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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: This week JNJ formally introduces the new DePuy plus Synthes. Usually corporate mergers of this kind underwhelm. But this time we see an interesting cultural effect. JNJ's strong branding, flexible work rules, high pay with high performance culture will, we predict, play well among former Synthes employees, where morale had been buffeted by both external events and an EU style culture.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Johnson & Johnson	24.93%	6.45%	We are actually optimistic about the DePuy/Synthes combination. Why? Culture. JNJ culture. It will work well at Synthes.
2	2	Orthofix	16.23	12.16	OFIX settles Mexican bribery case for $5.2 million. Settled DOJ last month. This is it, right? Still expect good news for Q2.
3	3	Integra LifeSciences	13.34	17.68	Strong price performance in face of an expected flat to down earnings report. Buyers are clearly attracted to something else.
4	4	ArthroCare	(0.67)	6.19	ARTC has surprised on the upside in 3 of the last 4 quarter. On average, the upside surprise was 14% above expectations.
5	7	Smith & Nephew	21.50	8.54	Why are buyers adding SNN to their portfolios? By and large, they think earnings growth will improve in 2013.
6	5	Zimmer	24.95	5.65	ZMH, SYK and Biomet face the same strategic issues with DePuy and Synthes merging. What now?
7	6	Stryker	23.68	3.03	Missing a CEO is starting to have an effect on investor sentiment. The biggest risk is that everyone marks time waiting.
8	9	Conmed	10.09	7.45	Inventory levels declined last quarter even as sales rose. That's recipe for strong cash flows. Most analysts are looking for 29% earnings growth this quarter.
9	10	NuVasive	6.63	20.50	Could the acquisition of NUVA be a reasonable competitive response to a Synthes + DePuy Spine combination? Wouldn't be surprised.
10	8	Symmetry Medical	5.29	8.84	Digesting acquisitions this year so sales growth will very likely exceed earnings growth.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	NuVasive	NUVA	$24.69	$1,066	20.50%
2	Integra LifeSciences	IART	$38.80	$1,048	17.68%
3	CryoLife	CRY	$5.40	$149	14.65%
4	Orthofix	OFIX	$40.85	$765	12.16%
5	Bacterin Intl Holdings	BONE	$1.34	$57	9.84%
6	Symmetry Medical	SMA	$8.25	$302	8.84%
7	Smith & Nephew	SNN	$50.71	$9,095	8.54%
8	Alphatec Holdings	ATEC	$1.80	$161	7.78%
9	Conmed	CNMD	$28.56	$808	7.45%
10	Johnson & Johnson	JNJ	$68.61	$202,421	6.45%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MAKO Surgical	MAKO	$14.61	$622	-39.02%
2	Tornier N.V.	TRNX	$21.02	$832	-3.27%
3	Wright Medical	WMGI	$19.70	$774	-1.89%
4	Synthes	SYST.VX	$166.16	$19,817	0.00%
5	Medtronic	MDT	$37.56	$38,501	1.10%
6	RTI Biologics Inc	RTIX	$3.57	$199	1.13%
7	TiGenix	TIG.BR	$0.59	$54	1.45%
8	Stryker	SYK	$53.05	$20,208	3.03%
9	Exactech	EXAC	$16.95	$223	3.35%
10	TranS1	TSON	$2.58	$70	4.88%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$37.56	$38,501	11.31
2	Zimmer Holdings	ZMH	$63.35	$11,158	12.85
3	Johnson & Johnson	JNJ	$68.61	$202,421	13.67
4	Stryker	SYK	$53.05	$20,208	13.92
5	Orthofix	OFIX	$40.85	$765	14.64

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$24.69	$1,066	57.42
2	Wright Medical	WMGI	$19.70	$774	50.51
3	Symmetry Medical	SMA	$8.25	$302	33.00
4	Exactech	EXAC	$16.95	$223	23.87
5	RTI Biologics Inc	RTIX	$3.57	$199	21.00

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$40.85	$765	0.81
2	ArthroCare	ARTC	$29.51	$816	1.16
3	RTI Biologics Inc	RTIX	$3.57	$199	1.17
4	Stryker	SYK	$53.05	$20,208	1.30
5	Zimmer Holdings	ZMH	$63.35	$11,158	1.42

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$24.69	$1,066	6.03
2	Wright Medical	WMGI	$19.70	$774	5.99
3	CryoLife	CRY	$5.40	$149	4.82
4	Symmetry Medical	SMA	$8.25	$302	2.75
5	Johnson & Johnson	JNJ	$68.61	$202,421	2.28

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.80	$161	0.82
2	Symmetry Medical	SMA	$8.25	$302	0.84
3	Exactech	EXAC	$16.95	$223	1.09
4	Conmed	CNMD	$28.56	$808	1.11
5	RTI Biologics Inc	RTIX	$3.57	$199	1.18

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.59	$54	46.69
2	MAKO Surgical	MAKO	$14.61	$622	7.36
3	Synthes	SYST.VX	$166.16	$19,817	4.99
4	TranS1	TSON	$2.58	$70	3.67
5	Tornier N.V.	TRNX	$21.02	$832	3.18

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

Top 25 Discectomy Hospitals in America

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

Got a nagging disc pressing on your spinal cord? If you opt for a discectomy, where should you go to ensure that you walk out—comfortably, soon, and with money still in your pockets? This month, in looking at which hospital gives the best "bang for the buck" for a procedure, we report on the top 25 hospitals in the country for discectomy.

What does it take to be the best? Hospital gowns that cover everything? Organic tea in the waiting room? Not exactly. Alas, these hospitals have it figured out! Behold the top 25 hospitals in the country for discectomy…(and this month we have a pretty even split between the North and South).

(See Table on Next Page)

RRY Publications LLC

This ranking takes into consideration:

- How many procedures
- How many problems
- And how much, namely, fusion volume, complication rates, and charge for the procedure.

Number 1: Arkansas Surgical Hospital, LLC

Arkansas Surgical Hospital was also number three in the country for spinal fusion…now they've hit the number one position in discectomy! Arkansas Surgical Hospital in Little Rock, Arkansas, holds the top spot for those seeking to ease their pain via discectomy. When asked about why their facility has been ranked number one in the nation, Carrie Helm, chief executive officer, commented to *OTW*, "The right surgeons and staff are key to any success we have here at Arkansas Surgical Hospital. They are some of the best in the nation. At Arkansas Surgical Hospital, we are focused on just a few specific surgical services. This includes spine surgery. This specialization allows the greatest innovation and quality allowing our patients to return to the life they want to live."

Responding to their nearly microscopic complication rate for this surgery—1.1%—Helms commented, "Again, our specialization plays into our outstanding outcomes. The nursing staff throughout the facility focuses on our areas of specialization. They know what to expect with each and every surgery. Each patient is unique and as experts in the field, we are able to anticipate patient needs, increasing the outcome of the patient."

And while they're not performing a complimentary community service, the average charge for a discectomy at Arkansas Surgical is pretty low, coming in at $16,434. Asked how they are able to keep costs down, Helms told *OTW*, "Consolidating purchasing power and increasing productivity and efficiencies, while maintaining a high quality and reliable results."

And when *OTW* asked, "Your length of stay for this procedure is one day. Why not two or three?" Helms responded, "We keep patients as long as needed to ensure they have the best outcomes possible. In the case of discectomy, we have determined that our patients are able to return home after a one-day stay."

Number 2: River Oaks Hospital, LLC

Lining up as a close second is River Oaks Hospital in Jackson, Mississippi. River Oaks President and CEO Tim

National Ranking	Provider Name	State	Average Charge	Average LOS	Complication Rate
1	Arkansas Surgical Hospital, LLC	AR	$16,434	1	1.1%
2	River Oaks Hospital LLC-River Oaks Hospital	MS	$36,270	3	2.1%
3	Mobile Infirmary Association-Mobile Infirmary Medical Center	AL	$21,406	3	3.9%
4	Bon Secours St. Francis Xavier Hospital Inc.	SC	$39,908	2	2.4%
5	Cookeville Regional Medical Center	TN	$15,840	3	1.8%
6	The Williamsport Hospital-The Williamsport Hospital & Medical Center	PA	$20,173	5	4.5%
7	Hendrick Medical Center	TX	$27,466	3	5.2%
8	Peacehealth-Sacred Heart-Riverbend	OR	$36,130	4	6.9%
9	Mercy Medical Center-Mercy Medical Psych Unit	IA	$20,830	3	5.5%
10	Jackson Madison County General Hospital	TN	$19,267	0	1.8%
11	Northwest Hospital-Northwest Hospital & Medical Center	WA	$34,612	4	4.8%
12	Jackson Hospital And Clinic, Inc.	AL	$31,835	3	3.1%
13	Oklahoma Spine Hospital LLC-Oklahoma Spine Hospital	OK	$32,032	2	7.6%
14	St. Cloud Hospital	MN	$30,542	4	8.7%
15	Tulsa Spine & Specialty Hospital-Tulsa Spine Hospital	OK	$29,920	3	9.3%
16	Suburban Hospital, Inc.-Suburban Hospital Health System	MD	$14,673	4	6.6%
17	St Francis Hospital And Medical Center	CT	$16,142	3	6.5%
18	Wayne Memorial Hospital Inc.	NC	$22,311	4	0.0%
19	Lancaster General Hospital	PA	$41,123	3	5.5%
20	St. Vincent's Hospital	AL	$25,454	3	10.4%
21	West Penn Allegheny Health System Inc.-Allegheny General Hospital	PA	$28,041	6	3.4%
22	Northern Michigan Hospitals	MI	$20,204	2	4.1%
23	Munson Medical Center	MI	$35,655	4	8.5%
24	Sacred Heart Medical Center	WA	$39,655	3	7.6%
25	Baptist Memorial Hospital	TN	$41,259	4	8.8%

