VOLUME 7, ISSUE 39 | DECEMBER 13, 2011

Orthopedics This Week

week in review

breaking news

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: The market's uptick two weeks ago is looking more and more like a head-fake. Europe's crisis is just not getting resolved. Despite the occasional positive headline, reality on the ground appears to be overwhelmingly negative. Double-dip recession is on the table. With these clouds on the horizon, it may be months before there is a sustained rally—maybe February or March.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Zimmer	27.75%	(4.66%)	ZMH earns 10% on its assets. Earnings yield, however, is 7%. That's how cheap ZMH is. Time to buy back stock.
2	2	Medtronic	28.63	5.34	One of the top performers in orthopedics this past month. Still very affordable with the lowest future PE in ortho.
3	3	Orthofix	14.72	2.65	Most analysts expect that earnings will grow 14% in 2012. Just based on continued operational gains, looks achievable.
4	5	Smith & Nephew	22.8	6.57	Strong buying interest lately. European exposure is a concern, but wound care is a pretty basic, non-elective procedure.
5	4	Stryker	25.23	0.74	Raises dividend 18% to 21.25¢ a share. That's 85¢ annualized. AND buying back $500 million in stock.
6	8	Integra	15.38	4.31	Could Integra be an attractive add-on for Covidien? Rumors have started making the trading desk rounds.
7	6	Johnson & Johnson	26.33	2.52	With Europe in turmoil, maybe "safe haven" stocks return to favor. If so, JNJ is a very safe port in a storm.
8	10	Kensey Nash	34.24	3.85	Received $6 million milestone payments from Spectranetics. With 34% operating margins, cash balances are rising.
9	7	Conmed	9.65	(3.11)	We like two aspects of CNMD: first, margins are rising. Second, price-to-sales is among the lowest in ortho.
10	NR	Symmetry	6.45	(3.92)	Buys Codman & Shurtleff for $165 million cash. Great strategic move. Back on the Power Rankings.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Tornier N.V.	TRNX	$18.42	$723	9.97%
2	Smith & Nephew	SNN	$46.07	$8,232	6.57%
3	ArthroCare	ARTC	$29.86	$822	5.70%
4	Medtronic	MDT	$35.92	$37,908	5.34%
5	Integra LifeSciences	IART	$31.98	$858	4.31%
6	RTI Biologics Inc	RTIX	$4.67	$258	4.24%
7	Kensey Nash	KNSY	$26.44	$229	3.85%
8	Orthofix	OFIX	$34.44	$634	2.65%
9	Johnson & Johnson	JNJ	$64.53	176,222	2.52%
10	Wright Medical	WMGI	$15.22	$599	1.60%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	MAKO Surgical	MAKO	$26.95	$1,123	-19.17%
2	Alphatec Holdings	ATEC	$1.61	$144	-17.44%
3	TiGenix	TIG.BR	$0.90	$82	-14.49%
4	Bacterin Intl Holdings	BONE	$2.31	$94	-13.48%
5	NuVasive	NUVA	$13.07	$552	-9.24%
6	Zimmer Holdings	ZMH	$49.26	$8,826	-4.66%
7	CryoLife	CRY	$4.41	$124	-4.13%
8	Symmetry Medical	SMA	$7.59	$276	-3.92%
9	Conmed	CNMD	$25.89	$723	-3.11%
10	Exactech	EXAC	$14.66	$193	-0.74%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Zimmer Holdings	ZMH	$49.26	$8,826	10.46
2	Medtronic	MDT	$35.92	$37,908	10.79
3	CryoLife	CRY	$4.41	$124	12.97
4	Johnson & Johnson	JNJ	$64.53	176,222	13.17
5	Integra LifeSciences	IART	$31.98	$858	13.21

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Wright Medical	WMGI	$15.22	$599	32.38
2	RTI Biologics Inc	RTIX	$4.67	$258	29.19
3	Synthes	SYST.VX	$166.76	$19,807	21.11
4	ArthroCare	ARTC	$29.86	$822	20.88
5	NuVasive	NUVA	$13.07	$552	19.51

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Orthofix	OFIX	$34.44	$634	0.81
2	RTI Biologics Inc	RTIX	$4.67	$258	1.03
3	Zimmer Holdings	ZMH	$49.26	$8,826	1.12
4	Stryker	SYK	$47.85	$18,311	1.24
5	Exactech	EXAC	$14.66	$193	1.33

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$13.07	$552	4.37
2	Wright Medical	WMGI	$15.22	$599	3.57
3	Kensey Nash	KNSY	$26.44	$229	3.13
4	Johnson & Johnson	JNJ	$64.53	$176,222	2.18
5	Smith & Nephew	SNN	$46.07	$8,232	2.09

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Symmetry Medical	SMA	$7.59	$276	0.76
2	Alphatec Holdings	ATEC	$1.61	$144	0.84
3	Exactech	EXAC	$14.66	$193	1.01
4	Conmed	CNMD	$25.89	$723	1.01
5	CryoLife	CRY	$4.41	$124	1.06

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$0.90	$82	131.44
2	MAKO Surgical	MAKO	$26.95	$1,123	25.34
3	Synthes	SYST.VX	$166.76	$19,807	5.37
4	Bacterin Intl Holdings	BONE	$2.31	$94	3.56
5	Kensey Nash	KNSY	$26.44	$229	3.19

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

On (and Off) the Record

By Elizabeth Hofheinz

Dear *OTW* Reader: **Tom Sculco, M.D.** leads an international consortium…ortho insider finds **Synthes** punishments unfair and unwise… award for **James Heckman, M.D.**… new research on how **hospital employment** could affect communities… **Dr. Peter Millett**'s take on shoulder issues…and more….

Synthes Punishment: Unfair and Unwise An engineer in the orthopedic field has been observing the controversy around the Synthes legal problems. This source tells *OTW,* "I don't know the whole story…no one does. But the bottom line is that these corporate executives pleaded guilty to a misdemeanor and were sentenced for maximum punishment to a federal prison to do 'hard time.' My colleagues and I are shaking our heads, saying, 'Why such harsh federal sentencing?' They obviously want to make an example of these individuals that were in the decision making roles for the company, as well as make a loud statement to the device industry. However, there could have been many other, wiser options as far as punishment; these folks have already lost the ability to maintain their livelihood in medicine. The legal system took good people with good minds and locked them up. Why not be creative and have their sentencing involve contributing to society in a positive manner…the judicial system can take the concept of 'community service' and amplify it for

these individuals. My hope is that it will impact the way companies and device users behave. Currently, there is really a disconnect here…physicians and surgeons are not regulated for off label use of devices and the device companies are left to police the practice of medicine. It is the device company's responsibility to enforce on-label use and regulate the physicians and surgeons, while proving to the regulatory body that their system has been validated for every potential 'off label' application—this is impossible, costly, and ineffective."

Economic Impact of Hospital Employment Dr. Richard Iorio, the director of adult reconstruction at the Lahey Clinic Medical Center and professor of orthopedic surgery at Boston University Medical School, is undertaking some fascinating new research. He tells *OTW,* "The average orthopedic private practice physician employes four to six individual—and there are many orthopedic surgeons in each group. I am working with the American Association of Hip and Knee Surgeons (AAHKS) to study the impact of the loss of those total joint practices on towns around the United States. We're looking at how much money is spent on salaries, benefits, rent, overhead, insurance, etc. We are doing a survey of the AAHKS membership—1,100 total joint replacement surgeons—and will aim to determine how exactly being 'absorbed' by hospitals affects their practices. Our membership performs roughly a third of all total joints in the country, so we should have a good indication of what's actually going on. We're also asking the U.S. Chamber of Commerce for their input. Our goal as far as timing…get it done before the 2012 election."

Thomas Sculco, M.D. Leads International Consortium In 2005 Dr. Thomas Sculco, Surgeon-in-Chief at Hospital for Special Surgery, launched the International Society of Orthopaedic Centers (ISOC). Dr. Sculco tells *OTW*, "I started this at the recommendation of a former orthopedic fellow from Mexico, who suggested that I form a coalition of the largest orthopedic specialty hospitals in the world. We now have 17 centers on 4 continents. We meet every 18 months and share our common experiences and bring our musculoskeletal focus to bear on the issues facing the field. We take the best practices of these big centers and share them, with our first goal being to improve clinical care…followed by efforts to enhance collaborative research. For example, we are looking at various guidelines for DVT prophylaxis for joint replacement. Participants have a chance to look at these and determine how they might adjust them for their own countries. We are also examining the best methods to study retrieved failed implants and strategies for the reduction and treatment of infection. We have also established a fellowship program where the trainee spends three months at a number of the centers. What drives us? Orthopedic surgery is now global and the old days of things being done in different fiefdoms are over."

Chinese Orthopedic Association Fosters International Cooperation The Chinese Orthopedic Association (COA) recently held its 2011 meeting, during which time it set the stage for an international cooperation platform to promote high-level medical services through education, research and best clinical practices. The event gathered world-class experts, presidents of international orthopedic societies, presidents of more than 60 national orthopedic societies, industry opinion leaders, and CEOs of leading orthopedic companies worldwide. Efforts were also made to provide a model to developing countries and even developed countries to help them reduce medical costs and cope with the global financial crisis together. Known as the "Beijing Declaration," the group is moving forward under the banner of CARE: Co-operation, Advocacy, Research and Education.

