distinction Centers for Knee and Hip Replacement designations will bring the nation's number of Blue Distinction designations to more than 1,600.

—EH (March 5, 2010)

Integra Beats Estimates in 4Q09

Integra LifeSciences Holdings Corporation reported on March 1, 2010 their financial results for the full year 2009 and the fourth quarter ended December 31, 2009. The company beat previous estimates and posted revenue growth in both the fourth quarter and the full-year results. Integra, headquartered in Plainsboro, New Jersey, distributes medical devices worldwide. The company produces orthopedic devices for spine treatment as well as orthobiologic products, neuroscience devices, and instruments for general surgery.

For the fourth quarter (4Q09) Integra reported that it generated $183.5 million in sales of products. That is up 5% from 4Q08 and higher than analysts' previous estimates of $182.3 million. In absolute terms, the company increased overall sales by $9.2 million. For the full-year 2009, Integra reported that it generated $682.5 million in sales of products. That is a 4% increase from 2008 and also higher than analysts' expectations. In absolute terms, the company increased overall sales by $27.9 million.

In commenting on the year's performance, Integra's President and Chief Executive Officer Stuart Essig said, "Given the unprecedented economic challenges of 2009, we are pleased with our financial performance."

Integra's divisions reported sales as follows:

	4Q09 Sales (in millions)	% change	4Q08 Sales (in millions)
NeuroSciences	$68.1	+6%	$64.3
Orthopedics	$68.5	+9%	$62.8
Medical Instruments	$46.9	-1%	$47.2

The orthopedics division had the highest year-over-year revenue growth, but, according to the company's recent press release, spine and orthobiologic product sales fell short of the 15%-20% long-term growth objective set by Integra's management. However, double-digit growth in revenue from extremity products helped raise the overall sales in orthopedics.

Commenting on Integra's orthopedic division, Matt Menze, PearlDiver Technologies Senior Analyst said, "The market for spine products did slow down in the fourth quarter, but Integra management could not point to any direct reason as to why their spine products fell short of growth objectives. However, this was not a significantly negative turnaround for Integra's orthopedic division, and the company still seems to be on track. Integra successfully acquired the Paramount System for minimally invasive spine surgery from Innovative Spinal Technologies, and the company's goal for 2010 is to continue to expand Integra's U.S. distribution network."

Looking ahead, CEO Stuart Essig said that he expects sales will rise 4.8%-7.7% for the full-year 2010 to reach $715 million-$735 million. The company's stock rose slightly by $0.86 or 2% after the announcement.

—DK (March 5, 2010)

$330 Million for ApaTech

On March 1, Baxter International said that it will acquire British-based ApaTech for up to $330 million.

The acquisition gives Baxter a bigger footprint in the rapidly growing orthobiologics and regenerative medicine market. Baxter gets

company news

ApaTech's Actifuse, a silicate substitute calcium phosphate synthetic bone graft material.

Baxter Enters Fusion Market

Ron Lloyd, Vice President and General Manager, BioTherapeutics and Regenerative Medicine, Baxter, said in a company press release, "Actifuse will allow us to immediately enter the emerging bone fusion category, and ApaTech's product pipeline is highly complementary to our existing commercial and technical capabilities in biosurgery."

The purchase price sets a marker for evaluating the worth of an orthobiolics company which generated sales of approximately $60 million in calendar year 2009.

The agreement between Baxter and ApaTech includes an upfront cash payment by Baxter of $240 million. Baxter may make additional payments of up to $90 million related to the achievement of sales milestones. The transaction is expected to close in the first quarter 2010, subject to customary closing conditions and expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act. This transaction is not expected to have a material impact on Baxter's 2010 financial results.

Old Greek Money/Wikimedia

ApaTech: Europe's Fastest Growing

ApaTech has achieved some commercial success with products sold in the United States, EU, and select markets around the world. The company was named Europe's fastest growing Biotech/Pharmaceutical/ Medical Technology/Equipment company in the Deloitte 2009 Technology Fast 500 for EMEA (Europe, Middle East and Africa).

Clinical Data

ApaTech's current major shareholders are Encore Ventures (a division of DFJ Esprit) and U.S. investor, Healthcor Partners. Other shareholders include MTI, which provided the early stage capital, founder shareholders and members of ApaTech's management team.

—WE (March 6, 2010)

legal & regulatory

First Ortho Doc Pleads Guilty

The new U.S. Attorney in New Jersey has bagged his first surgeon.

First came the $311 million Deferred-Prosecution Agreements to settle allegations that orthopedic device manufacturers secretly paid off orthopedic surgeons to endorse and use their products. Now comes the first guilty plea by an orthopedic surgeon stemming from that investigation.

Just in time for this week's annual meeting of the American Academy of Orthopaedic Surgeons in New Orleans. The U.S. Attorney's Office declined comment to *OTW* about the timing of the announcement.