Source: PearlDiver Data Technologies

Mitchell told *OTW*, "River Oaks Hospital, known for over three decades as one of the state's premier surgery centers, is doing a lot of things right. Our hospital's surgical services are delivered with the latest technology by expert teams of board-certified surgeons. We are fortunate to have some of the nation's top surgeons on our medical staff, which affords patients from across the state the opportunity to undergo complex procedures once only offered in large metropolitan cities. Specific examples of surgical excellence include:

- providing a neuro and ortho coordinator to manage surgeon's expectation/preferences
- frequent peer review of all surgery cases
- well trained surgical teams who collaborate to ensure the best patient outcome
- patient education coordinators that provide critical pre- and post-op information
- nurses and associates throughout the facility who are truly committed to the safety of a patient."

Shedding light on the reasons for their low complication rate for discectomy—2.1%—Mitchell told *OTW*, "River Oaks Hospital is proud to have a Center of Excellence in Infectious Disease Pre-

vention that is led by Dr. David Smith. This is instrumental in preventing surgical infection; Dr. Smith is a champion for this cause. We also utilize stringent standardized protocols during the pre op and post op stages. Our goal is to encourage patient involvement from the time they begin the surgery process through pre-testing labs and beyond. They are encouraged to ask questions and be actively engaged in the process. We also provide a video tutorial for our patients via Emmi Solutions regarding specific surgical procedures. We have found that an informed and engaged patient has measurably better outcomes."

As for River Oaks' average charge for this surgery—$36, 270—Mitchell noted, "Our mission is to never settle for less than the best for our patients. We will not compromise on that goal. At the same time, we utilize the latest technology and are always looking for ways to reduce costs. Standardized protocols and streamlining our efficiencies also serve us well in managing our costs. Regarding our length of stay for this procedure, which is three days, the length of stay varies dependent on the condition of the individual patients and their needs. We have an active resource management service that works with our physicians, patients and their families to determine an appropriate discharge plan. We have found that the more actively the patient is involved in the pre-op processes the more compliant the patient will be with the plan of care in the post-operative period."

Mitchell added, "We have a excellent team of board certified surgeons that specialize in this procedure. The Associates of River Oaks are committed to providing the best care possible. Communication, teamwork and our focus on the patient is what makes it all possible." ♦

This research was performed by PearlDiver Data Technologies, an Orthopedics This Week-affiliated company with a proprietary database that includes more than one billion patient records and includes de-identified Medicare and private payer data as well as specific industry data as compiled by PearlDiver analysts.

NOTE: Estimated volumes account for all payer types and all age groups based upon data from the National Inpatient Sample release by AHRQ. It is assumed that each facility follows the same age and payer type trend.

White Coat of Silence on Trial

By Walter Eisner

Andrew Huth and RRY Publications LLC

California orthopedic surgeon Steven Graboff, M.D. provided expert testimony against a fellow orthopedic surgeon in a medical negligence case in 2007. It wasn't the first time. Dr. Graboff has been an expert witness over 500 times over the last 20 years.

Steven Graboff, M.D.

Grievance Filed

On April 10, 2008, a grievance was filed against Dr. Graboff by the surgeon against whom he had testified, alleging violations of American Academy of Orthopaedic Surgeons (AAOS) Mandatory Standards. The grievance arose from statements made by Dr. Graboff in a medical-legal written report to plaintiff's attorney. The report was part of a medical liability lawsuit in which a patient claimed his orthopedic surgeon failed to remove certain hardware (cerclage wires) during two surgeries on the right femur resulting in an amputation.

According to a September 2009 story in the Academy's publication, *AAOS Now*, Dr. Graboff was initially absolute in his opinion that the defendant surgeon had violated the standard of care by not removing all hardware and that there was no medical or surgical condition precluding removal of the hardware.

But the article continued that Dr. Graboff then contradicted himself and acknowledged that removing all hardware from an infected femur is not always possible, safe, or standard of care. Dr. Graboff, according to the story, further admitted his report had been based on lack of information and that the defendant surgeon had neither fallen below the standard of care nor was responsible for the subsequent consequences.

Graboff's Defense

Dr. Graboff defended himself against the complaint during a grievance hearing on October 24, 2008, noting that he had only written a "draft" opinion for the plaintiff's attorney. The attorney, without Graboff's permission, whited out the "draft" from the document and used it to reach a settlement with the defendant surgeons.

AAOS Suspends Graboff

Nevertheless, the Grievance Hearing Committee recommended that Dr. Graboff be suspended from AAOS membership for two years. Daniel Rhynhart, AAOS's attorney, said the society questioned why Graboff signed and provided the report if it wasn't finished. Rhynhart said the report appeared and sounded like a final opinion.

Dr. Graboff appealed the recommendation of the hearing panel, and the AAOS Judiciary Committee conducted an appeal hearing in February 2009. The Committee unanimously agreed that the AAOS had afforded both parties due process and reaffirmed and adopted the report and recommendation to suspend. In their report, the Judiciary Committee opined that testimony is not narrowly defined within the context of oral depositions and/or courtroom examinations, but applies to written expert opinions as well as sworn testimony.

In a June 2009 meeting, the AAOS Board of Directors also considered five other grievances filed under the AAOS Professional Compliance Program and alleging violations of the AAOS Standards of Professionalism (SOPs) on Orthopaedic Expert Witness Testimony.

AAOS Now, reported on the disciplinary action against Dr. Graboff and the other five surgeons disciplined by the organization in that September 2009 story.

Graboff Sues, Wins

Dr. Graboff then did something very unusual and practically unprecedented. He sued the AAOS in a Pennsylvania federal court in 2010. He said the AAOS article showed him in a false light, defamed him and interfered with prospective contractual relations. He said AAOS had damaged his credibility as an expert witness, causing him embarrassment and loss of income.

Dr. Graboff also sued the attorney and law firm who had removed the "draft" designation from his medical opinion in the original case.

Wikimedia Commons

In May 2012, a jury held that AAOS falsely portrayed Dr. Graboff in the *AAOS Now* article and awarded him $380,000 to be paid by AAOS and the law firm that manipulated his draft report.

Rhynhart said it was a curious verdict since the jury sided with AAOS on most counts. AAOS is asking a new judge to throw out the jury's verdict.

Expert Witness Debate

Lawyers for both sides are portraying this case as something bigger than just the censure of one surgeon. Dr. Graboff's lawyer says this is about protecting physicians to provide unvarnished testimony in trials. AAOS' lawyer says this is about holding members accountable to strict disciplinary standards when providing expert testimony about colleagues.

Louise Andrew, M.D., a medical expert, told the *American Medical News* on June 25, that the judgment is among the first where an expert witness has challenged medical society discipline and won a jury award. Dr. Andrew said the verdict could encourage more expert witnesses to sue specialty societies that sanction their behavior.

"The more of these cases against medical societies there are, the more emboldened will be those 'experts,' whose testimony is exposed, to take this route. Medical societies are particularly vulnerable, because they do not enjoy any kind of immunity [that] medical boards do, and the pursuit of ethics cases takes up a lot of staff time [and] involvement of attorneys," added Dr. Andrew.

The "White Coat of Silence"

Dr. Graboff told *OTW* in a July 10 email that doctors injure patients as a result of medical negligence over 200,000 times a year.

"Those injured patients," said Dr. Graboff, "need compensation and closure. The responsible doctors need to be held accountable, and in some cases they need to be removed from practice. Medical malpractice lawsuits address these issues."

The American legal system is well equipped to deal with medical expert witnesses and expose their level of competence and credibility, says Dr. Graboff. But because of the "white coat of silence" the legal system is hampered by a lack of well qualified doctors willing to testify against those doctors whose negligence has damaged patients, and in some, who repeatedly cause injury to patients.

"This 'code of silence' unwritten rule that a doctor doesn't testify against another doctor is fortified by professional associations like the AAOS who through their 'professional compliance programs' intimidate their members by censure, suspension, expulsion, public humiliation, and damage to their reputations to not testify against their fellow doctors."

Finally, says Dr. Graboff, "This 'white coat of silence' needs to be removed and professional societies like the AAOS need to stop their practice of expert witness intimidation and 'back door tort reform.'"

