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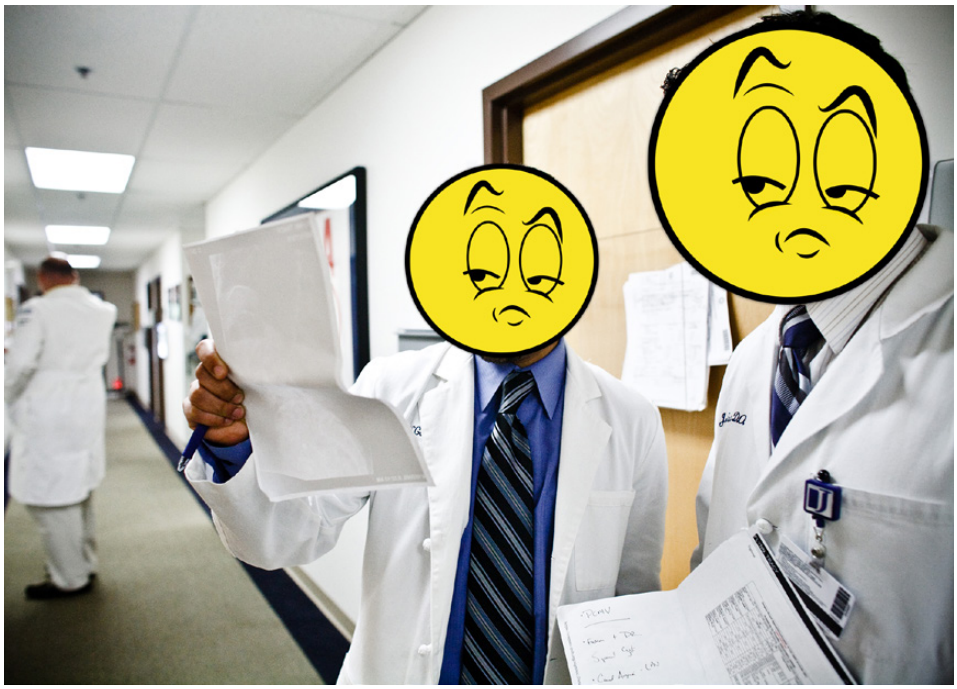
Orthopedics This Week

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: The U.S. economy keeps strengthening. The Fed's easy money policy gets most of the credit. But the Fed is changing policy. First rate hikes expected mid-2015. EU economy is sluggish. So are China and Japan. While the U.S. economy can handle tighter Fed policies, can the rest of the world? One very good sign, corporate spending, a lagging indicator, is accelerating—fast. Still bullish markets.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Integra LifeSciences	12.57%	3.04%	Of all the integrated ortho stocks, IART has the highest rate of expected earnings growth.
2	1	Stryker	11.52	(2.21)	Closes on the purchase of Small Bone Innovations. Now Wall Street broker Needham raises possibility of SYK buying SNN. Market doesn't seem to agree, yet.
3	4	Symmetry Medical	6.55	2.79	What to do, what to do—with all that cash. While $450 million sale of OEM business is still pending, the future possibilities still intrigue investors.
4	3	NuVasive	8.01	5.59	NUVA, while still among the 10 least expensive in orthopedics, is rising based on excellent operating results. Old school.
5	5	Medtronic	28.84	0.51	Zacks Investment Research arguing that MDT will beat market estimates for their first quarter of FY 2015.
6	8	Exactech	10.26	(3.90)	Despite great quarterly results (earnings grew at twice the rate of sales) buyers still pretty fickle when it comes to EXAC.
7	9	Johnson & Johnson	26.58	(1.03)	A year ago, JNJ was $90, today it is over $101. With a 2.80% dividend yield, this has been a great stock. But expensive now.
8	7	Orthofix	7.46	(2.09)	Someday OFIX will file its financial statement on time. Someday.
9	6	Zimmer	29.12	(5.17)	Most buyers focused on Zimmer's purchase of Biomet and what it means in terms of scale economics.
10	10	MicroPort Scientific	36.16	(6.46)	China incentivizing hospitals to buy homegrown medical devices. MicroPort well positioned to take advantage.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Alphatec Holdings	ATEC	$1.64	$161	21.48%
2	LDR Holding Corp.	LDRH	$27.07	$703	18.05%
3	CryoLife	CRY	$10.43	$291	15.38%
4	RTI Biologics Inc	RTIX	$4.73	$269	11.03%
5	NuVasive	NUVA	$35.52	$1,669	5.59%
6	MiMedx Group	MDXG	$7.08	$749	4.58%
7	Integra LifeSciences	IART	$48.49	$1,581	3.04%
8	Symmetry Medical	SMA	$9.21	$346	2.79%
9	Medtronic	MDT	$63.25	$63,009	0.51%
10	Johnson & Johnson	JNJ	$101.17	$285,328	-1.03%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	$4.85	$32	-29.70%
2	Baxano Surgical Inc	BAXS	$0.38	$19	-26.92%
3	Globus Medical	GMED	$18.43	$1,739	-19.59%
4	Aurora Spine	ASG	$1.88	$29	-12.56%
5	ConMed	CNMD	$37.47	$1,025	-11.90%
6	Wright Medical	WMGI	$29.04	$1,465	-8.77%
7	K2M Group Holdings	KTWO	$14.93	$554	-7.04%
8	MicroPort Scientific	853	$0.60	$849	-6.46%
9	Zimmer Holdings	ZMH	$97.48	$16,466	-5.17%
10	Tornier N.V.	TRNX	$21.39	$1,046	-4.47%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$63.25	$63,009	16.69
2	Zimmer Holdings	ZMH	$97.48	$16,466	17.34
3	Johnson & Johnson	JNJ	$101.17	$285,328	17.35
4	Globus Medical	GMED	$18.43	$1,739	18.93
5	Stryker	SYK	$80.47	$30,465	19.09