Desai Guilty

Paul Fishman, the new U.S. Attorney in New Jersey announced on March 5, that Shekhar Desai, M.D., of

legal & regulatory

Dr. Martin Luther King Federal Courthouse, Newark, N.J.

Indialantic, Florida, pleaded guilty before a U.S. district judge, to one-count Information charging him with conspiring to commit wire fraud. Bail was set at $100,000 and Desai was released pending sentencing scheduled for June 21.

DePuy Consultant

Desai admitted to the judge that he entered into a consulting agreement with DePuy Orthopaedics in September of 2003. He was to perform consulting services, including training sessions and operating room sessions. However, Desai admitted that he submitted invoices from July 2004 through November 2005 for services he never performed. He admitted that he received more than $70,000 and up to $120,000 in payments to which he as not entitled.

"This defendant defrauded the victims out of tens of thousands of dollars, money which was intended to improve the delivery of health care services to patients, but instead was wrongfully used to line his own pockets," said Fishman. "This Office, the Department of Justice, and the Department of Health and Human Services will continue to, when appropriate, aggressively investigate and prosecute such crimes, to root out fraud in the nation's healthcare system."

Desai faces a maximum sentence of five years' imprisonment and a $250,000 fine. In addition, the judge must order that Desai make restitution to the victims of his crime. *Florida Today* reported that Desai received his M.D. degree from University Medical College in India and did his residency at Maimonides Medical Center in Brooklyn, N.Y, where he underwent fellowship training. He also did a fellowship at Boston Children's Hospital.

Desai is part of Brevard County's largest physician group. His ties to Holmes Regional Medical Center and Palm Bay Hospital stretch back to 1993. Both hospitals are presently operated by Health First.

Fishman credited special agents with the U.S. Department of Health and Human Services Office of Inspector General, under the direction of Special Agent in Charge Tom F. O'Donnell, and Postal Inspectors of the U.S. Postal Inspection Service, under the direction of David L. Collins, for this successful investigation.

The case is being prosecuted by Assistant U.S. Attorneys Joseph Mack and Ronald Chillemi of the U.S. Attorney's Securities and Health Care Fraud Unit.

—WE (March 9, 2010)

biologics

Healing Traumatic Fractures With Periosteum

Melissa Knothe Tate and Ulf Knothe not only make a good team in marriage, they

biologics

X-Ray/Dr. Knothe, Cleveland Clinic

make a good research team as well. This husband and wife pair found that the periosteum, the thin tissue that covers bones like a sleeve, can be used to encourage bone growth and healing. In traumatic cases with serious bone loss, this method could be more effective than bone grafts and other invasive treatments.

Melissa Knothe Tate is a joint professor of biomedical engineering and mechanical & aerospace engineering at Case Western Reserve University, and her husband Ulf Knothe is an orthopedic surgeon at the Cleveland Clinic. They are presenting their research this week at the annual meeting of the Orthopedic Research Society, alongside the annual AAOS meeting in New Orleans.

How Does it Work?

Knothe Tate tested the procedure in Switzerland on sheep. She placed a sleeve of periosteum around one-inch gaps in the sheep's legs, and the animals were able to stand again within 24 hours. Within two weeks, substantial bone filled the gap. The key to this quick and simple bone growth is stem cells. And the most exciting discovery from Knothe Tate's research team is that it only required the direct and angular pressure on the stem cells to encourage the cells to grow into bone. By standing and shifting the weight on their bones, the sheep actually helped create the pressure that encouraged bone growth.

And from where exactly do these stem cells come? Knothe Tate told *OTW,* "The periosteum provides a habitat for stem cells, as does the marrow cavity. However, in this surgical procedure, the marrow cavity is filled by the intramedullary nail, which stabilizes the whole construct. For this reason (as well as from our imaging studies), we know that the stem cells are coming from the periosteum."

The research team also found that the periosteum procedure brought better results than the standard bone graft technique and performed better than a combination of periosteum and bone graft. The periosteum alone quickly encouraged the greatest density of bone growth.

An Artificial Alternative

There are also severe cases where there may not be enough periosteum

biologics

and bone to complete the procedure with a patient's own tissue. So the husband and wife pair also created an artificial periosteum product using all FDA-approved materials. Knothe Tate adds, "For our newly developed substitute periosteum implant, healing was improved by either the addition of autologous stem cells (from a patient's own bone rather than a donor) or by the addition of autologous periosteal transplant strips."

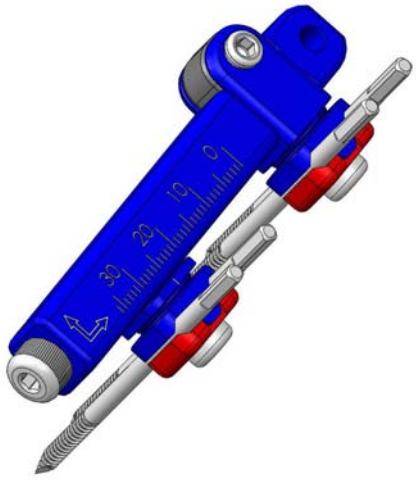
The next step for the research team is to bring this technology to the clinic. Because the membrane can be easily adapted to different patients and quickly sterilized in an autoclave, the team hopes their work will help patients not just at the top clinics, but in more remote areas as well such as rural hospitals and clinics on the battlefield.