"The court in my lawsuit against the AAOS, having unanimously ruled in my favor, obviously arrived at the same conclusion."

Dr. Graboff's attorney, Clifford E. Haines, a past president of the Pennsylvania Bar Association, said the verdict shows that expert witnesses cannot be unfairly silenced by medical societies.

"This case was really about standing up for the rights of medical expert witnesses and the patients for whom they testify," Haines said in a statement. "Medical organizations are trying to deal with medical malpractice not by making sure their surgeons are doing top-notch work, but by going after the guys acting as expert witnesses."

AAOS Appeals

AAOS's lawyer Rhynhart said the verdict was "strange" and inconsistent because the jury did not find the Academy liable on the defamation and other claims.

"If we didn't do anything wrong, and there's no false statements in the article, then how the heck does this portray him in a false light?" he said. "We thought it should have been a complete defense verdict."

In late May, AAOS asked the court to correct the verdict.

Expert Witness Governance

American Medical Association (AMA) policy states that testimony a physician gives as an expert witness is considered to be the practice of medicine. The Association encourages state medical societies to work with licensing boards to develop disciplinary measures for physicians who provide fraudulent testimony.

According to the Federation of State Medical Boards, most state medical boards have the authority to discipline doctors found to have provided unethical witness testimony. However each board's process of investigating complaints and enacting discipline differs.

Russ Pelton, a former general counsel for the American Association of Neurological Surgeons, said in the AMA story that expert witnesses that have challenged medical society sanctions in court generally have lost.

Graboff Qualifications

Dr. Graboff, according to his web site, is a board certified Orthopaedic Surgeon, a member of the American College of Forensic Examiners, and a Certified Forensic Physician. He is a diplomat of the National Board of Medical Examiners, American Board of Forensic Medicine, American Board of Forensic Examiners, and is appointed by the State of California as a Qualified Medical Examiner.

He received his medical degree from the University of California, Irvine in 1980. He did a general surgery internship at the University of California Irvine Medical Center and affiliated hospitals from 1980 through 1981, and he completed his Orthopaedic Surgery training in 1985 from Harbor-UCLA Medical Center and affiliated hospitals, Los Angeles, California.

Future Grievance Process

Whether or not AAOS is successful in getting their $180,000 penalty overturned is unknown for now. Dr. Graboff's economic award amount seems trivial with all the law firms involved and probably barely covered legal costs. His real victory was a jury's acknowledgment that a professional society had harmed one of its own after testifying on behalf of a patient against his surgeon.

Will this change operating procedures and the grievance process at AAOS? That's fodder for another story. ♦

On (and Off) the Record

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

What!? Congress Driving Physician Accreditation?…I Made a Bone: What Did *You* Do Today?… OREF Awards $200,000 in Grants… Three Best Papers From AOFAS…77% of Patients Deficient in Vitamin D…and more.

What!? Congress Driving Physician Accreditation? One year from now orthopedic residency programs will look very different. A consultant to the ACGME (Accreditation Council for Graduate Medical Education) tells *OTW*, "The ACGME is initiating a new approach to accreditation and orthopedic surgery is one of the seven specialties that will be the guinea pigs, as it were. While program directors will likely find the changes time consuming and burdensome while they learn the new system, the idea is that eventually the process of accreditation will take *less* time. The most significant shift will be away from the Program Information Form (PIF), an enormous document that includes detailed information on a program's resources. In the past, some programs have had to submit faculty CV's for 100 people!"

"We'll be going toward an outcomes approach, i.e., monitoring what skills residents have mastered as they move through the program and what skills they have under their belts when they graduate. Part of the reason for the shift is that Congress and other groups are interested in making sure that the ACGME does a better job than we have been doing in certain areas. There is a new bill in the Senate that is reiterating Congress' interest in ensuring that doctors graduating from our residency programs are well versed in all six general competency areas. Congress is saying, 'Residents graduating from ACGME-approved programs are technically proficient and smart, but have some work to do in the other four domains… areas which are related to the affective

domain (such as communication skills, systems based practice, etc.).' This is *not* just in orthopedic surgery, mind you. But we do need to take charge of this issue as much as possible. If Congress starts appointing doctors to review panels, well, these are probably physicians who are being appointed for the wrong reasons (so-and-so is a big donor, etc.)."

Three Best Papers From AOFAS David B. Thordarson, M.D. is professor of orthopaedic surgery at the University of Southern California and editor-in-chief of *Foot & Ankle International*. After attending the recent American Orthopaedic Foot and Ankle Society meeting, he shared his thoughts with *OTW*. "There was an impressive paper on synovial fluid markers for arthritis—lead author Kenneth J. Hunt, M.D. The researchers aspirated the joints at the time of surgery and showed that patients with arthritis in the ankle joint have inflammation biomarkers. Another novel paper was on the bioactivity of bone graft from various sites. The researchers, led by Christopher F. Hyer, D.P.M., M.S., saw that in bone from the iliac crest there were more osteoprogenitor cells and bioactive BMPs than from the distal tibia."

"The research award went to Charles Saltzman, M.D., whose paper was on a new paradigm for patient reported outcomes assessment. The Patient Reported Outcome Measurement Information System (PROMIS) questionnaire is now being piloted at multiple centers. Outcome instruments are usually 100 questions—quite onerous—but this attempts to capture what we need in only 7 questions. It can be completed in five minutes or less, and can be done by patients, doctors, or research assistants. One of the reasons this is critical is for our maintenance of certification; to get recertified one of the things they will examine is your patient outcomes. If the pilot study is a success, we will have a tool that will increase the amount and quality of the research in the field."

77% of Patients Deficient in Vitamin D…Raises Fracture Risk? Brett Crist, M.D., co-chief of Orthopaedic Trauma at the University of Missouri is thinking about the vitamin D issue. He tells *OTW*, "As a field we are continuing to move toward larger studies that look prospectively at the issue of vitamin D deficiency. My team and I are applying for grants and will conduct a study on the best way to manage how people with this condition are treated. Years ago we minimized the risk of the role of vitamin D in fracture healing. Our goal is to determine whether vitamin D2 or D3 is more effective at elevating vitamin D levels to normal. Our first study included 880 patients—a whopping 77% of them were deficient in vitamin D. We are now trying to figure out what it means clinically. The general assumption is that most people are getting enough vitamin D from milk and multivitamins. So it's either that we're not getting enough or a lot of people need supplements when they fracture—or maybe the testing is overcalling it. We will be testing people at different timeframes in our prospective study. It could be that the testing methods are finding things in the bloodstream, i.e., someone is having a stress response, which drives certain things up or down and the vitamin D levels are falsely low because the patient is going through a traumatic event. This is really on the cutting edge in orthopedics, and we are pleased to be presenting our work at the upcoming Orthopaedic Trauma Association meeting."

OREF Awards $200,000 The Orthopaedic Research and Education Foundation (OREF) has just awarded a $200,000 Prospective Clinical Research Grant to researchers at the Cleveland Clinic Foundation to study ways to reduce the risk of spine, neck and head injuries to adults and youth playing football. **Edward C. Benzel, M.D.**, principal investigator for the project and chair, Department of Neurological Surgery at the Cleveland Clinic, indicated that the OREF-supported study will explore how the design of football helmets and other protective equipment, as well as the rules of play, might be modified to better shield young collision sport players from catastrophic trauma. **Adam J. Bartsch, Ph.D., PE**, a biomechanical engineer and director of Cleveland Clinic's Head, Neck and Spine Research Laboratory, observed that similar logic has been applied to testing. This study was one of five projects selected for funding out of more than 75 applicants. The projects were chosen based on their potential to change clinical practice and provide better patient care. All five grants were made possible with support from Medtronic Sofamor Danek, USA.

I Made a Bone: What Did *You* Do Today? Columbia University bioengineers have succeeded in growing bone from stem cells. In the mix? A cheek bone, bone plugs, and a complex temporomandibular joint (TMJ). Behind this brilliance is Gordana Vunjak-Novakovic, Mikati Foundation Professor of Biomedical Engineering and Medical Sciences. She told OTW, "I have been doing tissue engineering for 20 years and at that time science came to the point of developing technology that could instruct cells to go in a specific direction. Over the years my laboratory began working on developing systems that result in large of pieces of bone (a one-half inch bone defect will not heal properly). When I came to Columbia engineering in 2005 we started thinking about doing something real because the human body is not made of cubes and plugs (the shapes of the previously cultivated pieces of bone). We were able to grow a TMJ [temporomandibular joint] condyle, which is the top part of the lower jaw."

"All we do is design the environment to please and direct the cells. We also provide them with a lot of oxygen; this is where control of the culture medium is important because if you have insufficient oxygen then the cells can't survive and build bone. Mechanical conditioning by flow is also important; fluid flows over the surface of forming bone and the bone cells are very responsive to mechanical signals. One thing we are not using is growth factors because they may cause uncontrolled growth. Instead, we use scaffold materials with the capability to induce bone formation."