SI-BONE: New Research Paul Anderson, M.D. professor of orthopedic surgery at the University of Wisconsin, Madison, is on the Surgeon Advisory Board for SI-BONE. Dr. Anderson tells *OTW*, "We have implanted iFUSE, sold by SI-BONE, into nine sheep and looked at how well healing progressed…the results showed a significant increase in bone density right adjacent to the implant—indicating a positive host reaction. At the final end point—six months—90% of the SI joints [sacroiliac joint] had fused on their own. The fusion across the sacroiliac joint with-

out decortication and bone grafting was remarkable, indicating excellent stabilization of the device. This has given us the basic science validity for the device; we are now awaiting the histologic analysis. This study has provided a proof of concept that the implant can provide stabilization and bone healing. Current studies are focusing on biomechanical effects."

James Heckman, M.D. Honored by AOA A former president of the American Academy of Orthopaedic Surgeons, Dr. James D. Heckman, is the recipient of the 2011 American Orthopaedic Association (AOA) Distinguished Contributions to Orthopaedics Award. The award recognizes an AOA member's personal achievement and broad contribution to the orthopedic specialty. The award emphasizes the important contributions of key individuals in effectively confronting issues or challenges in the profession. Dr. Heckman is editor emeritus of *The Journal of Bone and Joint Surgery—American.*

Peter McCann, M.D. Receives Lifetime Achievement Award The Chairman of The Department of Orthopedic Surgery at Beth Israel Medical Center, Dr. Peter McCann, has received the Lifetime Achievement Award in orthopedics from the New York Chapter of the Arthritis Foundation. The Chapter's Lifetime Achievement Award is presented to two physicians each year (one in the field of orthopedics, the other in rheumatology) in recognition of service to the Chapter and contributions to the medical community. For the past five years, Dr. McCann—who is also editor-in-chief of *The American Journal of Orthopedics*—has provided his time and talents to serve the Chapter as chair of the Review Committee for the Chapter's Research Fellowship Award in Orthopedics.

Shoulders? What to Do? Peter J. Millett, M.D., M.Sc., Director of Shoulder Surgery at The Steadman Clinic in Vail, Colorado, has been thinking a lot lately about shoulder acromioclavicular (AC) joint reconstructions and the management of shoulder separations. He tells *OTW*, "There is so much controversy now…'Should an AC joint injury be fixed surgically or treated non-operatively? If it is fixed, do it arthroscopically or open? What is the best surgical method?' I debated recently at The Arthroscopy Association of North America, and I held the position that high grade AC joint injuries should be fixed and fixed arthroscopically. I think AC joints have historically been treated nonsurgically and many patients are frequently unhappy with that. If we have an effective, minimally invasive way of repairing them or reconstructing the joint, then patients would be likely to opt for that. Our own data is showing that we can do the surgery arthroscopically, and we can do an excellent job right now. The surgical technique is in evolution, as we strive to improve our methods to allow for earlier movement and faster recoveries. We have undertaken biomechanical studies to validate methods of fixation so that we can perform this surgery even less invasively and create stronger constructs so that rehabilitation will go more quickly for our patients."

ORS to Hold Clinical Research Forum The Orthopaedic Research Society (ORS) is looking forward to a fruitful event at its 2012 Annual Meeting (February 6). The Clinical Research Forum will address, "The innovation cycle: How can we avoid wrong turns?" and will examine the complexities of innovation, several different orthopedic case histories, and the lessons that can be learned. The forum will feature a highly distinguished, international faculty. The forum will include five sessions with three dedicated to an in-depth discussion of current controversies: atypical proximal femur fractures, metal-on-metal bearings, and the use of bone morphogenetic proteins. The final session will help clinical researchers understand the steps they can take to minimize adverse events and other negative occurrences.

Rare Bone Disease: New Hope Scientists at Penn's Perelman School of Medicine Center for Research in FOP (fibrodysplasia ossificans progressive) and Related Disorders have developed a new genetic approach to specifically block the damaged copy of the gene for a rare bone disease, while leaving the normal copy untouched. Lead author Josef Kaplan, Ph.D., postdoctoral fellow; and senior authors Eileen M. Shore, Ph.D., and Frederick S. Kaplan, M.D., both from the Department of Orthopaedic Surgery, published this new proof-of-principle approach for treating the disease, called FOP, in the online edition of *Gene Therapy.* FOP is caused by a mutation in the gene for ACVR1/ALK2, a bone morphogenetic protein (BMP) receptor that occurs in all classically affected individuals. The mutation increases the amount of BMP in cells to greater than normal levels, which initiates the transformation of muscles and cartilage into a disabling second skeleton of bone. Using a special type of RNA molecule engineered to specifically silence the damaged copy of the gene rather than the normal copy, the scientists restored the cellular function caused by the FOP mutation by ridding cells of the mutant ACVR1/ALK2 mRNA. Confirmatory mouse models of classic FOP must be undertaken prior to its consideration for human use. ◆

Orthopedics This Week

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Ten Things To Be Thankful For

By Robin Young

I don't know about you, but this has been a tough year for many of us in orthopedics. Being in the news business, we probably see more than our fair share of depressing news.

New regulations, Milliman, transitioning from ICD-9 to ICD-10, politics (of all stripes), chaotic hospitals, the growing number of unemployed and uninsured patients, rising malpractice premiums, Department of Justice prosecution agreements, warning letters from the FDA or rule changes from Medicare.

So, for many of us in the musculoskeletal repair business, it's been a tough year.

And yet… when the news of the day fades into the background like so much white noise…when we start to reflect on the good and positive aspects of orthopedics, then I think we can see how incredibly blessed we are individually and how much good we collectively do as an industry.

So pat yourselves on the back. Here are the top ten things we can all be thankful for as we wind our way to the end of another year.

RRY Publications LLC

1 **You – in the mirror:** Yes, you. We work with people who are smart, educated, dedicated and who have a heart—after all, you entered this profession to help people. So we're thankful for you—the people of this industry who work so hard on behalf of those in pain and with disability. You are all men and women we respect and admire so much.

2 **Patients:** Thank you for thinking of us when you are in need. We got into this industry to find better ways of relieving your pain and fixing your aging frame. We particularly appreciate the opportunity to get you up and going again. There is no better feeling than that.

3 **Family:** Thank you for your patience and understanding—especially when we didn't really deserve it. Like when we had to man our company's booth at the fifteenth surgeon meeting this year. Or when we agreed to be on-call for the month of November. Or when we missed your ballgame/concert/play/pageant because we were at the hospital. Or when we weren't home when it snowed six inches and you strained your back shoveling. We don't say it near often enough, but we love you and we thank you.

4 **Start-up companies:** Thank you for being such a merry band of guys and gals nutty enough to attempt the impossible, improbable and utterly essential task of turning ideas into improved care for patients. You're our kind of crazy. Thank you for being creative, for working with new paradigms and for finding a future where there are no pre-determined formulas. Without you, we'd still be using leeches to extract bad spirits.

5 **Mentors:** Eighty percent of what we know, we learned ***after*** medical school. It was our mentors who helped us frame up the flow of new information. It was those

tough, demanding, occasionally irrational mentors who helped us see our skill gaps, helped us access new resources and exposed us to diverse perspectives. Their insights and support inspired and guided us. Because of that, we now know how to pass along perspective and experience to the next generation of clinicians, inventors and executives. In short, our mentors gave us the foundation for a lasting and successful career in orthopedics.

6 John Charnley / Leon Wiltse / John Harrington / Gary Michelson and every visionary past, present and future: Like Christopher Columbus you set sail on uncharted waters and showed the rest of us how to navigate past rocky shores and dangerous currents. Along the way you endured crushing failures, withering attacks and professional ridicule. Yet today your inventions and techniques are standard of care and we use your ideas to save literally millions of lives from early disability, pain or even death. Last, but not least, thank you for creating this industry which gives us and our families a livelihood.

7 DePuy/Stryker/Zimmer/Smith & Nephew/Medtronic: We also give thanks for the big guys of our industry. You deliver a level of efficiency, quality and consistency that helped make orthopedics the most reliably successful set of patient treatments in all of medicine. You also have taken the lead (we know, with a little help from the U.S. Attorney) in ensuring that we are also practicing unbiased medicine. At the end of the day, we couldn't maneuver through the problems of irrational reimbursers, shifting demands from patients, hospital administrators, and licensing agencies without your help.

8 Biologics: Marshall Urist pointed us in the direction of a particular protein—which he named bone morphogenic protein (BMP). We've learned to use BMP as a component of DBM (demineralized bone matrix), or harvested bone marrow, or in its recombinant form (InFuse) or any one of several other forms. The impact of protein biologics as adjuncts to surgery has had a significant impact on orthopedics. But 40 years of learning to use BMP appear to have been just a prologue to a future of living cells, human collagen sheets and new schemes for harvesting cells, proteins and other regenerative materials from the patients themselves. Biologics in all of its regenerative, anti-inflammatory and immune privileged glory is on the scene and promises to improve patient outcomes in significantly cost effective ways. What a time to be in orthopedics!

9 American Academy of Orthopaedic Surgeons (AAOS): We give thanks for AAOS. While we appreciate very much AAOS's consistency, annual meeting, ORS (Orthpaedic Research Society) and dozens of other affiliated surgeon groups, it is in fact their remarkable advocacy in Washington where AAOS has earned our special thanks. AAOS' staff tirelessly and effectively promote and represent

the orthopedic community before Congress, the FDA and CMS (Centers for Medicare and Medicaid Services). Under their remarkable leadership, over 200 orthopedic surgeons visit Capital Hill every year to lobby on our collective behalf for more rational Medicare reimbursement and medical liability reform. In this time of a shrinking public purse and unfair stereotypes regarding surgeons and their role in patient's lives, AAOS fights the good fight for us all in Washington.