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$33.31	$614	277.88
2	NuVasive	NUVA	$35.52	$1,669	67.91
3	MicroPort Scientific	853	$0.60	$849	33.37
4	CryoLife	CRY	$10.43	$291	31.33
5	Symmetry Medical	SMA	$9.21	$346	31.22

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	$10.43	$291	1.04
2	Exactech	EXAC	$23.41	$322	1.07
3	Globus Medical	GMED	$18.43	$1,739	1.24
4	ConMed	CNMD	$37.47	$1,025	1.63
5	Zimmer Holdings	ZMH	$97.48	$16,466	2.10

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$33.31	$614	15.10
2	NuVasive	NUVA	$35.52	$1,669	5.55
3	Smith & Nephew	SNN	$85.30	$15,239	2.89
4	Symmetry Medical	SMA	$9.21	$346	2.60
5	Medtronic	MDT	$63.25	$63,009	2.51

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.64	$161	0.78
2	Symmetry Medical	SMA	$9.21	$346	0.86
3	Baxano Surgical Inc	BAXS	$0.38	$19	0.91
4	Bacterin Intl Holdings	BONE	$4.85	$32	0.97
5	RTI Biologics Inc	RTIX	$4.73	$269	1.11

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.74	$118	20.68
2	MiMedx Group	MDXG	$7.08	$749	9.45
3	LDR Holding Corp.	LDRH	$27.07	$703	6.30
4	MicroPort Scientific	853	$0.60	$849	5.56
5	Wright Medical	WMGI	$29.04	$1,465	5.45

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

Pay-for-Performance Jury Still Out

BY WALTER EISNER

Pay-for-Performance (PFP) is supposed to slow the rise of healthcare costs and improve patient care as defined by quality measures. But what's the evidence so far? The cost savings are there, but evidence of improved patient outcomes is sketchy.

Insurers and other payers have lauded the effort and cited evidence of cost savings without compromising patient care. But physicians remain skeptical and are not convinced it's doing their patients any good and may in fact, make their jobs more difficult.

Andrew Huth/RRY Publicatins LLC

Photo creation by RRY Publicatins LLC

At the heart of the PFP strategy is a different way to pay hospitals and physicians for the services performed for patients. Logistically, the strategy is implemented with programs such as bundled payments. The expectation is that paying one bundled payment for results instead of volume (fee-for-service) will slow the pace of healthcare costs and improve patient care.