—DK (March 10, 2010)

biologics

510k for SBi

It's not going out on a limb when you've tested and retested… Small Bone Innovations, Inc. (SBi) has announced that after extensive evaluations by foot and ankle surgeons, it has received 510(k) pre-market clearance notifications from the FDA for Mini-Rail Fixation System ('Mini-Rail System') and large Cannulated Screw System for use in lower limb reconstruction and repair procedures.



Mini-Rail Fixation System/SBi

SBi expects its Mini-Rail System to be used in common procedures such as first MTP (metatarsophalangeal) joint arthrodesis and distraction, subtalar fusion, and Jones fracture management. There are approximately 65,000 of these procedures performed annually in the U.S.

As indicated by the company, the Mini-Rail System is a unique and highly adjustable fixation system that lets surgeons quickly achieve optimal placement in the bones of fixation "half" pins. SBi also notes that the system's ease of use can decrease OR time.

Guido LaPorta, DPM, FACFAS, Chief of Foot and Ankle Surgery at Community Medical Center, Scranton Pennsylvania., said in the news release, "The SBi Mini-Rail System offers a versatile solution for small bone reconstruction and trauma. The system's design allows it to be used as primary or complementary fixation in arthrodesis, osteotomy, bone lengthening and fracture repair. The system's unique instrumentation allows us to employ the Mini-Rail System as an anatomically accurate and rigid construct."

As for the large Cannulated Screw System (made out of stainless steel), SBi expects it to be used for a variety of foot and ankle procedures including triple arthrodesis, subtalar and ankle fusions. There are approximately 50,000 of these procedures performed annually in the U.S.

Anthony G. Viscogliosi, Chairman & CEO of SBi, said in the news release, "Both the Mini-Rail and large Cannulated Screw systems have been designed specifically for use in a wide range of lower limb procedures to reinforce and enhance the company's goal of developing the most attractive, anatomically-focused product portfolio available for use by foot and ankle surgeons. These systems reinforce SBi's commitment to work with key opinion leaders to provide product solutions that serve the full range of clinical needs of surgeons and their patients."

Commenting to *OTW,* Viscogliosi noted that the feedback from Dr. LaPorta and nine other foot and ankle surgeons who evaluated the new Mini Rail system, revealed that the use of an optional k-wire guide allows them to apply the device with one hand. He added, "Also, the ability to rotate the rail and half-pin carriages makes for ideal pin placement—two features that we think will offer significant competitive advantages."

—EH (March 4, 2010)

biologics

S&N Launches Meniscal System

FAST-FIX 360 Meniscal Repair System/Smith & Nephew

360 degrees, 365 days a year… Smith & Nephew's Endoscopy Division has launched its FAST-FIX 360 Meniscal Repair System, a device that will give surgeons easier implant deployment, speed, and superior fixation strength with minimal disruption to the meniscus. This is one of several new Smith & Nephew products being unveiled at the American Academy of Orthopaedic Surgeons (AAOS) annual meeting in New Orleans.

As indicated by the company, the FAST-FIX System, first launched in April 2001, offers the industry's gold standard (a vertical or horizontal mattress suture stitch), but does not require the open incision traditionally associated with meniscal repair.

With this new design surgeons have the freedom of 360 degree actuation, giving them the ability to deploy implants in any hand position—vertically, horizontally on either side of the meniscus—with a fast, smooth advancing motion. The spring-action design facilitates the advancement of each implant into the meniscal capsule.

"The state-of-the-art 360 degree active deployment improvement to the FAST-FIX 360 Meniscal Repair System is one of the most significant features," said Nick Sgaglione, M.D., Associate Chairman and Program Director, Department of Orthopaedic Surgery, North Shore Long Island Jewish Medical Center, in the news release. "This allows for easier deployment of the implants and minimal needle exposure behind the meniscal capsule."

Smaller implants and a pre-tied, self-sliding knot create smaller needle insertions, reducing disruption to the meniscus. The fact that both implants are enclosed means that surgeons can reposition the needle as necessary for optimal suture placement. There is also a low-profile, stiffer needle shaft that gives surgeons better control while enabling access and visibility to hard-to-reach areas of the meniscus. A new built-in, adjustable depth limiter also reduces the number of steps required to perform the procedure.

"In line with our strategy of investing for growth, the FAST-FIX 360 Meniscal Repair System is one of a number of premier arthroscopic repair devices that will be launching at AAOS this week," said Carl Vause, Vice President, Repair Marketing, Smith & Nephew Endoscopy, in the news release.