"We recently completed a large animal study where we implanted up to two-inch large, anatomically shaped bone grafts; the initial data are encouraging. The imaging data also look promising. We are in the process of analyzing the data and are moving toward the next steps of more validation, talks with the FDA, companies, and surgeons."

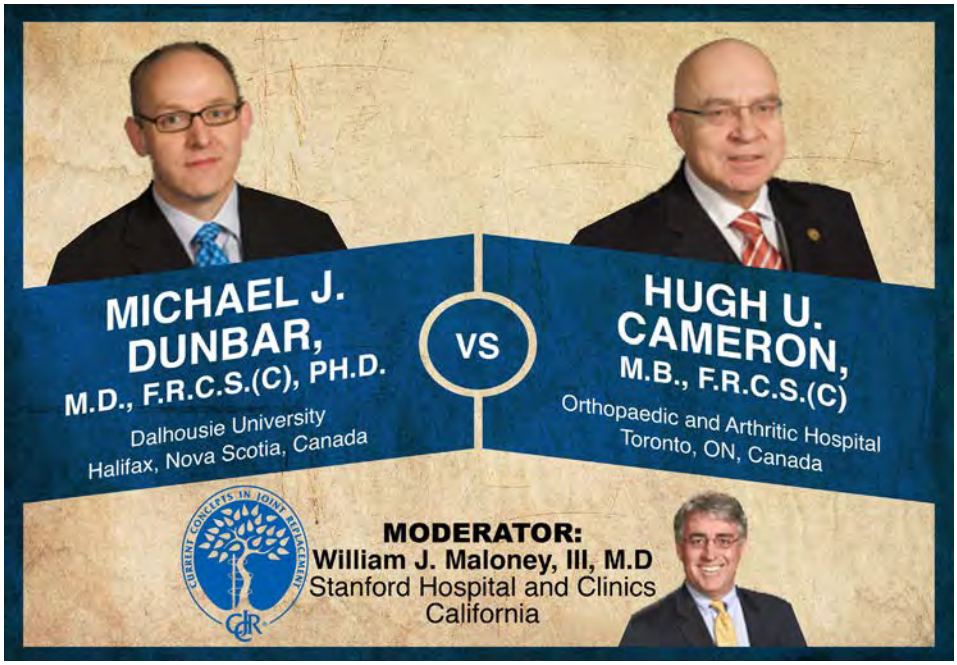
Christopher D. Harner, M.D. Named New President of AOSSM, Dr. Christopher Harner, Medical Director for the University of Pittsburgh Medicine Center Center for Sports Medicine, has been named the 41st president of the American Orthopaedic Society for Sports Medicine (AOSSM). Dr. Harner is the Blue Cross of Western Pennsylvania Professor of Orthopaedic Surgery at the University of Pittsburgh School of Medicine. He holds a secondary appointment as Professor of Physical Therapy, Health, and Physical Activity, and is dual certified in both orthopaedics and orthopaedic sports medicine. Since 1997, he has also been the Program Director for the Sports Medicine Fellowship Program and has trained more than 80 sports medicine physicians. In April of 2007, he was also appointed as the co-director of the UPMC Sports Medicine Biomechanics/Biodynamics laboratory. Dr. Harner earned his medical degree from the University of Michigan and went on to do his orthopedic residency at the University of Pittsburgh. He completed his sports medicine fellowship in Salt Lake City and then joined the faculty at the University of Pittsburgh. His accomplishments are many, including having been appointed to a ten year term on the Board of Directors of the American Board of Orthopaedic Surgery in 2000. ♦

Cementless TKA: Dunbar Debates Cameron

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

"The dream of cementless TKA does not meet the reality," says Michael Dunbar. "Cement/non-cement…they both work," counters Hugh Cameron. "But cement adds 20 minutes to a TKA. If you use cement over a lifetime of doing TKA this means that you'll be standing around for about a year waiting for the cement to harden."

This week's Orthopaedic Crossfire® debate is "Cementless Fixation: Down the Boulevard of Broken Dreams." For the proposition was Michael J. Dunbar, M.D., F.R.C.S.(C), Ph.D. from Dalhousie University in Halifax. Against the proposition was Hugh U. Cameron, M.B., F.R.C.S.(C) of the Orthopaedic and Arthritic Hospital in Toronto; moderating was William J. Maloney, III, M.D. from Stanford Hospital and Clinics in California.



Current Concepts in Joint Replacement/RRY Photo Creationon

Dr. Dunbar: "My challenge is to present to you that cementless total knees are the best way to go. So, what is the dream of cementless total knee arthroplasty (TKA)? Better survivorship, an implant that is ideal for young, high demand patients and which could perhaps preserve bone stock and ideally it would be cheaper."

"Dr. Cameron will argue that there are a lot of papers out there that tell us that uncemented TKA has exceptional outcomes. He will probably quote papers and his own experience, talking about 100% survivorship in up to 1,000 patients. But we need to understand that the papers produced by the design surgeons are not the reality in the rest of the world…and we see this in the registry data."

"There's no registry in the world that shows 100% survivorship at 10 years. The number we can hang our hat on is from the Swedish Knee Registry that shows about 93% survivorship at 10 years. This is compelling when you consider that the revision burden in the U.S. is higher than the revision burden in Sweden; so the question becomes, 'Where are all these revisions in the literature?'"

"Registry data: The Swedish Knee Arthroplasty Registry of 2011—basically all the knees are cemented. In the UK—the England and Wales registry—93% of all the knees are cemented. Outstanding survivorship for the cemented…it beats the cementless. In New Zealand…about 90% cemented…their data show a clear advantage for cemented. Australia is a bit of an outlier with 52% cemented. Regardless, cemented knees outperform cementless in these registries."

"I think we are forgetting the lessons that Leif Ryd taught us where if you have migration, prostheses fail prematurely. I think we are forgetting the data of Fukuoka from Japan who, at the time of surgery, placed a load cell on a tibial implant, then implanted RSA [Radiostereometric Analysis] beads with strain gauges and correlated the migration he saw at the time of inducable displacement to long term outcomes—and he found a strong correlation."

"And I think we're forgetting the fact that it's unequivocal that cemented fixation gives you better stability initially. Looking at an in vitro study utilizing RSA on two different constructs—a simple construct with simple cement versus the 'Inquisitional' looking device with belts, suspenders, large keel, and spikes, etc. And despite that, when you look at the RSA data, in every case whether it's maximal total point motion, subsidence, or liftoff, by far that simple cemented device outperforms a cementless device."

"We've randomized a trial at our center looking at an uncemented versus a cemented device. We found that the uncemented device using model-based RSA had significantly higher migration patterns. They didn't fail, but they moved a lot more; it was also interesting that the preoperative gait predicted that motion."

"This is germane based on Michael Meneghini's paper where he looked at 106 patients with the same device. And although we didn't find failures, he found in a group of tall, heavy, males a 7.5% failure out of those 106, suggesting that this migration may not be a good thing in our younger, high demand patients."

"And what about stress shielding and whether you get an advantage based on the fixation. It's a moot point because it's the materials; the modulus of 120 far outweighs any issues you're going to get with cemented versus uncemented in that stressed distal femur. And it's irrelevant if they fail prematurely."

"So, based on everything I've presented, the dream is broken."

Dr. Cameron: "The literature has not been favorable, but this has not been

my experience. I began working in porous metal in 1971. We did a lot of experiments to define the parameters of porous metal and eventually it was commercialized as the AML stem."

"I worked with Mike Freeman in London and I learned to use the ICLH knee, which was a non-cemented tibial component held in place with plastic pegs. After a couple of years I became unsatisfied with the trochlea because the patella kept falling off the side. So I went to Richards and they made a Tricon P for me."

"There were various forms of it—the Tricon P was the plastic tibial component, then the M, then we went to a long stem, and then to the Tricon II. So I've looked at these series, starting with the Tricon M, since 1984; we had about 400 cases. There were four revised for loosening, all in the tibia, none in the femur. We had more late sepsis than supracondylar fractures, but the big problem was wear (13.1%)."

"In 1986 we went to the Tricon Long Stem series…435 cases with 1.1% revised for aseptic loosening (all tibia, no femur). Three had end of stem pain, some late wear. It was getting better, but it was still 6.6%. When we went to the Tricon II in 1987 with 305 cases, some of them were HA [hydroxyapatite] coated. We compared an HA tibia with a grit blast tibia, which in retrospect was a mistake."

"The Tricon II results: loose femoral components were nil. Loose tibial components with the HA was one and the grit blasted was five, so HA is obviously better. Wear is no longer a major issue. We've only had seven cases revised for wear, so wear is going away as a problem."

"The Profix series, which we began in 1995, had about 600 cases and most of the femoral components were non-cemented. Some of them were cemented (68) because I didn't like the initial fixation. No tibial components were cemented in this series. This is probably the best tibial component ever developed. We never had a single case of loosening—or I never did."

"We revised 1.3% for loosening, but this was all on the femoral side, not on the tibial side. We revised none for wear; late supracondylar fracture and late sepsis are still issues, but wear has gone away."