It's been over 20 years since the country's first PFP programs were started (1992). Those early PFPs were run by local Blues (Blue Cross/Blue Shield) in Illinois and Pennsylvania. For many reasons including passage of the Affordable Care Act (ACA), researchers have started to look back at those early PFPs to see if they lived up to their promise.

Saving Money

Researchers at Medicare and at the private insurers have documented savings from PFPs in the hundreds of millions. And the move to bundled payments is growing. The Center for Medicare and Medicaid Services (CMS) recently announced that it will add roughly 4,100 providers to the already 2.400 existing providers utilizing bundled payment contracts.

In January 2014, CMS said the program has shown savings in excess of $448 million. CMS also reported that providers with bundled payment programs had significantly lower spending growth relative to Medicare fee-for-service while also exceeding quality reporting requirements.

BCBS reported in early August that it will direct more than $65 billion in medical spending to "value-based care programs." That amount of spending represents fully one in five Blues reimbursement dollars tied to programs that link quality, outcomes and cost measures.

Blue companies around the country are reporting fewer emergency room visits, hospital admissions and readmissions and other medical interventions. At the same time, the Blues claim there has been measurable improvements in pre-

vention, including better diabetes control and higher rates of screenings and immunizations.

Initial reports from a Blues survey of PFP programs show that they reduced costs by $500 million in 2012. BCBS will survey Blue companies and report findings for 2013 in the fall of 2014.

Patient Outcomes Inconclusive

Unfortunately, patient outcome data is not as rosy as the cost savings data.

Aaron Carroll, M.D., of Indiana University School of Medicine writes on July 28, 2014 in *The New Health Care,* that we're seeing disappointingly mixed results of improved patient care. Sometimes, he says, it's because providers don't change the way they practice medicine; sometimes it's because even when they do, outcomes don't really improve.

"Changing physician behavior is hard. Sure, it's possible to find a study in the medical literature that shows that pay-for-performance worked in some small way here or there. For instance, a study published last fall found that paying doctors $200 more per patient for hitting certain performance criteria resulted in improvements in care. It found that the rate of recommendations for aspirin or for prescriptions for medications to prevent clotting for people who needed it increased 6% in clinics without pay for performance but 12% in clinics with it."

Aaron Carroll, M.D., M.S./ Indiana University School of Medicine

Vanishing Improvements

Carroll cited one study in particular which appeared in *Health Affairs* and looked at the effects of a government partnership with Premier Inc., a national hospital system. That study found that while the improvements seen in 260 hospitals in a pay-for-performance project outpaced those of 780 not in the project, five years later all those differences were gone.

He also points to a similar study in *The New England Journal of Medicine* that looked at 30-day mortality in the hospitals in the Premier Hospital Quality Incentive Demonstration (PHQID) pay-for-performance program and compared those results with 3,363 hospitals that weren't part of a pay-per-performance intervention. "We're talking about a study of millions of patients taking place over a six-year period in 12 states. Researchers found that 30-day mortality, or the rate at which people died within a month after receiving certain procedures or care, was similar at the start of the study between the two groups, and that the decline in mortality over the next six years was also similar."

That study by Jha et al. closely approximates CMS's value-based purchasing program (VBP), which began providing financial incentives to more than 3,500 hospitals for performance improvement in October 2012. Thus, results from the PHQID may be predictive of the VBP success and instructive about defining performance and achievement goals in the future.

Modest Expectations

After reviewing the study results, the authors counseled that payers (and providers) expectations for improved outcomes from programs like the Premier HQID should "remain modest."

"Ryan found no evidence that PHQID affected 30-day mortality rates through mid-2006, and this finding was confirmed by Glickman and colleagues for Premier hospitals participating in a disease registry for acute myocardial infarction. In 2006, approximately 80% of HMO-purchaser contracts for over 100,000 hospitals nationwide included bonus or penalty for performance beginning in 2004. Thus it is unclear what percentage of PHQID and non-premier reporting hospitals had process or care improvement programs in place before the start of the present study in 2003, and readers are left to wonder whether improvement had already been at least partially realized within each group."

Effective Motivations

"Given the conclusions of these recent publications, the present study encourages us to ask, 'Are economic incentives the best motivation available to hospital systems for improving performance?' Biller-Andorno and Lee have suggested that perhaps outcome transparency and non-financial incentive schemes such as performance ranking are sufficient incentives to improve outcomes."