Commenting to *OTW* on the development process was Joe Metzger, Vice President of Communications for Smith & Nephew Endoscopy, who said, "The launch of our FAST-FIX 360 Meniscal Repair System at the American Academy of Orthopaedic Surgeons annual meeting is the result of significant behind the scenes acceleration of our development and clinical efforts. Because we targeted AAOS for the launch, we also knew that we needed 510(k) clearance ahead of the meeting…which I'm pleased to say was received at the end of January."

—EH (March 9, 2010)

large joints

S&N Launches BIORAPTOR

Shouldering out the competition…Smith & Nephew's Endoscopy Division has just launched its BIORAPTOR Knotless Suture Anchor, a device used to repair a torn labrum in the hip and shoulder. The anchor, making its grand entrance at the American Academy of Orthopaedic Surgeons (AAOS) annual meeting, enables the surgeon to determine the final suture tension and tissue shift after implantation, which, says the company, is not possible with competitive anchors.

"Smith & Nephew has been building on an innovative technology base to introduce new anchors for shoulder and hip repair. The BIORAPTOR Knotless Suture Anchor for both shoulder and hip labral repairs offers the surgeon greater control over the suture tension placed across the labral tissue while eliminating knot tying and a knot stack," commented Dr. Mike Terry, Assistant Professor of Orthopedic Surgery at Northwestern Feinberg School of Medicine, in the news release.

"Providing surgeons full control over final suture tension was our main focus during the development process," added Laurie Staveski, Senior Market Manager, Smith & Nephew Endoscopy. In addition, by eliminating a traditional knot tying step, surgeons will also save time with less procedural steps and benefit from a surgical solution that minimizes the risk of intra articular damage due to knot stacks."

BIORAPTOR/Smith & Nephew

Commenting to *OTW* was Joe Metzger, Vice President, Corporate Communications for Smith & Nephew Endoscopy, who stated, "We knew that AAOS would be the most efficient and exciting venue for the introduction of the FAST-FIX, and targeted our efforts to create a superb educational venue right on site. Surgeons can come to the Smith & Nephew booth and test their skills on this new product in our drylab. We are also holding a handful of educational courses each month around the country in a variety of institutions."

—EH (March 10, 2010)

Post-Op Shoulder Function Questionable

One shoulder's got its own moves…researchers from Henry Ford Hospital are reporting that shoulder motion after rotator cuff surgery remains significantly different when compared to the patient's opposite shoulder.

Researchers used X-rays providing a 3D view of motion of the arm bone in relation to the shoulder blade, to compared motion in the shoulders of 14 patients who had arthroscopic surgical repair of tendon tears and no symptoms in their other shoulders. Researchers analyzed the motion of both shoulders at 3, 12 and 24 months after surgery, looking at changes in shoulder motion and shoulder strength.

"Although patient satisfaction is generally very high after surgical repair of a torn rotator cuff, the data suggest that long-term shoulder function—in particular, shoulder strength and dynamic joint stability—may not be fully restored in every patient," said Michael Bey, Ph.D., Director of the 3,000-squarefoot. Herrick Davis Motion Analysis Lab at Henry Ford Hospital, in the news release.

"We found that the motion pattern of the repaired shoulder is significantly different than the patient's opposite shoulder," added Dr. Bey. "These

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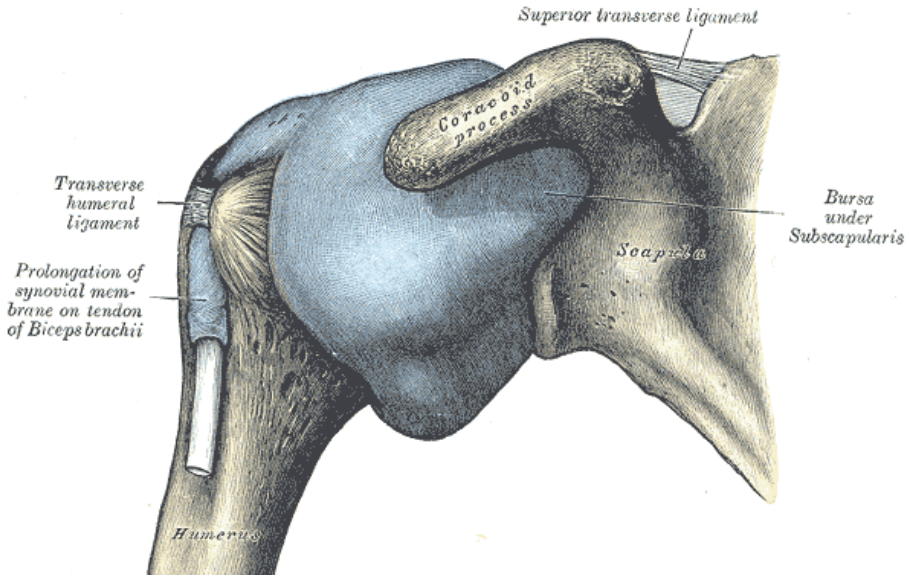

Gray's Anatomy/Wikimedia Commons

differences in shoulder motion seem to persist over time in some patients."