"I now use the PFC Sigma, and I've done several hundred of them in the last seven years. I have the odd loose case, but now, when I get one, it's usually both sides and I assume that it is infected."

"Conclusion: the non-cemented Tricon femoral component had *no* loosening in 25 years. The PFC Sigma now has a rougher, thicker coating that should eliminate the loose femoral components. The non-cemented Profix tibial component—*I never had any loosening*. We now know that a femoral component should have a three degree opening wedge design. HA seems as good as porous metal and has the advantage that it can be removed by simply hitting it. The absorption of HA over time is worrying, so it's probably better to stick with porous. Cement/non-cemented…they both work. But cement adds 20 minutes to a TKA. If you use cement over a lifetime of doing TKR this means that you'll be standing around for about a year waiting for the cement to harden."

Dr. Dunbar: "Well, you started off by saying that you weren't going to use the data to support your argument and I think you were successful in doing that. The largest series you showed was 600 patients; I showed you 700,000 patients. And yes, it takes 15 minutes more, but like the credit card commercial, the price of doing a cemented implant: 15 minutes. The price of avoiding a revision: priceless."

Moderator Maloney: "Hugh?"

Dr. Cameron: "There is no margin for error if you're going to go with a cementless knee replacement. And that means that you're not going to get much teaching of cementless knee replacement in a university hospital. The only place you're ever going to get decent cementless results in knee replacement is in a high volume private system. And with better instruments more guys could do it. But if that tibia rocks even a little bit it won't work."

Dr. Dunbar: "Exactly."

Moderator Maloney: "If there's no margin for error, Mike, can we use it in the general population?"

Dr. Dunbar: "No. That's the exact point of the registries."

Moderator Maloney: "Registries group patients and devices together. Is that fair?"

Dr. Dunbar: "That's fair."

Moderator Maloney: "All cementless implants are not created equal."

Dr. Cameron: "The only time I cement is when I screw up."

Moderator Maloney: "In your work you showed early migration of a specific implant, but you had a recent publication showing that it didn't make any difference."

Dr. Dunbar: "Great point. That is an unforeseen and previously unknown RSA migration pattern, so there's some-

thing happening with these advanced porous metals…with the way they can deform under load, which may be promising. But I don't want to say—based on that—that uncemented technology is the future."

Moderator Maloney: "Hugh, your point is, 'They all work.' I agree with that. Cementless is a harder operation. Maybe the high volume surgeon can get away with it…but why? What about the cost argument? Cementless is $1,000 more."

Dr. Cameron: "If you're a high volume surgeon you don't pay less. You negotiate. I pay 50% of list price."

Moderator Maloney: "You're Canadian. In this country we have to take the burden of price. Mike, are you going to save time on the cementless side…is that a valid argument?"

Dr. Dunbar: "Invalid argument. Tell that to a trial lawyer…why you wanted to save the 15 minutes."

Moderator Maloney: "Hugh, you can't tell me it takes you 20 minutes longer to do a cemented TKA. I've seen you operate."

Dr. Cameron: "You can't just start closing the wound when you cement the femoral component. You have to wait until the cement has hardened and go around the back and take the excess off."

Moderator Maloney: "But a lot of surgeons don't do that. They assemble the implant, cement it in, do one sweep around, and start closing. Mike, what are your thoughts?"

Dr. Dunbar: "It's a mistake. You're there to make the patient better for 20 years and if you need to spend an extra 10 minutes you should do it."

Moderator Maloney: "Mike, you did that randomized study…did you look at the difference in operative times cemented/uncemented?"

Dr. Dunbar: "No, but it's probably a bit quicker to do uncemented."

Dr. Cameron: "Over a lifetime that's a year sitting around with your thumb in your ear waiting…"

Dr. Dunbar: "You'll need that year to do all the revisions."

Moderator Maloney: "Thanks for a great debate." ♦

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July 13, 2012
Retraction of the Week – Sanna's "Odd Statistics"

By Walter Eisner and Robin Young

Talk about cognitive dissonance. Professor Lawrence Sanna, formerly of the University of Michigan, published the results of a series of studies which had different averages (means) but uncannily similar standard deviations—and those deviations were highly significant.

With apologies to Shakespeare's Queen Gertrude: "The researcher doth deviate too much, methinks." Of course, the subject matter under consideration IS experimental psychology. So, in one sense, pushing the envelope goes with the territory. Still…there are boundaries…as Professor Sanna discovered.

Each week, *OTW* publishes a recent scientific journal retraction arising from shoddy, lazy or downright fraudulent research. These are examples of researchers who omitted or falsified data, used data out of context or employed such awful logic that they were forced to retract their study.

The examples are collected by *Retraction Watch* (*RW*) and we are honored to be able to present them with permission from *RW* to our readers. *Retraction Watch* was started in 2010 by Adam Marcus and Ivan Oransky, M.D.

Sanna's "Odd Statistical Patterns"

Dr. Sanna was trying to determine if riding in an elevator affected a person's ability to make moral judgments. Specifically, he asked the question—does increasing people's vertical height, such as by riding an ascending escalator, affects their moral virtues?

Journal of Experiemental Social Psychology

He then designed some tests to answer that particular, pressing question.

Like we said, pushing the envelope. Here are the studies he designed.

1. *Rising up to higher virtues: Experiencing elevated physical height uplifts prosocial actions*, cited twice, according to Thomson Scientific's Web of Knowledge
2. *Think and act globally, think and act locally: Cooperation depends on matching construal to action levels in social dilemmas*, cited three times
3. *When thoughts don't feel like they used to: Changing feelings of subjective ease in judgments of the past*, cited three times

So this other researcher, one Uri Simonsohn, was reading Sanna's studies when he noticed an "odd statistical pattern".

Uri Simonsohn, by the way, isn't just your run of the mill lab rat researcher. Dr. Simonsohn is, apparently, the proof reader's proof reader. Ed Yong, writing in the July issue of *Nature*, credits Simonson with also spotting questionable data in studies by social psychologist Dirk Smeesters.

So, here is Dr. Simonsohn whiling away a July afternoon, perusing the latest literature on embodied cognition and he comes across these studies

with such titles as "when thoughts don't feel like they used to…" and "cooperation depends on matching construal to action levels in social dilemmas" when he spotted something strange.

Yes, everything he was reading was normal—until he spotted the strange numbers. Only in academia.

So he's looking at the numbers in Sanna's studies and something just didn't add up. Recall's Dr. Simonsohn for the journal *Nature*: "The evidence was very strong compared to the other papers and it puzzled me. Every result was super-significant, and there were very large effects."

Simonsohn also commented in that same *Nature* story that although the results of tests had different means, they had uncannily similar standard deviations. "I ran simulations and the similarity was extremely unlikely for proper random samples," he recalls. Simonsohn found three other papers by Sanna and several from other researchers that used one of the methods found in the elevation paper.

That particular study method, by the way, was a cooperation game that involved fishing. We're not making this up. The other question is who would fund these studies? Can we get the name? Phone number?

In September, Simonsohn sent an eight-page report detailing his concerns to Sanna and two of his senior co-authors. He received back raw data, which revealed almost identical ranges between the maximum and minimum data points, across different conditions. "That's extremely rare," Simonsohn says.

According to *RW*, Sanna then contacted the publisher of the *Journal of Experimental Social Psychology* and asked them to retract three papers published from 2009 to 2001.

The publisher complied.

Resignation

Sanna, according to Yong, told Simonsohn that he resigned his professorship at Michigan at the end of May. The reasons for Sanna's resignation are not known.

In both Smeesters' and Sanna's work, Yong says that odd statistical patterns in the data raised concerns with Simonsohn. "But the similarity between the cases ends there. Smeesters' resignation was announced on 25 June by his institution, Erasmus University Rotterdam in the Netherlands, which undertook a review and concluded that two of his papers should be retracted. Sanna's resignation, by contrast, remains mysterious: UNC [University of North Carolina where Sanna was a professor of psychology] did not release the results of its review, and the University of Michigan will not explain why Sanna resigned.

Co-Authors Not Involved

Yong writes that Simonsohn exchanged e-mails with Sanna and his co-authors throughout October, offering to discuss his concerns. Eventually, the replies stopped. When Simonsohn contacted three graduate students (who each appeared as co-authors on at least one of the four papers), all said that they were not involved in collecting or analyzing data. Simonsohn adds that he has no evidence or suggestion of any data manipulation by the co-authors.

According to Microsoft Academic Research, Sanna is credited with 76 publications and 862 citations.

Professor Lawrence J. Sanna/Microsoft Academic Research

These retractions bring up the dangers of drawing wishful conclusions and associations from data that may or may not be accurate, properly peer-reviewed or is biased. Also concerning is when co-authors are later found not to have collected or analyzed data, particularly when they are subservient to the lead author.

On the positive side, Sanna apparently knew how to obtain funding for some pretty ethereal studies. Surely there's a place for someone with such talents.