10 Digitalization of Medicine: Finally, we're thankful for digitized medicine. Unless we stop and think about it, we probably don't realize how completely our lives have changed because of digitalization. Digital X-rays are just the tip of the ice berg. Because of dirt cheap memory, powerful processors and programming that has more in common with Halo 2 (if you have to ask…) than Excel, we are treating our patients with robots, punching up wireless formulary apps that fit on our smart phones and using RFID (radio-frequency identification) data to track implants, equipment, laptops and even wheelchairs. On the near horizon is registry data tailored to our personal or patient needs. How long ago were we sharing information with our colleagues by faxing or hand-carrying paper charts? Seems like ancient history, but it was really just a few years ago.

So, we're going to keep the whining to a minimum and reflect on how lucky we are to live and work with such phenomenal people in the greatest industry on earth. Orthopedics. ◆

Wall Street's "Friday Mediscare"

By Walter Eisner

The orthopedics device and provider community experienced a "Mediscare" on Friday, December 2, after news that Medicare was going to require 100% pre-authorization before paying for a range of orthopedic surgical procedures swept through Wall Street's trading desks.

In effect, the news said, hospitals were being put on notice by Medicare that they would be performing "spec" surgeries and hoping to be paid after the payer agrees the procedure was "reasonable and necessary" and patients had received his or her treatment.

The news was limited to 11 high, Medicare-enrollee states until Recovery Audit Contractor (RAC) audits are were completed on all procedures.

Still, the notion that one more layer of bureaucracy was about to be imposed on hospitals by CMS was enough to pull orthopedic, cardio and hospital stock values down by billions of dollars.

The list of the affected orthopedic DRG's included:

- 458 -- Spinal fusion except cervical w/spinal curve, malign, or 9+ fusions w/o CC
- 460 -- Spinal fusion except cervical w/o MCC
- 470 -- Major joint replacement or reattachment of lower extremity w/o MCC
- 490 -- Back and neck procedures except spinal fusion w/CC/MCC or disc device/neurostimulator

Screen shot from Carnival of Souls/Wikimedia Commons

The list also included a number of cardio DRGs.

Orthopedic, cardio device manufacturers and hospital stocks dropped like a rock, falling anywhere from 4% to 10% by the end of December 2.

Hospital manager Tenet Healthcare Corporation tumbled more than 10%, while Boston Scientific Corporation, Medtronic, Inc. and St Jude Medical, Inc., which make heart and spine devices, all fell between 6 and 7%. Zimmer Holdings, Inc., Stryker Corporation and other ortho stocks had similar declines.

Monday Morning Recovery

By Monday, December 5, however, the news didn't look as dire as analysts began parsing through CMS's (Centers for Medicare and Medicaid Services) pronouncements and it became clear that only Florida was instituting a 100% pre-payment audit now for the procedures. Buyers returned and hospital and device stocks began to recover Friday's lost ground.

Larry Biegelsen, Wells Fargo's Senior Analyst, put out a statement on December 5 saying that the firm had learned that only Florida had officially announced that it will perform 100% pre-payment audits on inpatient hospital stays for 15 cardiovascular and orthopedic DRGs on January 1, 2012.

Biegelsen noted that the other 10 states that are part of a CMS Recovery Audit Prepayment Review Demonstration

Wikimedia Commons and Ryan Lawler

announced in November, had not said which DRGs they will target and what percent of Medicare inpatient claims they will audit on a pre-payment basis.

According to the American College of Cardiology (ACC), whose Florida chapter's president had originally reported on November 21 that the program was being implemented nationally, said that Medicare indicated that the percent of claims the other 10 states will audit on a pre-payment basis will be less than 100%.

Ahh, the glamorous life of a Wall Street analyst.

To Biegelsen's credit his report and conference call with investors on December 2, was to our knowledge, the first alarm bell to a Medicare pilot project that seeks to achieve the government's goals for cutting improper payments by 2012 through reducing overall payment errors by $50 billion, cutting the Medicare fee-for-service error rate in half, and recovering $2 billion in improper payments.

Societies and Surgeons Respond

With the Friday reaction and Monday recovery out of the way, *OTW* reached out to device companies and medical societies to find out how they viewed the Medicare demonstration project announced in November and First Coast Service Options, the Florida CMS contractor's implementation of the project.

AAOS

Dan Berry, M.D., president of the American Academy of Orthopaedic Surgeons (AAOS) told *OTW* that the academy strongly supports CMS's efforts to improve quality and reduce waste within the Medicare system. "However," he added, "AAOS remains wary of the incentives driving RACs and does not support onerous and duplicative programs that further add to physicians' administrative burdens and threaten quality by compromising the valuable time they spend with their patients."

AAOS
American Academy of Orthopaedic Surgeons

Courtesy of AAOSS

The incentives driving RACs cited by Berry result from the auditors getting paid on a contingency basis for the funds they recover. This means that it is in the contractor's best interest to identify improper payments, and that the process is almost sure to expand to state-run programs within the next few years. In 2007, $10.8 billion were reportedly identified as improper payments by the exclusive four contractors selected by CMS. We were unable to determine exactly how much the contractors have been paid by CMS.

ISASS

The International Society for the Advancement of Spine Surgery (ISASS) provided *OTW* with a statement that said spine surgeons in Florida are very concerned with this recent action and feel it will threaten patient access to medically indicated spine surgeries.

ISASS INTERNATIONAL SOCIETY for the ADVANCEMENT of SPINE SURGERY

Courtesy of ISASS

"This is doubly troubling since there is not unanimous agreement among professional medical societies, payers and their actuaries, and others on when lumbar fusions are medically appropriate or necessary; this step may make

surgeons hesitate to perform surgeries that they know will improve a patient's life, but where the indication may not fit neatly into Medicare's increasingly more stringent guidelines for such a surgery."

"In short," continued the statement, "this action takes the clinical decision-making autonomy away from the surgeon and prioritizes cost-cutting over improved outcomes. We don't know if this is another step in what appears to be a continued assault on lumbar fusions by public and private payers, but we will be watching this closely to determine if patients are being denied life-changing surgeries."

Jeff Fernyhough, M.D., of the Florida Back Institute in Boca Raton, told us that the recovery program is the biggest potential limitation to patient access he has seen in his 22 years of working in Florida. He told us that his office will now generate more paperwork to pile on hospitals and may require patients to sign Advanced Benefit Notices (ABN). ABNs are a promise by the patient to pay the bill for surgery if Medicare denies the claim.

Finally, Fernyhough speculated that the audit program is a way for Medicare to get free care for beneficiaries. Some patients will receive care and providers won't be compensated, said Fernyough.

How much less compensation?

Bruce Nudell, an analyst at Credit Suisse said, in a *Bloomberg* story, that the procedures targeted in Florida's program account for about $14 billion of Medicare's spending on individual services. If the Florida program was expanded nationwide, the $14 billion would be reduced by 3% to 4%, meeting Medicare's goal of cutting overpayments in half.

But Nudell added that, "Any broad attempt at Medicare rationing, 'pulling the plug on grandma,' in an election year is likely to be suppressed by politicians, who didn't appear involved in the decision."

Chris Kauffman, M.D. an orthopedic surgeon at University Medical Center in Lebanon, Tennessee, went even further than Fernyhough. Kauffman, a NASS (North American Spine Society) activist told *OTW* that the new audit program looks like an effort to shorten a patient's hospital stay and change the setting from inpatient hospital to outpatient

settings, where physicians have more responsibility for the patient's care.

Industry Response

We also spoke to the major orthopedic device companies looking for comment. None would comment for the record, but they all pointed to the corrections put out by analysts following "Mediscare Friday" that said the program was unlikely to have a big impact on procedure volumes and device sales.

Since Biegelsen was the first analyst to notice CMS's proposed change, we give him the final word on the potential impact of the program on orthopedic device sales.

Assuming a 5% to 10% decline in procedures for the 15 targeted DRGs, Biegelsen expects the impact on worldwide sales on Johnson & Johnson, Medtronic, Stryker, Zimmer and Smith & Nephew to be under 1% for all companies, except for NuVasive, Inc. which could see a 2.16% impact on sales

Politics of Payment

Device manufacturers and physicians, who are heavily dependent on public reimbursement, should be very concerned about this audit program. If the audits are conducted fairly without the financial incentives cautioned about by Berry, the providers will only suffer if the procedures currently performed don't demonstrate significant benefits to patients and don't have a clear base of evidence agreed upon by societies. But as we have reported in previous stories (*Spine Fusion Surgery Reimbursement: Science or Politics; OTW November 7, 2011*), payer policies are not consistent or always based on agreed upon standards.

As usual, our orthopedic surgeons told us, the person at the payer's end deciding what is "reasonable and necessary" is where the rubber will meet the road. ◆

Houston Do we Have a Problem With Metal – Metal Pseudotumors? Murray Takes on Schmalzried in Orthopaedic Crossfire®

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

Proposition
Metal-Metal Reactivity: Houston, we have a problem!

For the Proposition:
David W. Murray, M.D., F.R.C.S.
Nuffield Orthopaedic Centre
Oxford, United Kingdom

Against the Proposition:
Thomas P. Schmalzried, M.D.
Joint Replacement Institute
Los Angeles, California

Moderator:
Clive P. Duncan, M.D., F.R.C.S. (C)
University of British Columbia
Vancouver, British Columbia

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Mr. Murray: "We only have experience with hip resurfacing, so my remarks will focus on that. We have observed patients following hip resurfacing with a variety of symptoms; when we investigate we find a soft tissue mass—either solid or cystic. We call these inflammatory pseudotumors; this is controversial, but it is a catch phrase to describe all the lesions that have been described under different names."