"Our study suggests that surgery may restore normal shoulder strength but doesn't necessarily restore normal shoulder motion," said Dr. Bey. "It could be, however, because the shoulder pain goes away, there is value in surgery. The biplane X-ray system allows us to investigate subtle nuances of shoulder function that cannot be detected with conventional laboratory techniques."

Elaborating, Dr. Bey told *OTW,* "The biplane X-ray system is a high-speed radiographic imaging system that is capable of recording x-ray 'movies' at up to 1000 images per second. By simultaneously acquiring these 'movies' of a given joint (e.g., knee, shoulder, elbow) from two different angles, we are capable of measuring the three dimensional motion of the bones to within half a millimeter. The hardware alone for the biplane X-ray system costs about a million dollars and this system is one of only three like it in the United States."

Dr. Bey also told *OTW,* "There were a couple findings that were surprising to us. First, there appears to be somewhat of a disconnect between patients' satisfaction and the functional performance their shoulder after rotator cuff surgery. This finding may suggest that eliminating or reducing pain is perhaps the most significant contribution of the surgery, at least for this particular patient population. The second finding that was somewhat surprising was the subtle yet important differences in joint mechanics between the dominant and non-dominant shoulders of young, healthy individuals. These findings may have implications for the development of rotator cuff tears that are strongly associated with increasing age."

—EH (March 10, 2010)

DePuy Issues "Urgent" Notice for ASR Cup

DePuy issued an "Urgent Field Safety Notice" on March 8, after the Australian National Joint Registry reported a higher-than-expected revision rate of the company's ASR Cup and XL head used with DePuy stems in total hip replacements.

Reasons for the revisions included component loosening, component malalignment, infection, pain, fracture, dislocation, and metal sensitivity.

The notice came two days before the American Academy of Orthopaedic Surgeons held a meeting outlining their work in establishing an American Joint Replacement Registry.

Pamela Plouhar, Ph.D., DePuy's VP, Worldwide Clinical Affairs, in a letter to clinicians wrote, "Recent analysis... suggests a higher-than-expected revision rate for the DePuy ASR Articular Surface Replacement and ASR XL Monoblock Metal-on-Metal System linked to usage of monoblock cups with corresponding head sizes less than 50 mm in diameter."

To achieve optimal implant performance and survivorship, Dr. Plouhar recommended the following actions:

large joints

- Ensure that the cups are implanted with an inclination of between 40 to 45 degrees as recommended in the IFU. Optimal implant positioning is particularly important for femoral heads less than 50 mm in diameter (cup sizes 56 mm and smaller)

- Do not implant in contraindicated patients, including but not limited to females of childbearing age

- When assessing patients for selection please give careful consideration to those with poor bone quality and to those needing head sizes less than 50 mm in diameter (cup sizes 56 mm and smaller)

- Ensure that the patients presenting post-operatively with pain/swelling/discomfort are appropriately assessed

The Australian Registry had reported a cumulative percentage revision rate of 5.4% at three years for the device. The data, wrote Plouhar, "suggests that smaller heads (less than 50 mm diameter) are associated with a higher rate of revision (up to 8-9% at three years)."

"While the analysis does not demonstrate conclusive findings regarding the relationship between gender and implant head size, DePuy believes that the analysis of the collective dataset provides reasons to take special care in patient selection and cup placement."

—*WE (March 11, 2010)*

Electromagnetic Pulses Help Knee OA

Electrifying the field of osteoarthritis treatment… researchers from Henry Ford Hospital in Detroit have found that electromagnetic pulses significantly decrease pain and inflammation associated with osteoarthritis (OA) of the knee.

In this double-blind, randomized placebo-controlled study, 34 patients used a portable battery-operated device that emits a low-intensity pulsating electromagnetic frequency. Incredibly, they reported more than 40% pain relief on their first day.

"Our results show pulsed electromagnetic fields caused a significant decrease in pain," says Fred Nelson, M.D., in the news release. Dr. Nelson is Associate Program Director for Research and Director of the Osteoarthritis Center, Department of Orthopaedics, Henry Ford Hospital.

Dr. Nelson elaborated, saying that in the laboratory, electromagnetic signals have been shown to decrease calcium in cartilage cells. This sets off a series of chemical events that can lead to reduced inflammation. Previously, the electromagnetic fields have been used to control pain related to cosmetic surgery.

"We are really fine-tuning what we are doing to the cell environment with a very specific pulse sequence and frequency," added Dr. Nelson.

All participants were given a device with a coil that appeared to work but some were assigned active coils and others were given non-active coils. The electromagnetic device was developed by Ivivi Health Sciences of Montvale, New Jersey.

Dr. Nelson told *OTW,* "This field is a very low intensity pulsed electromagnetic field that is imperceptible and has a very specific carrier frequency, and cycle. It is used for two 15-minute sessions a day."