Drs. Thomas H. Lee and Toby Cosgrove laid out a cocktail of incentives to change physician behavior in a recent *Harvard Business Review* article, including appealing to their better angels, financial self- interest, respect of colleagues and fear of becoming outliers. If those don't work, they suggested firing the physician.

Carroll says that some even fear that pay-for-performance could backfire. "Studies in other fields show that offering extrinsic rewards (like financial incentives) can undermine intrinsic motivations (like a desire to help people). Many physicians choose to do what they do because of the latter. It would be a tragedy if pay-for-performance wound up doing more harm than good."

The English Experience

Another recent study titled, "Long-Term Effect of Hospital Pay for Performance on Mortality in England," published in the August 7, 2014 issue of *The New England Journal of Medicine*, concluded that, "Short-term relative reductions in mortality for conditions linked to financial incentives in hospitals participating in a pay-for-performance program in England were not maintained."

Akin Demehin, MPH, senior associate director for policy at the American Hospital Association (AHA) in Washington, told *MedPage Today* (August 6, 2014) that the English study was an interesting one, but "in terms of implications for pay-for-performance here in the U.S., it's a little tough to draw direct conclusions because the structure of the programs is different and the financing structure in the U.K. is different."

The Challenge of Measuring Outcomes

In addition, "when you're looking at outcome measures, they are affected by care provided by hospitals and other providers, but outcomes can also be influenced by a patient's clinical factors and the kind of communities patients live in, so that makes one-to-one mapping a little more difficult," he said.

Nancy Foster, the AHA's vice president for quality and patient safety policy, told MedPage, "These measures are not perfectly aligned with the outcomes they're using, and therefore you see somewhat of a muffled impact of the pay-for-performance program."

Physician Recommendation and Perspective

Jon Tilburt, M.D. of the Mayo Clinic's Biomedical Ethics Program and Center for the Science of Health Care Delivery said in a 2013 survey of physician attitudes about controlling health care costs, "Physicians feel stuck in a dif-

ficult position. Despite their sense of responsibility to address health care costs, physicians consistently express a commitment to the best interests of patients even when it is expensive. Given this finding, we recommend that cost-containment strategies aimed at physician behavior should focus on innovations that not only promote savings but also preserve physicians' commitment to individual patients."

Tilburt's survey also assessed physicians' attitudes about strategies to constrain health care spending.

Major findings included:

- Most expressed enthusiasm for cost-containment initiatives aimed at improving the quality and efficiency of care, and favored improving conditions for making decisions based upon cumulative medical evidence. For example, 69% were very enthusiastic about promoting chronic disease care coordination, and 63% were very enthusiastic about limiting corporate influence on physician behavior.

- Physicians' opinions were mixed on making payment changes to control costs. For example, 65% were not enthusiastic about paying a network of practices a fixed, bundled payment for managing all care for a defined population, and 70% were not enthusiastic about eliminating fee-for-service payment models.

A Physician Sentiment Index report put out by athenahealth in 2013 found that most independent physicians were skeptical about models that offer incentives to doctors and hospitals to reduce the cost of care. Surveyed physicians said that shifting reimbursement models away from fee-for-service arrangements would improve quality of care—but most of those same respondents said that these same models would likely hurt profits and make it harder to get paid.

Jury Still Out

So the jury that matters most, the physicians making individual healthcare decisions for individual patients, not populations, is still out on the value of pay-for-performance. If the Mayo survey accurately represents the opinions of most physicians, then saving dollars at the expense of patient care or even at the expense of the physician, isn't going to cut it.

With 4,100 providers being added to CMS' bundled payment experiment next year, we should start seeing some evidence of patient outcomes soon. But physicians aren't holding their collective breaths. ♦

First Time Ever! Clear Quantification of Gender Running Differences

BY SOPHIE BODEK

"To our knowledge there exists no study comparing knee and hip joint adduction angles and impulses between males and females with a high training volume." — principal study authors, University of Freiburg in Germany.

Indeed, while sports medicine doctors can anecdotally attest to the different injury patterns and tendencies based on gender, actual study data has been essentially non-existent until this group of intrepid researchers designed the study protocol, raised the funds and went to work.