"We often see local destruction, with the lesion spreading through the tissue planes; by definition no organisms are seen or cultured. Histology usually shows metal wear debris, an inflammatory response, and extensive necrosis."

"We have good results with revisions for fracture, infection, and loosening, but the results following pseudotumor are poor…in fact the scores are similar to those which patients have before primary hip replacement. In about 50% of cases following revisions for pseudotumors there are major complications, and a third have had re-revisions."

"It was only when we'd been doing resurfacings for six years that we realized there was a problem…the problem has been increasing. We set out to determine the incidence of revision for pseudotumor. In Oxford our incidence is 1.8%; in other UK centers it is higher. Designer surgeons have a lower rate, but the main designer surgeons have now all reported appreciable numbers."

"Survival analysis: end point is revision for a pseudotumor, at eight years we have a 4% revision rate…it is increasing. The cause is multifactorial: in our practice most are associated with high levels of wear caused by edge loading. We think the lesions are a manifestation of a local toxic effect caused by metal wear particles; a small proportion may be true hypersensitivity."

"We must focus on indications, technique and design. The risk factors in our series are women, particularly those under 40, small size, and dysplasia. These risk factors are interrelated. A Cox regression suggests that gender is the most important risk factor, age is important, size is possibly important."

"To avoid it, avoid impingement. Also, acetabular orientation is critical; an inclination of 40° and anteversion of 20° is optimal. If you take a zone of plus or minus 10° around this, if the surgeon hits this zone the rate of pseu-

dotumors decreases significantly. Also, we need implants with optimal coverage, clearance…also, better metallurgy and machining, as well as alternate bearings."

"We have little experience with metal on metal (MOM) pseudotumors after conventional hip replacement. There is little consensus; some series have low rates whereas a few have very high rates. We need longer follow-up. We have always been cautious about MOM in conventional hips because unlike hip resurfacing, you don't have to use a MOM articulation."

Dr. Schmalzried: "Houston, I understand the problem. This is not a boogeyman that jumps out and bites your patient for no reason. There are some similarities between the Oxford experience and my personal experience, but I've done an X-ray analysis and a retrieval analysis."

"The Oxford Group is a multiple surgeon group; I'm going to present a single surgeon series. We both use the posterior approach, and that may be an important consideration for the occurrence of pseudotumor. Both groups have used multiple resurfacing implants. At Oxford the incidence is >1%; in my experience it's 0.51%. The problems I've had have been in females. When David reports his results, I've seen frontal plane radiographs…I'll discuss lateral plane radiographs."

"Our histology is similar. We've done an extensive retrieval analysis; I haven't seen that from Oxford. Regarding etiology, there have been rumblings from Oxford of a biologic basis; my conclusion is there's a primary mechanical basis involving corrosion products."

"A large mass can also present with a metal on polyethylene bearing—not MOM. The source of corrosion is a cobalt chrome to cobalt chrome taper. The histology is very similar to the histology that Willert subsequently coined as 'ALVAL' [Aseptic Lymphocytic Vasculitis Associated Lesions]. The original report from Oxford described 20 hips—MOM resurfacing—all women. Histology was consistent with ALVAL, but not much talk about the mechanics and pathophysiology."

"I use the term, 'Adverse Local Tissue Reactions (ALTR)' because there is not one single reaction that occurs histologically...there are at least two and probably three. My experience includes 588 hips, all with greater than a 36mm MOM bearing; 77% are male and it's predominantly a resurfacing experience through a posterior approach. I have one female with a surface replacement that has high wear and metal reactivity; one female surface replacement with a bilateral pseudotumor; another female total hip patient with a pseudotumor. If you look at the frontal plane X-ray you would say the lateral opening angle and the coverage of the hip looks good. *But that's not the important plane.*"

"Metal reactivity—high wear—is a result of a relatively high amount of combined anteversion (on the acetabulum plus the anteversion on the femur) leading to edge wear and subluxation, high wear rate, with production of particles and the typical foreign body response leading to osteolysis."

"My overall MOM outcomes have been excellent. I've had one revision for infection, one for loosening but none for instability or squeaking. But you get to the unique tissue reactions—one revised for reactivity, three for sensitivity…all females, none in modular total hips."

"When looking at the lateral radiographs and the wear plots of the four hips in the three females that were revised, they were all small because the patients with high combined anteversion natively tend to be small females. There was no difference in their lateral opening angle compared to the other patients in the series. When you look at the retrievals the important finding is edge wear and corrosion."

"In my experience it is a female issue. Component position influences wear and ion levels (from multiple reports). The primary role of mechanics in ALTR…it's a gender *association* and a resurfacing *association*—not a causation. Why? Why do you do a resurfacing on a female in her 40s or 50s? Mostly because of dysplasia; they have small size, low offset, higher combined anteversion, and reduced head/neck ratio because of the resurfacing. Edge loading, subluxation, wear and corrosion are the pathomechanics. The most important factor is component position."

Moderator Duncan: "It seems that in the UK they are not as much in denial about this issue as we are. It is being accepted widely, except perhaps at the centers where the innovators work, as being a looming problem in practice…at some centers surface replacement has stopped. In others it is being refused to female patients."

Mr. Murray: "The reason it's become a problem in the UK is that relatively large numbers have been done by many surgeons over ten years…and you don't really appreciate the problem until you've been doing it awhile. It will become more of a problem here."

Moderator Duncan: "Tom, it is critical to get the alignment correct and so important in the pathogenesis of this issue. Is it safe for the occasional surface replacing surgeon to do the operation without computer assistance…at least on the acetabular side vis a vis anteversion?"

Dr. Schmalzried: "Surgical technique…it's difficult to give a categorical answer when you're talking about thousands of surgeons, so the answer is that some guys are going to have problems and some won't. There were seeds planted—meaning cases that were done—during a time when the mechanical orientation wasn't as well understood, so it makes sense that over time you'll have an increasing occurrence as those seeds mature and the problems related to that bearing come forward. I will distinguish between what was done when those seeds were planted and what I think is the important factor—understanding why it happens when it happens…there is a mechanical basis that we can understand and move forward. It doesn't just have implications for MOM, but for hard-on-hard bearings categorically in order to get the desired wear mechanism."

Moderator Duncan: "Over the next five years you think it's going to be a diminishing problem, or the burden of this is going to be greater…in new cases?"

Dr. Schmalzried: "New cases will emerge because they are the product of surgeries that were done prior to the understanding of the mechanical orientation."

Moderator Duncan: "David, in your opinion there have been many in which the alignment of the components was perfect. I'm paraphrasing what you said a few minutes ago…you couldn't criticize the technique used by the surgeon, and yet this patient has returned with this pseudotumor. How can you explain that?"

Mr. Murray: "Despite perfect orientation we had pseudotumors. It decreases the risk, but they still happen. That example of the bilateral cystic pseudotumors…they were absolutely correct and they were done by the best resurfacer in the UK. One of our most interesting studies showed that, particularly in the flexible young women—with perfect positioning they can get edge loading. "

Dr. Schmalzried: "We're saying the same thing. You don't have femoral anteversion measurements on any of your patients, right?"

Mr. Murray: "Tom, we have patients with pseudotumors with perfectly positioned components."

Dr. Schmalzried: "Do you know what the femoral anteversion is? The reason is because the pathomechanics look like this—when they extend they have low offset and high anteversion, and they sublux on the edge and they go back in. That abrasive wear mechanism accelerates corrosion. I'm not saying that the component position in that patient is bad. It's important to get past, 'What is the pathomechanics?' because understanding the pathomechanics defines the way forward. Do you disagree?"

Mr. Murray: "Absolutely. It matters, but that is why you can't do it in flexible young women. In the stiff men you probably can…you're not going to get a lot of edge loading. It's indications, it's patients, implant, and technique. You can decrease the incidence, but you're not going to eliminate it completely."

Moderator Duncan: "On patients who have already had surgery, should surgeons now alter their method of post-market, post-implantation surveillance?"

Dr. Schmalzried: "The value of metal ions in an asymptomatic patient is questionable. In a symptomatic patient if you have an elevated ion level you've got a combination that would push towards revision. If you have a positive ultrasound in an asymptomatic patient I wouldn't know what to do with that…"

Moderator Duncan: "Tom, let me interrupt. Are you going to order those in your patients once a year or what?"

Dr. Schmalzried: "I don't do either one routinely."

Moderator Duncan: "David?"

Dr. Murray: "We don't do either one routinely. Anyone with any symptoms we'd do an ultrasound. We've screened a large number of patients at five years with ultrasound and we found a significant proportion have lesions. When we speak to them they are mildly symptomatic. So probably patients with symptoms often have an underlying problem…and if they do have symptoms they should be investigated with some form of scanning."

Moderator Duncan: "Excellent presentation. Thank you." ◆

Please visit www.CCJR.com to register for the 2012 CCJR Spring Meeting, May 20-23 in Las Vegas, Nevada.

company

Stryker Stocking Stuffer for Shareholders

Just a month after announcing that Stryker Corporation was going to lay off around 1,000 employees worldwide to reduce costs by over $100 million starting in 2012, the company announced on December 7 that its Board of Directors increased dividends 18% to shareholders. The company also announced the board authorized the repurchase of an additional $500 million of its common stock.