Current treatments include drug therapies like anti-inflammatory medication or pain relievers; physical therapy; support devices; health and behavioral modifications such as weight loss; surgery and joint replacement.

Dr. Nelson explains that medications often have variable success and can produce considerable side effects such as changes in kidney and liver function, a reduction in the ability of blood to clot as well as abdominal pain, nausea and indigestion.

"The exciting thing about this new approach is that it has been found

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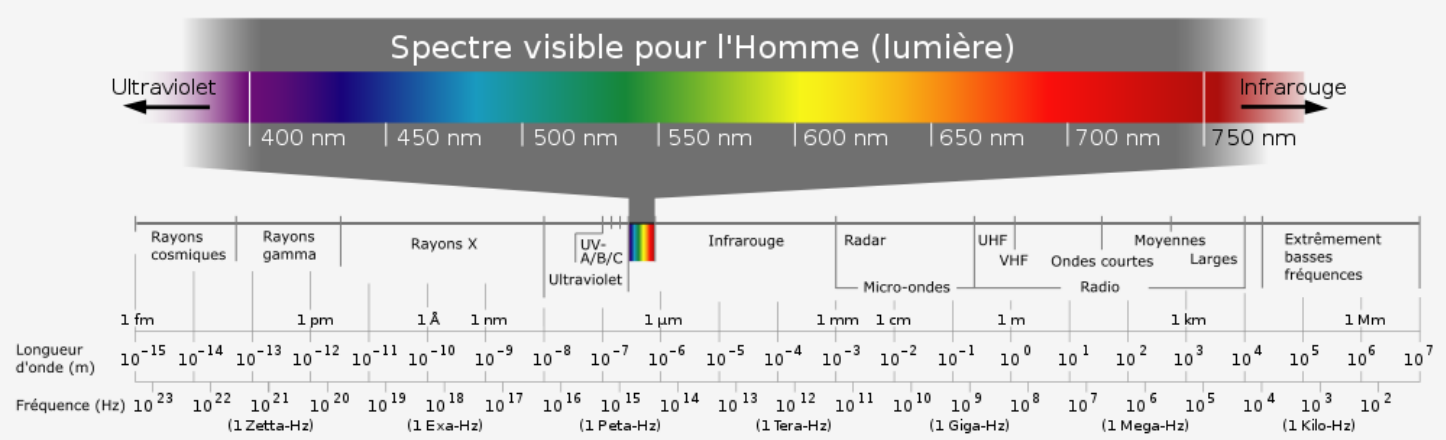


Electromagnetic spectrum-fr.svg/Wikimedia Commons

to have no side effects, it is relatively low-cost in the long-run and the onset of pain relief is immediate," says Dr. Nelson. "We look at electromagnetic pulses as a potential way to improve quality of life and independence for those who suffer from osteoarthritis of the knee."

Commenting to *OTW* on his future work, Dr. Nelson said, "The next project will be expanded to 40-100 patients where there will be 4 sets of individuals: those who get the field for all 12 weeks, those who have no field for 12 weeks, those who have an active field for six weeks and then no field, and those who have no field in the first six weeks but have an active coil at the last six weeks. We will also get some serum and synovial fluid studies at the beginning."

—EH (March 12, 2010)

reimbursement

Medicare Cuts Delayed Until October

The U.S. Senate voted on March 10 to delay the 21.2% cut in Medicare payments to physicians that was to take place April 1. The action postpones the cuts until October 1. The vote was 62 to 36 after breaking a Republican-led filibuster.

The Senate had voted on March 2 to delay the cuts until April. This vote is a "band-aid fix that only serves to increase the size of the cuts and the cost of reforms," said James Rohack, M.D., President of the American Medical Association.

U.S. Senate in Session/Wikimedia Commons

A previous effort in the House to fix the payment schedule was defeated at the urging of Congressman and orthopedic surgeon Tom Price of Georgia because the fix would add to the federal debt.

The payment cut delay is part of a $140 billion bill that includes an extension of unemployment benefits, continued subsidization of premiums for the unemployed under COBRA and a variety of tax breaks. The legislation also extends several other Medicare protections, including the exceptions process for Medicare beneficiaries who exceed their cap on therapy services and provisions affecting doctors and other healthcare providers who serve rural communities.

—WE (March 11, 2010)

The Picture of Success: Dr. Matthew Jimenez

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

He is a professor, but he is anti-dogma. He is a traumatologist, but doesn't thrive on an adrenaline rush. Dr. Matthew Jimenez, Chief of Orthopaedic Trauma at the Illinois Bone and Joint Institute (IBJI), is just enigmatic enough to elevate the standards in the field.