These studies bring to mind the words of Steve Jobs in historian Walter Isaacson's biography of the same name: "You can't understand me if you haven't dropped acid." ♦

company

Spinal Restoration Completes Back Pain Study Enrollment

ClinicalTrials.gov and Spinal Restoration

The lack of definitive answers over the source of lower back pain continues to confound surgeons and patients and give payers fodder to limit payment coverage.

However, addressing and understanding discogenic pain may have taken a step forward when Austin-based Spinal Restoration, Inc. announced on July 11, the completion of enrollment in the Phase III Investigational New Drug (IND) study of the company's Biostat System.

According to the company's web site, research indicates that a specific diagnosis of back pain can only be made in 20% of cases based upon neurological evaluation and imaging studies. Discography studies show that approximately four million patients annually, have back pain attributable to disruptions of the internal structure within the intervertebral discs. This condition, referred to as discogenic pain, currently has no widely accepted therapy other than surgical spinal fusion.

The company believes that application of the system's fibrin sealant to the disc may alleviate discogenic pain by sealing the painful disc disruptions, reducing inflammation, and enhancing tissue repair.

Clinical Trial

The Phase III clinical trial is a 260-subject, randomized, blinded, placebo controlled study designed to assess the ability of the Biostat System to reduce pain and improve function in patients with chronic discogenic low back pain. The study is being conducted at 20 centers across the U.S.

The Principal Investigator Kevin Pauza, M.D., of Spine Specialists in Tyler, Texas, made quite a stir on May 6, 2012, when a national TV program (CBS Sunday Morning) focused attention on the Phase III clinical study.

The purpose of the investigation is to establish the safety and efficacy of the Biostat System when used for treatment of chronic low back (lumbar) pain due to symptomatic internal disc disruptions (IDD) by comparing safety and efficacy outcome measures between one group receiving Biostat Biologx Fibrin Sealant through the Biostat Delivery Device and another group receiving a preservative-free normal saline control delivered with the same delivery device.

Potential Far-Reaching Impact

The study is, "one of the most ambitious clinical studies ever attempted by interventional spine physicians," said Gary Sabins, president and CEO of Spinal Restoration. "If successful, the Phase III study of the Biostat System could have an extensive, far-reaching impact on the diagnosis and treatment of millions of patients who suffer from the debilitating effects of chronic discogenic low back pain."

The company believes the system is the first intradiscal biologic therapy for discogenic pain to complete enrollment of a Phase III IND study. Enrollment of the study was initiated in 2010 after the company reached Special Protocol Assessment (SPA) concurrence with the U.S. Food and Drug Administration for the study design, endpoints, and planned statistical analysis. Study success will be determined by comparing the success rates of the investigational and control groups at the six-month primary endpoint.

Under an SPA, the FDA is supposed to grant clearance if certain pre-set, agreed upon criteria are met upon the final data analysis. This should be a good measure of the FDA's new emphasis and commitment to promoting innovation.

Additional information about the Biostat System study is available at www.clinicaltrials.gov (Study identifier: NCT01011816). Spinal Restoration expects the outcomes from this study, along with data from its previous preclinical and pilot clinical studies, to provide the basis for a Biologic License Application to the FDA in 2013.

—WE (July 15, 2012)

legal

NASS Review of Spine Journal Controversy

The June 2011 issue of *The Spine Journal* accusing researchers of less than honest work because of alleged payments to researchers by Medtronic, Inc., was controversial enough to cause then outgoing North American Spine Society (NASS) President Greg Przybylski, M.D. to devote a substantial part of his farewell address to the subject. Przybylski praised the work of the journal's editor-in-chief, but distanced the society from the controversy by noting that the journal was owned, operated and controlled by Elsevier Publications.

We learned at the recent Spine Technology and Education Group meeting, hosted by Frank Phillips, M.D., Todd Albert, M.D. and Alex Vaccaro, M.D., that the spine society has undergone a review of the June edition. We understand that the internal inquiry involved a review of the process the journal undertook as, Eugene Carragee, M.D., editor-in-chief of the publication, temporarily stepped aside as editor to author the controversial accusations.

We emailed NASS Executive Director Eric Muehlbauer to confirm the existence of the review and ask when the findings of the inquiry would be made available.

Muehlbauer was unavailable for comment, but a society spokeswoman emailed us with the following response:

"...whenever we have something to share with our members, we publish it in SpineLine. If it was something for patients, the public or lawmakers, we have vehicles, such as news releases or statements, for that, as well."

We followed up and asked if this was confirmation that a review had taken place? We have not received a reply.

We hope that NASS, (or Elsevier the owner of *The Spine Journal*), make any findings as transparent and publicly available as soon as possible. An independent Yale review of the clinical evidence gathered by Medtronic for the product at the center of the controversy, InFuse, is expected by the end of summer.

Given the high level of anxiety demonstrated by NASS members at the Town Hall Meeting during their last annual meeting over "who to trust," full and timely disclosure is paramount to restoring trust with patients, payers, researchers and, most importantly, surgeons.

—*WE (July 15, 2012)*

Magnifying Glass and The Spine Journal

New User Device Fee Now Law

The President has signed the bipartisan Food and Drug Administration (FDA) bill that includes a medical device user fee of $609 million over the next five years.

Wikimedia Commons and Pete Souza/President Signing a Bill

The FDA has promised to hire more reviewers with the device money to speed up reviews of premarket application and 510(k) devices.

According to the Congressional Budget Office, the FDA would collect $4.1 billion in fees for review of brand-name prescription drugs, $1.6 billion for generic drugs, $609 million for medical devices and $128 million for less costly versions of biotechnology products.

Health and Human Services Secretary Kathleen Sebelius praised the bipartisan effort as Obama signed the legislation on July 9.

"[The Bill] is the culmination of the work of the administration and Congress, in partnership with patients, the pharmaceutical and medical device industries, the clinical community, and other stakeholders, to provide the Food and Drug Administration with the tools needed to continue to bring drugs and devices to market safely and quickly and promote innovation in the biomedical industry, and to help secure the jobs supported by drug and device development," she said in a statement.

The legislation sets performance goals for the agency, including deadlines that would reduce the time it takes for new products to reach the market. The goals were negotiated by the agency and drug and device companies.

The FDA took 73 days on average in 2010 to complete reviews of 510(k) devices, down from 80 days before companies paid fees in 2001, according to a Bloomberg study. .

Industry user fees, first enacted in 1992, give the FDA millions of dollars annually to review new products for the U.S. market but must be renewed every five years. The current version is set to expire in September.

—WE (July 15, 2012)

Retired NFL Players Experience Depression, Dementia

Tests performed on retired National Football League players found that more than 40% suffered from depression and dementia, according to Maureen Salaman, writing on June 29 for *HealthDay*. Researchers at the Center for Brain Health at the University of Texas, Dallas, examined 34 former professional football players for such problems as depression and dementia. The average age of the players was 62.

Of the 34 players, 20 tested normal while 14 were found to be suffering from depression, deficits in memory and thinking or a combination of these problems. The doctors also gave MRI scans to 26 of the players.

Study author John Hart, M.D., medical science director at the center said, "We picked up that many guys were depressed but didn't know it. The cognitive impairments...were more than what's expected for their ages. A lot had damage to their brain's white matter, so for us it's a real clue or marker to look for."

According to Salaman, the incidence of depression was the finding that most surprised Hart. "There was a lack of energy, initiative or sex drive and disrupted sleep, with weight gain or loss," he said. "They would ruminate or get anxious about stuff, but they weren't crying. They [the former players] were shocked or surprised [at the finding]; because they didn't think they had symptoms at all."

The study involved former NFL athletes who came from the North Texas region. For comparison purposes, the researchers also looked at the brains of 26 people with no signs of mental deficits, selected from the general population and matched for age, education and IQ.

Salaman noted that in June more than 2,100 NFL players filed suit against the league claiming that the organization hid information linking football-related head injuries to permanent brain damage.

—BY (July 9, 2012)

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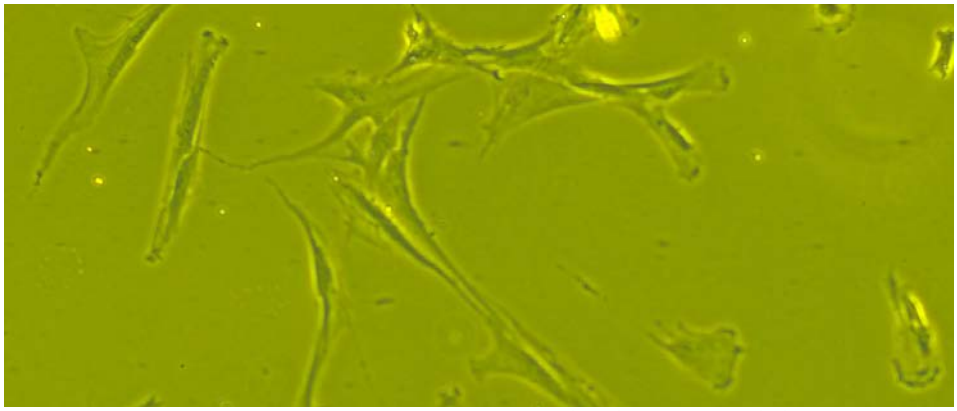
biologics

Sorting Hype From Fact in Stem Cells



Wikimedia Commons and Chinmaya Mahapatra

Every so often an article comes across an editor's desk that makes so much sense that she is tempted to reprint all of it. Such an article is one by Harold DeMonaco, Director, Innovation Support Center, Massachusetts General Hospital, Boston and medical editor of ***Healthnewsreview.org***. DeMonaco wrote about the hype presently surrounding stem cells. Below, with his permission, is some of what he had to say, edited for space and to highlight his principal points.