"With the 18% increase in our dividend along with the additional share repurchase authorization, we are demonstrating our commitment to maximizing shareholder value by leveraging our strong balance sheet and consistent cash flow generation," said Stephen P. MacMillan, Chairman, President and Chief Executive Officer of Stryker. "Although the macro environment remains challenging, we have continued to make sizable investments in R&D while further diversifying our revenue base through targeted acquisitions. Combined, these actions position us well to continue our history of delivering innovation and driving long term sales and earnings growth."

Over the past four years Stryker has, according to the company, returned approximately $2.9 billion of capital to shareholders consisting of approximately $850 million of dividends and approximately $2 billion of share repurchases. In 2011, the company has paid approximately $280 million of dividends and has repurchased shares worth approximately $625 million as of December 7, 2011.

The dividend is payable on January 31, 2012, to shareholders of record at the close of business on December 29, 2011.

—WE (December 7, 2011)

Image creation by RRY Publications, LLC/Source: Morguefile and Alvimann

DePuy Spine Addresses Neuromuscular Scoliosis

DePuy Spine has a new offering to address spinal and pelvic deformities in patients with neuromuscular scoliosis.

The company announced the launch of the Expedium Neuromuscular System on December 6. The modular system has pre-contoured rods and proximal connectors, open and closed iliac screw designs and wires.

Expedium Neuromuscular System/DePuy Spine

DePuy's new spine boss, Namal Nawana, Worldwide President, DePuy Spine, said, "We heard from surgeons that treating neuromuscular scoliosis is a challenging part of their practice and that they needed a system designed specifically for this type of patient. The Expedium...provides a procedural solution that simplifies the correction procedure and optimizes the time in the operating room."

Randal Betz, M.D., a pediatric spine surgeon from Philadelphia said, "Surgery for neuromuscular scoliosis is very challenging in that most cases require correction of a coronal, sagittal and axial deformity, including pelvic obliquity. This deformity can occur in patients with little or no muscle tone or in those with severe muscle tone and spasticity due to diseases like muscular dystrophy or cerebral palsy."

The company says that according to the Scoliosis Research Society (SRS), incidence of neuromuscular scoliosis ranges from 25% in people with cerebral palsy to 90% in people with Duchenne muscular dystrophy. Surgery is performed in these patients to prevent further curve progression, improve sitting balance and tolerance, reduce pain and improve quality of life.

Kirk Dabney, M.D., the associate director of the Cerebral Palsy Program at the Alfred I. duPont Institute in Delaware added that the modularity of the system allows for "easy fixation to the pelvis without the need for intra-operative modification of implants or complex rod bending. It also allows for the cantilever correction of severe pelvic obliquity and spinal deformity that was previously corrected with the unit rod."

—WE (December 7, 2011)

legal

California AG Subpoenas Medtronic Over Infuse

Medtronic, Inc.'s Infuse continues to generate negative publicity and legal actions.

The latest occurred as the company disclosed in its recent 10-Q filing that it has received a subpoena and request for documents from California's Attorney General, Kamala Harris. The subpoena is in connection with Infuse.

On an interesting side note, Harris is a daughter of Dr. Shyamala Harris, a breast cancer specialist who traveled to the U.S. from India to pursue her graduate studies.


Kamala Harris/aog.ca.gov

It isn't the first subpoena request from Medtronic over Infuse. The company received a subpoena from the U.S. Attorney Office for the District of Massachusetts in October 2008. U.S. Senators have also requested documents relating to the company's financial relationships with researchers conducting studies of the product.

In October 2011? we saw the first private lawsuit filed against the company for allegedly promoting the product off-label. As evidence, the suit cites a controversial June issue of *The Spine*

Journal accusing researchers of ignoring complications in their studies due to alleged payments to them by the company.

Medtronic has commissioned Yale University to oversee two independent, systematic reviews of all Infuse-related clinical data. According to the 10-Q statement, it expects results of the reviews to be concluded in the next fiscal year. Medtronic also said it will make all of the Infuse clinical data and results available to medical researchers.

Yale Review Update

On December 6, we learned that the Yale School of Medicine has farmed out parts of the project to the Oregon Evidence-based Practice Center (EPC) based at Oregon Health and Science University (OHSU) and the Centre for Reviews and Dissemination at the University of York in the United Kingdom.

Rochelle Fu, Ph.D., biostatistician at the Oregon EPC and an associate professor in OHSU's Department of Public Health and Preventive Medicine, will be the lead investigator on the Oregon EPC analysis. OHSU is also the home of famed spine surgery researcher, Richard Deyo, M.D., M.P.H.

OHSU's Department of Family Medicine appointed Deyo, Kaiser Permanente Professor of Evidence-Based Family Medicine in October 2007. We spoke to Dr. Deyo on December 9. He told us that he will not be participating in the Infuse review.

—WE (December 9, 2011)

October 2011 FDA Approval Summary

The FDA granted four original Premarket Approvals (PMAs) during the month of October 2011. None were for orthopedic devices. The approvals were for:

- Siemens Healthcare Diagnostics' Advia Centaur HBeAg Assay, an in vitro diagnostic immunoassay for the qualitative determination of the hepatitis B e antigen (HBeAg) in human serum and plasma (potassium EDTA, lithium or sodium heparin) from individuals who have signs and symptoms of hepatitis.
- Gen-Probe Incorporated's Aptima HPV Assay, an in vitro nucleic acid amplification test for the qualitative detection Of E6/E7 viral messenger RNA (mRNA) from 14 high-risk types of human papillomavirus (HPV) in cervical specimens.
- Medtronic Vascular's Assurant Cobalt Iliac Balloon-Expandable Stent System, a device indicated for improving iliac luminal diameter in patients with de novo and restenotic lesions in the common and external iliac arteries.
- Roche Diagnostics' Elecsys Anti-HBc IgM Immunoassay intended for the in vitro qualitative determination of IgM antibodies to hepatitis B core antigen (anti-HBc IgM) in human serum or plasma (potassium EDTA, lithium heparin, sodium heparin, sodium citrate).

Three orthopedic Supplemental Approvals were granted. Those approvals were for:

Image creation by RRY Publications, LLC. Source: Wikimedia and FDA

- Medtronic Sofamor Danek's Infuse Bone Graft/L-T Cage Lumbar Tapered Fusion Device. Approval was for replacing the Plastisol caps used to hold the fusion cage component with polyethylene bags.
- Smith & Nephew, Inc.'s Reflection Ceramic Acetabular Hip System (RCHS) and Birmingham Hip Resurfacing System (BHR). Approval was for the addition of an alternative site for the porous coating process for the R3 Acetabular Shells.
- Synthes Spine's Prodisc Total Disc Replacement. Approval was for a change from a manual polishing process to an automated polishing process and the addition of a passivation process after the plasma coating process.

A summary of the FDA's October 2011 PMA/Supplemental activity was as follows:

- Total number of PMA Originals under review—88. 41 are active and 47 are on hold. Three applications have been under consideration more than 180 days.
- Total number of PMA Supplements under review—554. Of those, 437 are active and 117 are on hold. 11 are older than 180 days.
- The FDA received 2 new PMA and 66 Supplement applications during the month.

—WE (December 6, 2011)

Physician Report Cards From Medicare Data Coming

Medicare wants to make its extensive claims database available to produce physician and hospital report cards.

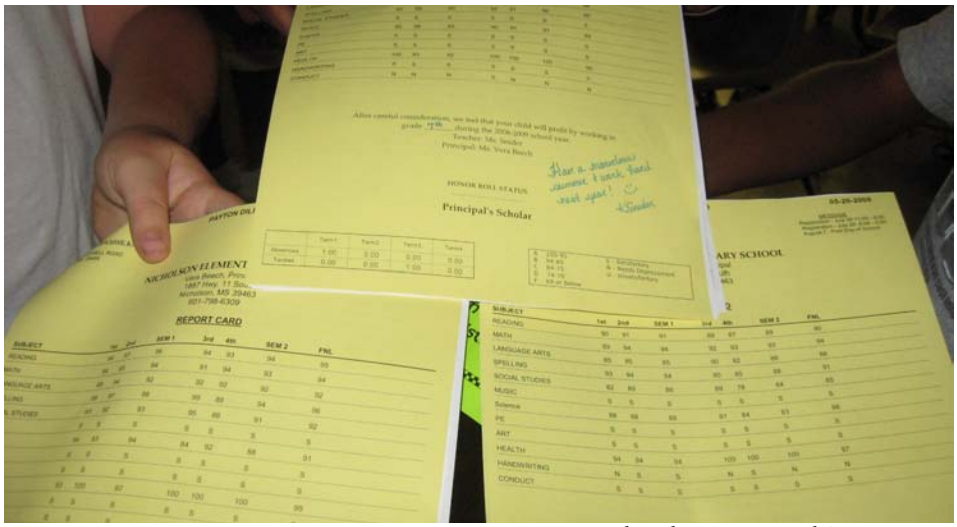
Citing physician privacy and a decades-old court ruling, the agency has historically fought efforts to use its database to find out about individual physicians.

But on December 5, Marilyn Tavenner, Medicare's new acting administrator, said that the agency will now make its database available to be used by employers, insurance companies and consumer groups to produce report cards on local doctors and hospitals.

The new health care overhaul changed federal law to explicitly authorize release of the information. Medicare has now followed through in regulations.

"This is a giant step forward in making our health care system more transparent and promoting increased competition, accountability, quality and lower costs," said Tavenner. "This provision of the health care law will ensure consumers have the access they deserve to information that will help them receive the highest quality care at the best value for their dollar." Consumers could start seeing performance reports by late 2012, said a Medicare spokesperson.