A Clinical Associate Professor at the University of Illinois at Chicago, Dr. Jimenez was born in Salt Lake City and received a Catholic education up until he donned his high school cap and gown. "Despite the fact that I didn't do well until 8th grade, my parents were rather mellow about grades. But then Sister Ellen got hold of me. When I broke my leg in 8th grade, I couldn't go to gym class and instead spent time every day with Sister Ellen doing schoolwork and discussing my future. She shone a spotlight on me, and said, 'You are bright, but you are not applying yourself.'"

"Her faith in me, as well as my natural interest in science and math, helped me turn my attitude—and life—around. Also, I was increasingly affected by my mom's love of her career. She was a cardiothoracic nurse and always talked about how much fun she had in the OR. My dad was a businessman, and along with my mom, set a positive example for us. They gave my four siblings and me complete unconditional love; we were expected to work hard, but we were never chastised if we didn't bring home an 'A.'"

Medical School Mentors and Advice

Sister Ellen's daily "devotions" paid off. Matt Jimenez graduated cum laude from the University of Utah in 1984 and entered medical school at The University of Iowa. "As I wound my way through the various specialties, the fact that as a child I had broken seven bones helped set the stage for a career in orthopedics. For me, the entire concept of 'doctor' was someone who took care of your bones. The same orthopedist treated me for all of those injuries. It wasn't lost on me that he truly had fun at work…and that he never talked down to children."

This "question every doctrine" doctor developed his skepticism when he spent an extra year of medical school in the NIH Physician Scientist Training Program. Dr. Jimenez:

> *"Not only was I interested in biomechanical research, but it was clear that participating in such an activity makes one stand out in the residency applicant pool. It was fascinating to*

learn that things put forth as law in textbooks could actually be flawed. Taking a year to delve into the world of research allowed me to see how that information is created and how it can be biased. For example, is the study well controlled, what is the power analysis, what is the level of statistical significance, who wrote it, what kind of lab did it emanate from, etc. That year really opened my eyes as to the necessity of closely examining the literature."

A nod to his future bride then determined the next step in Dr. Jimenez's career. "While I interviewed at a number of programs around the country, my fiancée had her heart set on Chicago. I knew that the residency at Northwestern University was very surgically intense, so I was pleased to be selected for that program. My primary mentor, Dr. Armen Kelikian, became a dear friend and imbued my days with his sense of enthusiasm for the field."

Although Dr. Jimenez selected his next training program based on brains, he also found heart. Trauma, he learned, is personal. "In 1995 I began a fellowship at the University of Toronto Orthopaedic Trauma and Joint Reconstruction program. The director was Dr. Marvin Tile, a premier thought leader in pelvic and acetabular trauma. It was an exceptionally busy trauma center, and the one-on-one intellectual mentoring I received was amazing."

"Dr. Tile spent a good deal of time making sure that his trainees understood the value of balancing one's life," continues Dr. Jimenez.

"'Don't forget your wife and kids,' he would say, 'and don't fall into the trap of treating your patients as diagnoses.' It's easy to reach the point where your language becomes, for example, 'I did a femur fracture today.' I actually think that this is one of the major challenges in trauma education today, namely, maintaining a personal relationship with the patient. These are human beings with other psycho-social issues and we must continue to teach our young surgeons to hold onto the caring aspect of medicine and surgery."

Becoming an "Official" Orthopedist

In 1995 Dr. Jimenez received an offer to go back to Chicago. "The Director of IBJI, Dr. Wayne Goldstein, said that he saw 'something' in me and said that he would like to have me become a partner upon completion of my fellowship. It was a superb offer, and once my excitement settled in, it was in part replaced by fear…it is somewhat nerve wracking to be an 'official' orthopedist all of a sudden. Now those patients staring you in the face and asking pointed questions about why they have an infection or are in pain…well, those are your patients and yours alone."

And because the visionary Dr. Jimenez could see the number of patients needing assistance was on the rise, in 1997 he created an unusual program. "Of all of my accomplishments I am perhaps most proud of our Physician Assistant Residency Training Program, one of only a handful of such programs in the country. Orthopedics will only see an increase in manpower needs in the coming years, so the fact that we are training individuals who are qualified to take call, see patients in the ER, and assist in the OR, is critical."

And while they weren't exactly barring the doors and locking up the prescription pads, the hospital administration initially had to undergo

a bit of education. Dr. Jimenez: "Physician Assistants (PAs) were not something that was often seen in Chicago at the time. We had to work with hospital administration to help them understand what a PA does. They came to see that PAs can result in an increase in productivity without a decrease in the quality of care."

Elevating Standards

As for Dr. Jimenez, he would like to have fewer patients in the waiting room. As Founder and CEO of the Foundation for Education and Musculoskeletal Research (FEMR), he was determined to help the elderly adopt an attitude and practice of prevention. "Fragility fractures in the elderly are outrageously common. A past mentor used to say that we human beings come in through the pelvis and out through the hip. FEMR is meant to educate the elderly in my community—and hopefully nationally—on things they can do to have healthier bones and prevent falls. The challenges are huge, in part because there are so many charities competing for funding. And it's not just that…how do you make bone health compelling, or to use the common parlance, sexy?"