"Few other treatment modalities exemplify what is both good and bad with American medicine as stem cell therapies. For years, we have been inundated with promises that cures for some awful diseases were just around the corner. And while there is progress, that progress has been painfully slow.

"The most promising cells, mesenchymal stem cells, are harvested from bone marrow and fat. These cells, like any stem cell, can be programmed to do many functions. Enter the entrepreneurs. Companies like Celltex and Regenerative Sciences and others have quickly moved into the stem cell business supplying cells to physicians and researchers alike. Texas, in large measure due to the efforts of its governor, has become the epicenter of mesenchymal stem cell companies.

"Normally, this would be viewed by everyone as a good thing. Private investment in a technology has been shown to push innovation. Making new technologies available has been an economic engine for many parts of the country. But there is an important legal issue associated with stem cell processing. When do stems cells become drugs? If deemed to be drugs, their use and processing are subject to FDA oversight well beyond that of simple blood products. The distinction between drug and blood product is murky at best at the moment.

"All prescription drugs are approved by the FDA after exhaustive clinical trials. The gold standard is the randomized, double blind, controlled trial where the drug, in this case stem cells, is compared to an inactive placebo. If mesenchymal stem cells are indeed drugs, they should be approved only after extensive clinical study. At least that is the FDA view.

"The regulatory issues are important because they frame the clinical issues. If the cells are sufficiently manipulated to fall under the FDA's drug regulations, they are subject to a long and arduous road to approval. Their sale would be limited to only those indications for which there was sufficient data. Their manufacture would be subject to more intense FDA scrutiny.

"A counter argument is that companies like Celltex and Regenerative Sciences are not altering a patient's own cells. What they do is what blood banks do with whole blood, separating out cells for specific use. Since platelets, whole blood, packed red cells and the like are not drugs, they are not subject to FDA oversight other than those activities specific to cell processing. Shouldn't mesenchymal stem cells fall into the same paradigm? The FDA and Regenerative Sciences have been locked in a court battle since 2008 over whether or not stem cells, when used for specific therapies, are in fact drugs."

"In either case, drug or not, the use of the stem cells processed by commercial sources by a physician, for any purpose, is the practice of medicine. The FDA does not regulate the practice of medicine. The good news is that physicians can innovate to their hearts content. Physicians are free to use a patient's own stem cells for any purpose. They do not need to have any agency approve the use.

"Mesenchymal stem cells may prove to be of great benefit to people suffering from joint diseases. Unfortunately, there are no compelling data to support their use at the moment. There are ongoing clinical trials and answers may be forthcoming."

—BY (July 14, 2012)

large joints

Blood Test to Track RA Progression

A team of researchers from the University of Alabama at Birmingham (UAB) is simplifying things in the world of rheumatoid arthritis (RA). They have found that a simple blood test may help physicians track the progression of RA disease activity; their work has been published online on in *Arthritis Care and Research* according to the June 26 news release. This work was an international effort, with UAB at the helm. Jeffrey R. Curtis, M.D., MS, MPH, associate professor in the Division of Clinical Immunology and Rheumatology at UAB was lead author of the study.

The blood test—known as Vectra DA—emphasizes the underlying biological pathways, essentially measuring inflammation. Because it doesn't put the emphasis on external signs and symptoms, the researchers indicate that it should provide information that is different from clinical assessment. They also indicate that the test may help assess treatment response in patients. The test could show in just a few weeks whether a particular therapy is effective, rather than within three to four months as in current practice.

Also participating in the study—which involved 512 patients from three RA registries—were researchers from Leiden University Medical Center, Leiden, Netherlands; Crescendo Bioscience, Inc., South San Francisco, California; Oklahoma Medical Research Foundation; Brigham and Women's Hospital, Boston; Rheumatology Associates of Long Island, New York; University of Texas Southwestern Medical Center, Dallas; and Mount Sinai Hospital, University of Toronto.

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Dr. Curtis told *OTW*, "The Vectra DA test is quite simple and far easier and widely accessible than the other ways we sometimes obtain additional information that is needed (e.g. joint MRI, musculoskeletal ultrasound). Also, there is a chance that the test may serve as predictor of potential disease flare-ups, and also as a predictor of future joint damage. As for cost, if you could, for example, make a treatment decision at 2-4 weeks after starting a new drug rather than the 3-6 months that we normally wait to assess response and make a treatment decision, that would save a lot of money. It would also speed up drug development for new treatments and keep patients on placebo less time than the 12-16 weeks that is typical for phase 2 studies. These applications are tentative but exciting prospects."

Vectra DA was developed by Crescendo Bioscience, Inc. of South San Francisco.

—EH (July 12, 2012)

DJO Global Launches World's Lightest Knee Brace

Bringing high tech from the basketball court to the water cooler…DJO Global, Inc. has announced the launch of OA Nano, calling it the world's lightest off-loading knee brace—14.2 ounces—for patients with mild-to-moderate osteoarthritis. Sold under the DonJoy brand by DJO Global, the OA Nano is clinically proven to reduce pain and increase the stability of the knee. The brace also offers a range of design benefits that ensure patients will use as directed, thus improving their quality of lives.

"Increasingly, physicians and surgeons are advocating for a conservative care treatment regimen that preserves joints and helps patients avoid or stave off more expensive, addictive or riskier treatments. Noninvasive, non-addictive treatment options, such as knee bracing, can empower patients to proactively take control of their osteoarthritis without the cost, recovery time or potential for adverse events associated with surgical procedures or narcotic pain management," said Mike Mogul, president and CEO of DJO Global. "OA Nano is based on the advanced knee brace technology that professional athletes have used for years and helps patients reduce pain, increase stability and maintain their desired activity levels."

OA Nano, which decreases pressure on the knee by offloading stress, is manufactured using nanoMAG TTMP, a new kind of metal that is as light as magnesium with the strength of aircraft-grade aluminum.

"In addition to the weight and aesthetics, my patients cite the comfort of the brace as one of the most important factors in whether or not they will comply with my treatment recommendations and use osteoarthritis braces consistently," said Dr. Joseph Hellmann of OMNI Orthopedics in Canton, Ohio, in the July 9, 2012 news release. "In the growing movement of conservative care, compliance is one of the most important factors that can enable patients to successfully preserve their knee joints and maintain mobility. Given that The National Arthritis Foundation granted the OA Nano its Ease of Use commendation, I can be assured that my patients will actually be able to put on the brace."

Mogul told *OTW*, "DJO Global found that people wanted a brace that effectively decreased pain and increased stability, while being comfortable and lightweight. OA Nano is designed to address these factors and to help the growing segment of Americans with osteoarthritis return to their active lives. Patient compliance has been an issue for other OA knee braces, given that they have historically been bulky, heavy and uncomfortable. The OA Nano is low profile and the world's lightest OA knee brace, meaning that patients can wear it all day."

Regarding the development process, Mogul told *OTW*, "The OA Nano was designed by the same team of engineers that develops braces for professional basketball and football players and 21 of the top 25 AP college football teams."

—EH (July 11, 2012)

DJO Global, Inc.

Stryker Hip Stem Recall Raises Warnings

While a blue ribbon FDA panel was wrestling with problems associated with metal-on-metal hips, Stryker Corporation was voluntarily recalling its Rejuvenate and ABG II modular-neck stems used during hip replacement surgery. The recall was announced July 6.

Is this the next phase of hip failures?

Only July 9, *OTW*'s Elizabeth Hofheinz reported that Ryan Nunley, M.D., an assistant professor of orthopedics at Washington University in St. Louis, said, "...the next line of metal related issues that we're beginning to see is with modular metal necks. Traditional total hips were all one piece (monoblock), but more recently some companies have jumped on the modular neck bandwagon. We are seeing corrosion at the location where the modular metal neck snaps into the body of the femoral stem, which is leading to a significant amount of metal ion release."

"Companies are saying that these necks have been tested and are stable—and yes, they are likely not overly susceptible to fracture anymore. But there is clearly micro motion rubbing at the junction generating the metal debris and causing tissue necrosis and pseudotumor formation. The use of larger diameter heads on these modular necks with the same size trunion might also be causing more micro motion. While a bigger head may be a good thing in some respects for reducing dislocations, the downside is that the larger you make the head the more you increase the torque on the trunion taper, which causes the metal to shear and flake. This could be our next wave of failures with use of modular femoral necks in total hip replacement surgery."