The Associated Press reported that while physician groups had fought dis-



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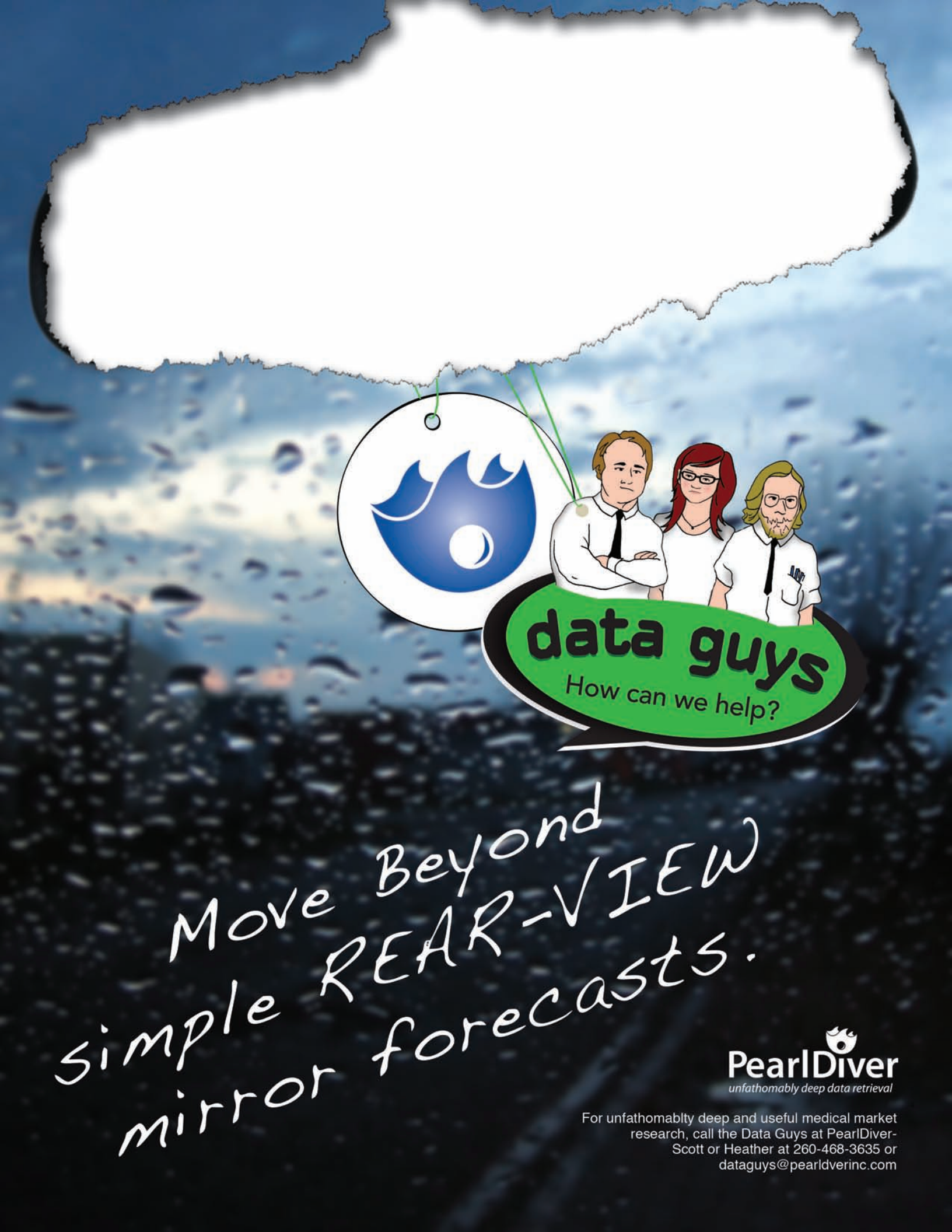
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Scott or Heather at 260-468-3635 or
dataguys@pearldverinc.com

closure of specific physician data, the organizations have lately shifted to putting conditions on its use.

For example, Medicare's rule gives individual providers the right to see their information before it is publicly released, and 60 days to challenge it.

The American Medical Association, according to the AP, had previously argued that such data could be misleading to untrained consumers. For example, a surgeon who has lots of patients who develop complications may actually be a top practitioner who takes cases that others less skilled would turn away.

Medicare says it will screen the analytical methods of groups that are requesting access to the data. The organizations will have to meet other qualifications, such as having access to claims data of their own. And they will have to pay for access to the Medicare files.

The final rule makes a number of important changes from the original proposed rule. The final rule makes this data less costly for qualified entities, gives qualified organizations more flexibility in their use of Medicare data to create performance reports for consumers, and extends the time period for health care providers to confidentially review and appeal performance reports before they become public. The rule also includes strict privacy and security requirements to protect patients, health care providers, and suppliers as well as stringent penalties for any misuse of Medicare data.

For more information on the final rule, click here (insert pdf) http://ryortho.com/CMMS_FinalRule2011.pdf

—WE (December 5, 2011)

biologics

ImageIQ + Rutgers in Armed Forces Bone Study

Rutgers University's Center for Biomaterials has selected ImageIQ, Inc., a not-quite-one-year-old imaging contract research organization, to perform image and image analysis services for a study on how to grow bone. The ultimate aim of the project, funded by the Rutgers-Cleveland Clinic Consortium of the Armed Forces Institute of Regenerative Medicine, is to treat service members suffering from significant bone damage and loss.

The study, which is a preclinical one, will be working with rabbits and, perhaps, later goats to determine the efficacy of a new scaffold that it is hoped will regenerate bone over a "critical size defect." According to Brett Hoover, vice president of ImageIQ, the firm's staff will use Micro-Computed Tomography (Micro-CT), instead of histologist imaging, to determine how much new bone is growing in the scaffold, where and at what rate it is growing.

In comparing the more traditional histologist imagining with Micro-CT, Hoover said, "You could have someone look at a thousand histology slices through a microscope and try to classify them or do Micro-CT instantly and effectively. Micro-CT gives much better resolution; say 300 microns and sometimes 10 microns—even down to one micron. These provide very minute details so we can make qualitative assumptions about the quality of the bone."

Amit Vasanji, Ph.D, Chief Technology Officer at ImageIQ, said, "We have a great deal of experience in applying 3D imaging and image analytics to improve bone tissue scaffold R&D timelines, reduce costs and enhance performance measurements."

Commander Denis Rivet performing spine surgery at sea; Source: Wikimedia Commons and Timothy Wilson

"We chose ImageIQ for its clinical lineage and history of excellence in providing application-specific imaging and image analysis for orthopedic research and development," said Jaochim Kohn, Ph.D., professor of chemistry at Rutgers University and director of the New Jersey Center for Biomaterials. "The sophistication of our biomaterials and scaffold research and development programs requires cutting-edge imaging analytics and a solid understanding of bone biology. Pairing our research staff with the ImageIQ engineers enhances our ability to generate robust, quantitative, clinically relevant data and maximizes our chances for success."

Tim Kulbago, CEO, while acknowledging the start-up nature of ImageIQ, notes that the firm got a "running start" for ten years as a department inside the Cleveland Clinic doing imaging work for researchers. He anticipates that the Rutgers study will move to a clinical trial of the bone scaffold on humans within a year or two. An additional benefit ImageIQ brings, he believes, is that his firm's work will create a "preclinical bridge" when the transition takes place to a clinical trial. "We will have employed a consistent imaging and performance analysis from the preclinical stage into the clinical trial stage," he said.

Looking ahead, Hoover anticipates that, if the study is successful, units of the bone scaffold will be stocked in army surgical clinics in war zones so that the healing process for wounded soldiers can begin immediately." You risk tissue loss, infection, vascular damage when you have to wait for treatment," he said.

—BY (December 6, 2011)

extremities

58 Orthopedists Working for Free

No more going without relief… thanks to Operation Walk, an international effort that has improved the lives and mobility of more than 6,000 patients in developing countries, 58 orthopedic surgeons provided free hip and knee replacement surgery to more than 85 patients at 25 hospitals, in 16 different states, over a two-day span this December 2 and 3 for Operation Walk USA 2011.


Dr. Adolph Lombardi

Concerned about those who go without the surgery because they might not have the financial capacity to afford the procedure, Operation Walk will provide all aspects of treatment—surgery, hospitalization, and pre-and post-operative care—at no cost to the patients. Operation Walk USA 2011 is a collaborative effort between The Hip Society, The Knee Society, and the American Association of Hip and Knee Surgeons (AAHKS).

"Rising health care costs and economic workforce issues in the United States can make it a struggle for some people to access medical care," said orthopedic surgeon Adolph Lombardi, M.D., and president of The Hip Society, in the November 29, 2011 news release.

"The goal of Operation Walk USA 2011 is to help these patients who are in pain, but are out of options for care," Dr. Lombardi added. "Joint pain interferes with their daily lives. Some can't play with their kids, walk in the park, or even perform at work. Operation Walk USA 2011 gives us an opportunity to get those people moving and mobile again. I know it will be an incredibly rewarding experience for all involved."

Dr. Lombardi will perform surgeries at Mount Carmel New Albany Surgical Hospital in New Albany, Ohio.

"Operation Walk USA 2011 is providing an early holiday gift to these individuals and their families. It will certainly be a new year for them," said Dr. Larry Dorr, the founder of Operation Walk.