While Dr. Jimenez brings passion to his trauma work, he knows when being dispassionate is the more appropriate route. "In 2003 I started the Chicago Trauma Symposium, which has gradually grown to 50 lecturers, 300 surgeon-attendees, and 50 industry sponsors. When I initiated the symposium, most non-society courses were associated with a single vendor (device company), with the faculty typically being consultants representing that vendor. While they weren't necessarily biased, I could see that we were running the risk of having the course become an infomercial. In fact, because I was experiencing increasing pressure to have faculty solely from a certain vendor, I decided to switch to a multi-vendor format to prevent even the hint of bias."

And that was a fitting decision for someone on the AAOS Board of Councilors who is poised to head the state orthopedic society. Dr. Jimenez, President-elect of the Illinois Association of Orthopaedic Surgeons, states, "I hope to encourage orthopedic surgeons to remain actively involved in advocacy and politics. By getting involved at the local, state and national levels, orthopedic surgeons can help maintain and improve patient access to quality care."

Regarding his work with the Board of Councilors, he adds, "This position has enabled me to meet thought leaders from around the country, as well as like minded people who enjoy donating their time. To be able to address the question, 'How we can do orthopedics better in this country?' is truly exciting."

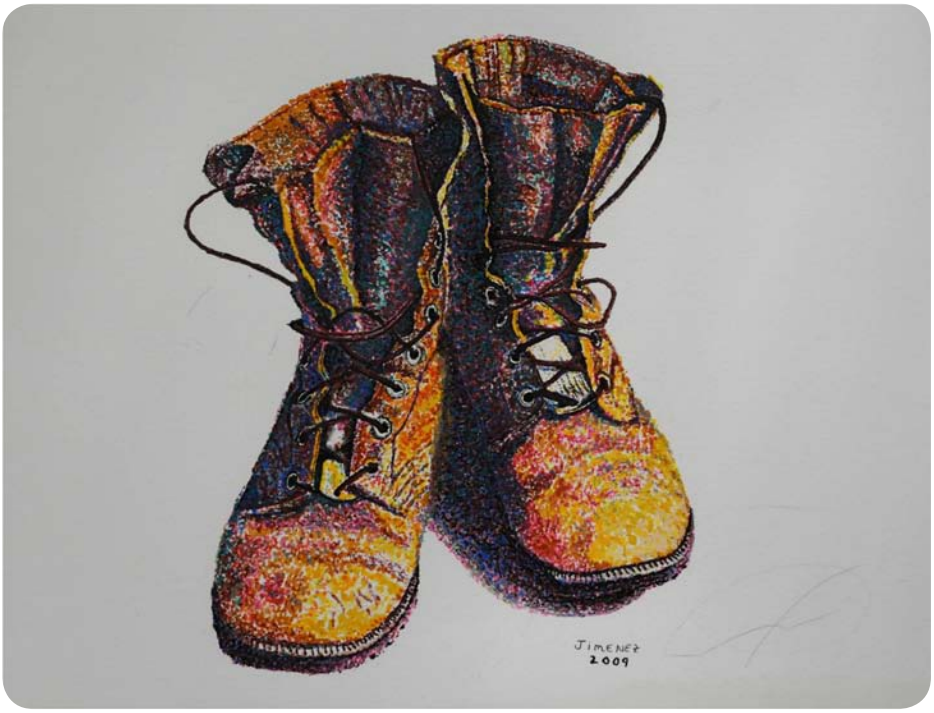
A thinker and a doer, Dr. Jimenez approaches trauma with the eye of a scientist and the hand of an artist. "Trauma is not really an adrenaline rush at all," he states.

> *"It is more like a challenging puzzle that needs to be reconstructed. Each patient requires hours of preoperative planning and thoughtful analysis to choose the appropriate surgical approach and then execute the procedure successfully. Remember, surgery is not a pure science, rather an art predicated on science. Like an artist, an accomplished surgeon develops a body of work over time."*

Life at Home

And his personal body of work? It greets him at the door each evening… times three. "My wife and I have been blessed with triplets—Jack, Luke, and Sophie—who are now four years old. Thank goodness our 16-year-old daughter Grace is around to help with the nightly feeding, cuddling, bath marathon."

"I can sometimes be found running ultra marathons, i.e., 50 mile races. I was inspired by a runner named Dean



Fallen Soldier by Matthew Jimenez

Karnezis, and thought, 'what one man can do, another can do.' My average week consists of 70 miles on the road or treadmill, depending on the weather (cold Chicago winters). This year I am slated to run four marathons (26.2 miles) and one ultramarathon (50 miles). The best part? I can eat whatever I want and not gain a pound!"

But his newest love is painting. "While I never thought my art would amount to anything, it has actually been featured in the AAOS art show, has traveled around the U.S. and then ended up at the Chicago Cultural Center."

Dr. Matthew Jimenez…envisioning and creating the possible.

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