Fretting and Corrosion Risks

Stuart Simpson, Stryker's vice president and general manager, hip reconstruction, said on July 6, "While modular-neck stems provide surgeons with an option to correct certain aspects of a patient's anatomy and hip biomechanics, given the potential risks associated with fretting and corrosion at the modular neck junction, Stryker Orthopaedics decided to take this voluntary action."

Stryker has notified healthcare professionals and regulatory bodies of this voluntary recall. Patients who received a Rejuvenate Modular or ABG II modular-neck stem are encouraged to contact their surgeon.

"Personalized" Hips

When Stryker released the "personalized" Rejuvenate Modular Primary Hip system back in February 2010, the company told *OTW* that the system was developed to optimize anatomic restoration by providing options that offer enhanced stability, proven modularity and intra-operative flexibility. With a wide range of femoral stem and neck combinations and an extensive range of length, version and offset, the company said surgeons would be better able to personalize the implant to a patient's unique anatomy.

The system is comprised of separate femoral stem and neck components made of TMZF alley, a proprietary Stryker material with a plasma sprayed coating of commercially pure titanium and PureFix HA. The necks are made of CoCr alleoy.

OTW/Stryker Rejuvenate Stem

Industry Impact

Due to minimal sales to date, analysts do not expect this to have a material impact on Stryker's results. However, the potential problem may not be limited to Stryker.

Mizuho Securities USA Inc. analyst Mike Matson, says a white paper on Stryker's website seems to indicate that the problems can occur with most modular hip stem designs.

Wrote Matson in an investor note; "It's unknown if these issues are specific to Stryker's stem designs or an issue for the entire product class. If it's the latter, we could see additional product recalls and/or product liability litigation at other companies as well.

While Stryker's sales of modular hip stems is very small, other companies have more exposure. We estimate that Zimmer Holdings Inc.'s M/L Taper with Kinectiv modular hip stem has annual sales of less than 1% of Zimmer's total annual sales and we believe that a significant portion of Wright Medical's hip stems are modular.

A dedicated patient call center can be reached at 1-888-317-0200 and additional information can be found at www.AboutStryker.com/Modular-NeckStems.

—WE (July 15, 2012)

Surgeon Replaces Knee on 3'10" Patient

A Mumbai surgeon, Dr. Nilen Shah, operating at the SK Mehta hospital, successfully performed knee replacement surgery on a patient who was only 3' 10" tall. Ramesh Shah, who suffers from achondroplastic dwarfism, a rare congenital genetic disorder that does not allow proper bone formation, had been suffering for three years from arthritis of the knee. Several doctors had turned him down because of their perceived inability to find implants to match his size. "Due to my rare condition, I was told that knee replacement will not work for me," he said.

Then he found Nilen Shah, M.D., a surgeon with the same name, who, after a long search, found a knee implant that he could make fit. "This is the first such case I have seen in 20 years of my career as an orthopaedic surgeon. Dwarfism itself is rare. The life span of these people varies, and only a few reach adulthood. This guy is one of them," said Shah.

According to the surgeon Shah, there are several 'dwarfs' residing in the country who do not opt for knee replacement surgeries due to a lack of awareness that the surgery could be available to them. He hopes that successful surgeries like this one will encourage them to try. Achondroplastic dwarfism, in which the cartilage does not mature and become bone, especially in the long bones of the hands and legs, affects 1.3 people out of every 1,00,000 [sic] births per the July 6 press release.

Wikimedia Commons and Sciencefirst

—BY (July 8, 2012)

Patient's Charged $800; Ministry Says "Cease and Desist"

A kerfuffle has developed at Brantford General Hospital in Brantford, Ontario, over the hospital's practice of charging $800 for patients who request a custom-fitting procedure for a new knee over the basic package. The Ontario Ministry of Health has issued a cease and desist order to the hospital, according to a report July 4 in the *Brantford Expositor*.

"We have been giving patients who required knee-replacement surgery an option," James Hornell, president and CEO of the Brant Community Healthcare System, said. "They could have the standard knee-replacement surgery or the custom-fitting surgery. If they wanted the custom-fitting procedure, we asked them to pay $800 and most of the patients were happy to do it."

Hornell said that the specialized custom-fitting procedure is more expensive and is not entirely covered by the province's health insurance plan. The hospital does not have money to absorb the extra costs and if the hospital cannot charge patients it can no longer provide the service. The standard procedure for knee replacement is covered entirely by the Ontario Health Service.

Brantford General Hospital has been performing the custom procedure since 2010. At the time it was the only hospital in Canada using the technique, considered to be revolutionary because it removed any guesswork in the operation and gave patients a custom-fitted knee.

Prior to surgery doctors took an MRI to provide accurate measurements of a patient's knee. The MRI was then sent to OtisMed in California where technicians use specialized computer software to make a three-dimensional model of the knee. They then shipped customized cutting blocks to the hospital that the surgeon used to provide the patient with a custom-fitted knee. Brantford General Hospital has suspended its new knee-replacement surgical procedure after receiving the cease and desist order from the Ontario Ministry of Health.

—BY (July 8, 2012)

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extremities

Global Sports Medicine Market Booming

If the publication *Official Wire*, of London, England, is correct in its estimates, the global sports medicine implant market, valued at $1 billion in 2011, will grow to $1.6 billion by 2018. That is a compound annual growth rate (CAGR) of 6.7%.

The growth in the market is being predominantly driven by an increase in injury rates experienced by an aging population along with the more technologically advanced implant options.

The U.S. has the largest share of the sports medicine implants market, accounting for 49% of the global market last year. In 2011 the U.S. market value reached $517.8 million. By 2018 this value is forecast to reach $820 million, growing at a CAGR of 6.8%.

Among the advances in implant technology that are set to play a role in boosting the sports medicine implants market are the advantages of newer implants which enable easier post-operative imaging, revision surgery, and the enabling of bone formation within the screw.

Biodegradable implants are increasingly being used in the field of operative sports medicine. The report notes that, today, surgeons have available to them a tremendous variety of implants and devices such as interference screws, staples, sutures, tacks, suture anchors, and devices for meniscus repair.

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Analysts also note that there is a growing preference for implants constructed from biocomposite materials, due to their greater perceived efficacy and safety when compared to traditional metal varieties.

—BY (July 8, 2012)

spine

Ascendx Spine Expands Across Europe

Ascendx Spine has announced the expansion of its distribution networks into Germany, Austria, Switzerland, Italy, Portugal, Spain and France. The company is slated to begin commercial shipments to these markets imminently.

"We are expecting rapid market validation of our Ascendx VCF Repair System and the Acu-Cut Vertebral Augmentation System, both of which are designed for the treatment of spinal fractures," said Julian M. Mackenzie, CEO, in the July 9, 2012 news release. "Our distribution partners in Europe will soon be able to offer spine surgeons and interventional radiologists a uniquely improved proprietary balloon kyphoplasty method designed to secure effective clinical outcomes for their patients with vertebral compression fractures," added Mackenzie.

When *OTW* asked, 'Why these countries and why now?' Mackenzie said, "These countries were selected based on: their high population of osteoporosis, patient demand for the procedure and favorable reimbursement. Additionally, since receiving CE Marking for both the Acu-Cut and Fracture Reduction Systems, the selected distributors in those countries were very interested in representing Ascendx as they felt they could close orders quickly based on the physician demand to inject bone cement with our balloon still inflated in the vertebral body and the fracture reduced."

Wikimedia Commons, NASA

Regarding the establishment of these connections, Mackenzie told *OTW*, "We are fortunate to have an experienced sales manager in Europe that has gained many professional contacts over the past 15+ years. Also, due to our published regulatory clearances and favorable clinical data, many distributors and physicians sought us out in Amsterdam at the Spine Week meeting in May with interest in representing Ascendx throughout Europe and Asia."

—EH (July 10, 2012)

people

AAOS Executive Honored by Basketball Association

Frederick Azar, M.D., second vice president of the American Academy of Orthopaedic Surgeons (AAOS) and team doctor for the Memphis Grizzlies, has been voted Physician of the Year by the National Basketball Athletic Trainers Association. The association will present the award in Memphis when the play the Memphis Grizzlies next season.

Azar, who is chief of staff at Campbell Clinic in Germantown, Tennessee, has been the head team physician for the Grizzlies since the team came to Memphis in 2001. He is also point of contact for other NBA teams soliciting second opinions on injuries and orthopedic needs. He headed up the Hoops for St. Jude efforts for team physicians around the league.

Azar earned his medical degree at Tulane University in New Orleans and completed his residency in orthopedic surgery at the University of Tennessee-Campbell Clinic. His additional training includes a sports medicine fellowship in Birmingham, Alabama. He is a member of the American Orthopaedic Society for Sports Medicine ad the Arthroscopy Association of North America.

Azar is also professor and director of the sports medicine fellowship program at the University of Tennessee-Campbell Clinic Department of Orthopedic Surgery and serves as team physician for several other area sports teams.

—BY (July 9, 2012)

Dr. Frederick Azar, Campbell Clinic

And he reads Orthopedics This Week.

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