Device manufacturers Biomet, DePuy, Smith & Nephew, Stryker and Zimmer, and Wright Medical Technology donated the hip and knee implants. Nike will provide a new pair of shoes for each patient.

When asked about post operative care for these patients, Dr. Lombardi told *OTW,* "Operation Walk USA 2011 is taking place at centers that have in house or onsite physical therapy departments. Many physicians typically utilize outpatient physical therapy centers. Physicians have discussed postoperative care with both of these respective groups at length, as post operative care and rehabilitation is critical to the long term success and overall patient satisfaction of a total joint replacement. These physical therapy groups have graciously agreed to help the patients of Operation Walk USA."

—EH (December 7, 2011)

Young Patients Getting Tommy John Surgery

Tommy John surgery, named for the Hall of Fame and former Dodgers and Yankees pitcher, was supposed to be for professional players only. Red Sox pitchers Daisuke Matsuzaka, John Lackey and Rich Hill had that surgery this year.

But increasingly, Tommy John surgery is being performed on amateur pitchers in college, high school and even on pitchers from youth leagues, according to a report November 29 by Christopher Smith of the *Eagle Tribune*. Of the 1,607 surgeries performed at Andrews Sports Medicine & Orthopaedic Center in Birmingham, Alabama, from 1994 through 2010, 374—23%—were performed on youth and high school athletes. The percentage is going up. In 2010, 31% of Tommy John surgeries at Andrews were on youth and high school pitchers. Ten years earlier, the figure was 18%.

Source: Wikimedia Commons and Tech77jp

"The most rapidly growing demographic of Tommy John surgery is actually in youth baseball," said Dr. Thomas Gill, chief of Massachusetts General Hospital sports medicine service and former Boston Red Sox medical director.

Young pitchers are throwing year-round because of the availability of indoor practice facilities. Under pressure to impress their coaches, pitchers as young as Little Leaguers are throwing with elbow pain and throwing too many pitches during games. Some coaches are also using young pitchers to play other positions, such as catcher and shortstop, with the result that they are throwing hard and often on what should be their days of rest, he explained.

"Probably the most common cause is overuse in our young population," said Dr. Luke Oh, a sports medicine orthopedic surgeon at Massachusetts General Hospital and a Boston Red Sox team physician.

Gill said young pitchers risk damage even though they are throwing at slower speeds than professionals because their elbow musculature is not as well formed. "So they have much less protection of the ligament and the stresses that the ligament sees," Gill said.

—BY (December 6, 2011)

Frozen Shoulder: XIAFLEX Dosing Begins

Auxilium Pharmaceuticals, Inc. has announced that the first patient has been dosed in its open-label phase IIa trial of XIAFLEX (collagenase clostridium histolyticum) for the treatment of idiopathic adhesive capsulitis of the shoulder, aka frozen shoulder syndrome.

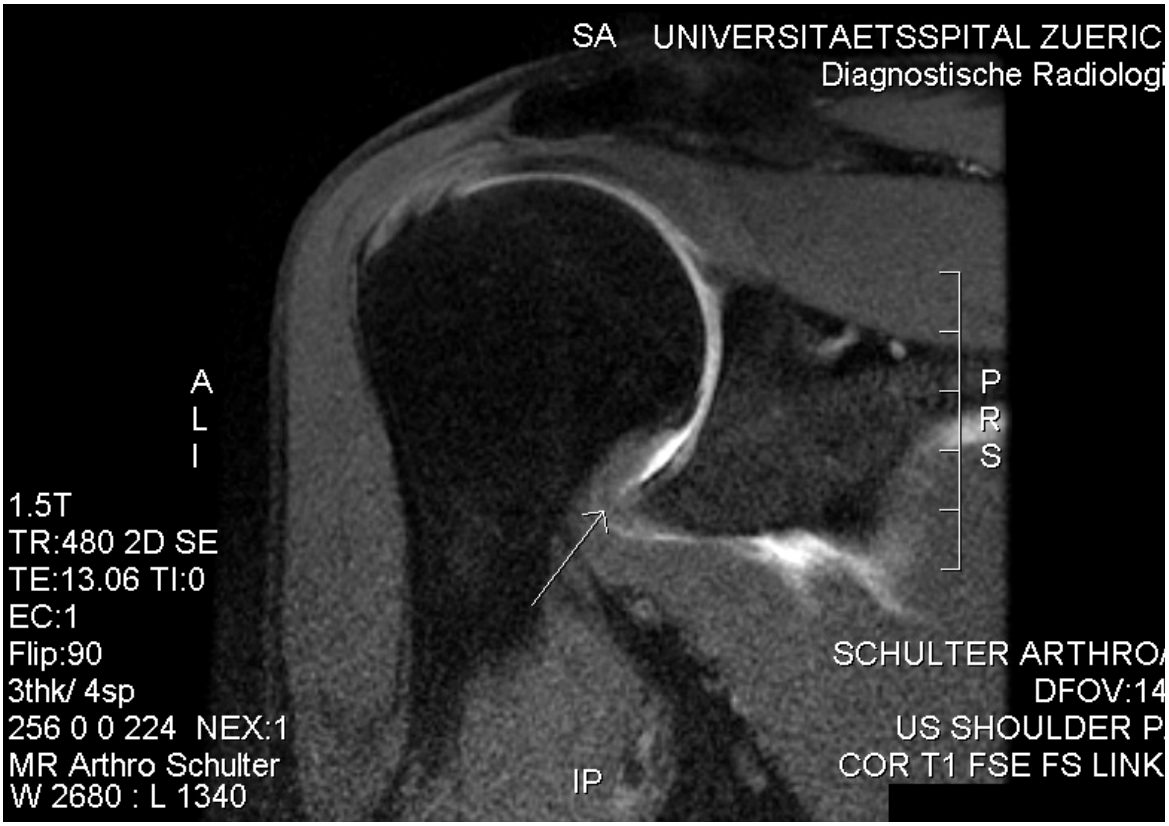
"The shoulder joint is crucial for many essential activities and when its function becomes limited, it can have a significant impact on patients' daily living," said Dr. James Tursi, chief medical officer of Auxilium, in the December 5, 2011 news release. We are pleased that the trial is underway and anticipate that the results may demonstrate the potential of XIAFLEX as an innovative acute option for orthopedic surgeons to treat frozen shoulder syndrome over approximately six weeks with a minimally invasive treatment option."

"Initiation of the frozen shoulder syndrome trial represents another important development milestone for Auxilium and we are excited to advance the third potential indication for XIAFLEX," added Armando Anido, chief executive officer and president of Auxilium Pharmaceuticals. "We believe that XIAFLEX represents a pipeline in a product and expect to develop multiple future indications, in addition to its proven benefit in treating adult Dupuytren's contracture in patients with a palpable cord."

The phase IIa study is an open-label, controlled dose-ranging study designed to assess the safety and efficacy of XIAFLEX for the treatment of frozen shoulder syndrome in comparison to an exercise-only control group. The study will involve approximately 50 adult men and women at approximately nine sites throughout the U.S. Topline study results are expected in the first half of 2013.

To qualify for the frozen shoulder syndrome study, patients must have unilateral idiopathic adhesive capsulitis of the shoulder with restricted range of motion in the affected shoulder for at least three months, but not more than 12 months. Following screening and determination of study eligibility, subjects will be assigned to four groups that vary in dosing (injection volume and concentration) or a fifth group receiving shoulder exercises only. Patients may receive up to three ultrasound-guided injections of varying doses of XIAFLEX separated by a minimum of 21 days and all patients will be instructed to perform home shoulder exercises. The study's primary endpoint is the change (degrees) from baseline to the day 92 follow-up in forward flexion (active) in the affected shoulder. Safety assessments, including immunogenicity testing, will be made during all study visits.

—EH (December 6, 2011)



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Print Your Own Bone!

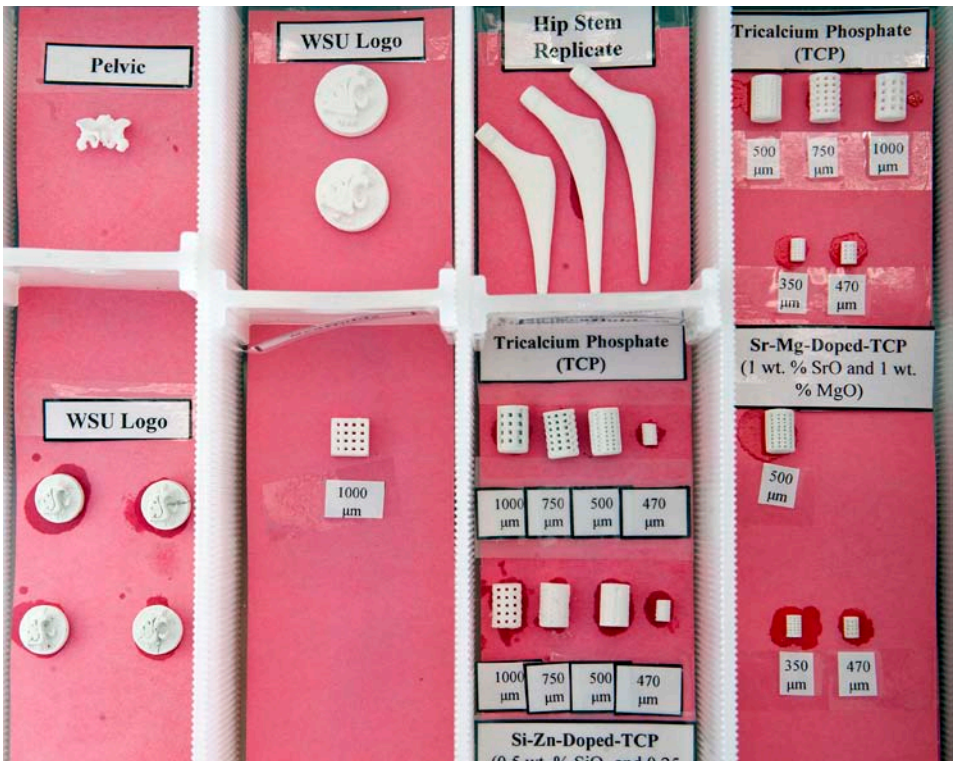
Washington University

What is going on at Washington University?! Bone…from an inkjet? Just how souped-up is this thing? Researchers, led by Susmita Bose, Ph.D., have successfully used a 3D printer to create a bone-like material and structure that can be used in orthopedic procedures, dental work, and to deliver medicine for treating osteoporosis. Paired with actual bone, it acts as a scaffold for new bone to grow on and ultimately dissolves with no apparent ill effects.

The authors report on successful in vitro tests in the journal *Dental Materials* and say they're already seeing promising results with in vivo tests on rats and rabbits. It's possible that doctors will be able to custom order replacement bone tissue in a few years, said Dr. Bose, co-author and a professor in Washington State University's School of Mechanical and Materials Engineering.

"If a doctor has a CT scan of a defect, we can convert it to a CAD file and make the scaffold according to the defect," Dr. Bose said in the November 29, 2011 news release.

The material grows out of a four-year interdisciplinary effort involving chemistry, materials science, biology and manufacturing. A main finding of the paper is that the addition of silicon and zinc more than doubled the strength of the main material, calcium phosphate. The researchers also spent a year optimizing a commercially available ProMetal 3D printer designed to make metal objects. The printer works by having an inkjet spray a plastic binder over a bed of powder in layers of 20 microns, about half the width of a human hair. Following a computer's directions, it creates a channeled cylinder the size of a pencil eraser. After just a week in a medium with immature human bone cells, the scaffold was supporting a network of new bone cells.



Washington University

Dr. Bose told *OTW*, "The outstanding benefit of these materials as a graft for repair or reconstruction of bone defects lies with the resorption characteristics, which will provide a controllable space for guided bone regeneration (GBR) during healing. These 3D printed scaffolds made with bone like material can be made with controlled chemistry, shape, size and geometry, where adding growth factors can provide even faster healing. We expect to design and tailor resorbable tissue-engineered bone replacement based on application needs such as spinal fusion, craniomaxillofacial applications, other small scale bone defects, osteoporosis and bone cancer."

She also commented to *OTW*, "If we understand the strength loss mechanism in CaP based material and scaffold to develop bone graft for specific application, e.g. craniomaxillofacial applications (relatively rapid biodegradation is desirable), or spinal fusion (where slow degradation and slow strength loss is desirable till the new bone grows."

—EH (December 5, 2011)

trauma

Soccer May Cause Head Injuries

Be careful heading that soccer ball. A study, presented at the annual meeting of the Radiological Society of North America, found that soccer players who had headed the ball frequently in their playing lives had "brain abnormalities similar to those found in traumatic brain injury patients."

The retrospective study, reported by Bob Cook in *Forbes*, looked at adult amateur soccer players who had participated in the sport since children and found that those who had reported at least 1,320 headers showed more signs of damage than those who had reported fewer.

Michael L. Lipton, M.D., Ph.D., associate director of the Gruss Magnetic Resonance Research Center at the Albert Einstein College of Medicine and medical director of MRI services at Montefiore Medical Center in New York, said in a November 29 press release, "What we've shown here is compelling evidence that there are brain changes that look like traumatic brain injury as a result of heading a soccer ball with high frequency. Given that soccer is the most popular sport worldwide and is played extensively by children, these are findings that should be taken into consideration in order to protect soccer players."

Dr. Chris Koutures, a pediatrician and sports medicine specialist in Anaheim Hills, California, commenting on the paper, said the retrospective imaging study was fascinating, but needs more data to effectively determine safe header limits, especially for younger players.

—*BY (December 7, 2011)*

Source: Wikimedia Commons and Master Sgt. John E. Lasky

spine

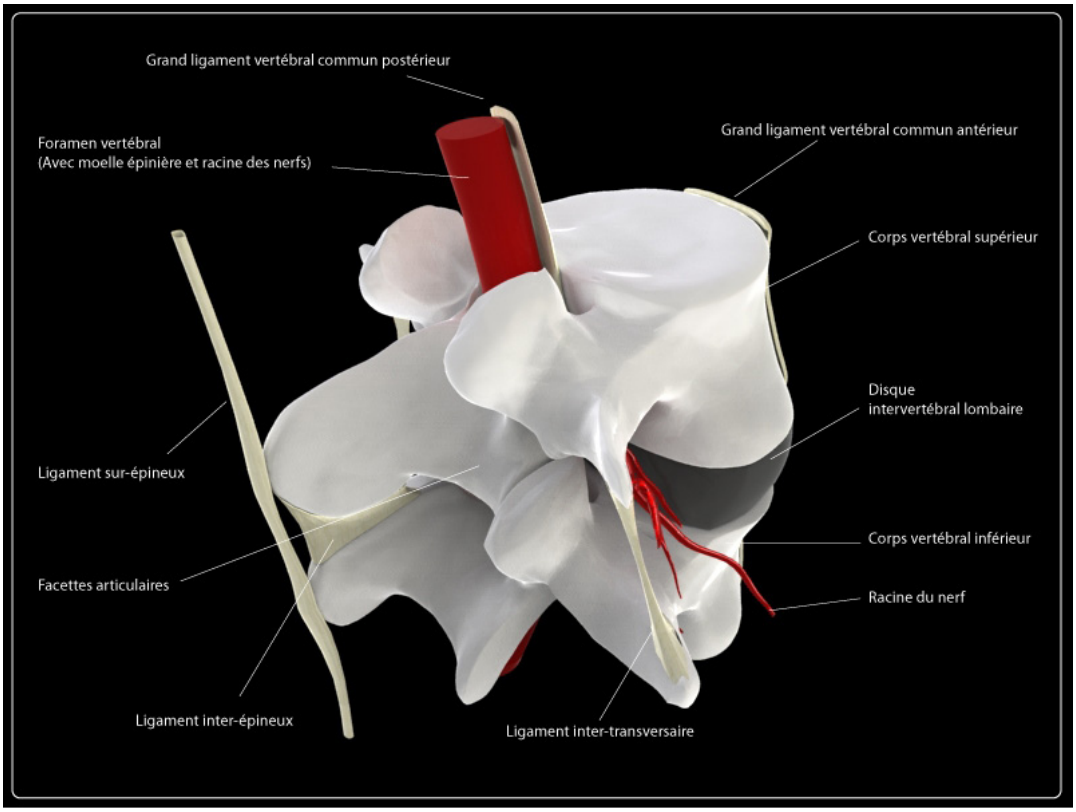
Definitive Back-Pain Study?

Can a single injection of stem cells repair and regenerate diseased lumbar discs? That question may soon be answered by the first of its kind nationwide study that will test the safety and efficacy of the use of mesenchymal precursor cells (MPCs) to replace bone, cartilage and muscle.

Headquartered at the University of California, Davis, the study will be directed by Dr. Kee Kim, associate professor and chief of spinal neurosurgery at UC Davis Health System. He will collaborate with Scott Fishman, professor and chief of pain medicine and co-principal investigator, to monitor the patients' progress.

An estimated 30 million people in the United States suffer from back pain. Degenerative disc disease is the most common cause of low-back pain, which develops with the gradual loss of a material called proteoglycan, which cushions the bones of the spine and enables normal motion.

"Many scientists and clinicians have injected all different kinds of material into the degenerated disc, hoping that something good will happen. Thus far, we have not been very successful, but we hope that a stem cell-based therapy will be the answer that we have been seeking for decades," Kim said. In preclinical studies on sheep with discs that were damaged or degenerated, a single injection of the stem cells was found to make the discs indistinguishable from healthy ones.



Source: Wikimedia Commons and Kaudris

"If safety and efficacy are shown in the study, this would be revolutionary," Kim noted. "It would imply that we can possibly turn back the clock on aging by not only stopping the progression of degenerative changes in the disc, but also reversing the degenerative process," he said. The researchers plan one single injection of adult stem cells directly into the diseased lumbar discs.

Researchers will enroll approximately 100 study participants, 10 at UC Davis and the rest at 11 other medical centers throughout the country. The participants will be individuals who have suffered from moderate low-back pain for a minimum of six months and whose condition has not responded to other, conventional treatments.

The patients will be divided into four groups. One group will receive a high dose of MPCs plus hyaluronic acid, a substance that facilitates the localization and retention of the stem cells. A second group will receive a lower dose of MPCs, plus the hyaluronic acid. A third group will receive the hyaluronic acid alone and a fourth group will receive only the saline solution.

"As an investigator, the design of this study is one of its most attractive features. This type of randomized study where the patients are blinded to the treatment is as good as it's going to get to eliminate any possible bias," Kim said.

The current study is sponsored by Mesoblast Ltd., of Melbourne, Australia, which is investigating stem cell technology to regenerate and repair bone and cartilage. The MPCs are derived from a single adult donor's bone marrow to ensure homogeneity, thus minimizing the risk of rejection by the recipient. **Kim will not receive compensation from Mesoblast for his participation in the study.**

—BY (December 6, 2011)

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