"The purpose of the present study was to determine whether hip and knee joint kinematics and kinetics in runners with a high weekly mileage are gender-specific over a range of running speeds. Specifically, we hypothesized that women would demonstrate increased knee and hip adduction loading."

Wikimedia Commons and Adamsandle

Gender Injury Patterns Make a Huge Difference

Although girls and women are leveling the playing field by participating in a wider variety of sports at higher levels, the field remains uneven especially in terms of injuries. When it comes to running, a Vancouver area sports injury clinic found that women represented 54% of injuries while men represented 46% of injuries after evaluating about 2,000 patients in 2002.

According to Runners Connect, a website that shares information and helpful tips about running, women are 50% more likely to suffer from patellofemoral pain syndrome or runner's knee, iliobital band syndrome, stress fractures, medial tibial stress syndrome or shin splints, Achilles tendonitis, and plantar fasciitis. Although it appears that female runners are more injury-prone than male runners, few studies have been conducted to examine the gender-specific running patterns that may be responsible.

In 1978, Cutting et al. found that the gender of a walker can be determined through a kinematic assessment. Titled "A Biomechanical Invariant for Gait Perception," the study focused on the perception and psychophysics of the human gait. Since then, several studies have been published concerning gender-specific gait patterns and have found a specific skeletal motion associated with each gender.

Despite the well-documented locomotion patterns of men and women while walking, the differences between sexes while running remains relatively obscure. In 2003, Ferber et al. found that women had significantly higher hip adduction angles and knee abduction angles. However, all the participants were evaluated at one predefined running speed so further differences were not evaluated as physical demand increased. In 2008, Chumanov et al. evaluated the hip joint in men and women as they walked and ran at different speeds and inclinations. However, the study only looked at kinematics and kinetics of that specific joint, leaving other joints unevaluated.

The Groundbreaking University of Freiburg Study

Dominic Gehring, Ph.D.; Guillaume Mornieux, Ph.D.; Jana Fleischmann; and Albert Gollhofer, Ph.D. authored the study titled "Knee and Hip Joint Biomechanics are Gender-specific in

Runners with High Running Mileage." Published in 2014 in the *International Journal of Sports Medicine*, the study evaluated 32 individuals with high training volume. Each participant ran over 50 kilometers per week and were known rearfoot strikers, meaning their heels hit the ground first when running. The 16 men and 16 women were healthy and suffered no injuries during the 12 months preceding the study.

To evaluate the gait, cadence, and kinematics of each participant, the doctors installed a 3D-motion analysis system on a 35-meter track. The motion analysis system consisted of 12 near-infrared cameras that recorded the kinematics of each runner's right leg. A force plate was also installed on the track and the participants were to run over it at three predetermined speeds, 3 m/s, 4 m/s, and 5 m/s. The doctors had the athletes run 10 trials at each speed. All athletes wore the same standard running shoe when being evaluated.

"Each participant performed 10 valid running trials in each speed condition. A trial was considered to be valid when the right foot came into complete contact with the force plate, the participant maintained the correct speed and a natural running style was retained," the study explains. "High-speed videos were used to verify that the intended rearfoot strike pattern was apparent in all subjects."

All the participants also wore retroreflective markers on the rearfoot, shank, thigh, and pelvis of their right side. Markers were also attached to anatomical landmarks like the greater trochanter, part of the femur; the posterior and anterior superior illiac spines, part of the wing of the pelvis; the malleolus, the bony protuberance of the ankle; the tibia; and parts of the knee. The doctors also placed markers on the heel cup and toe box of the shoe. These markers helped the researchers determine the length of the bone segments and the location of the joints.

Study Protocol

The doctors first performed a static standing trial to determine the segment length and joint centers in each participant. The athletes then ran across the track at a predetermined speed. The researchers used a Joint Coordinate System approach engineered by Grood and Suntay to determine joint kinematics. Specialized software computed the kinematic and kinetic information by evaluating the joint movements and ground contact of each participant's legs and feet.

Results

After the doctors let the athletes and computer system run, they found sig-

nificant differences in the joint kinetics between the male runners and female runners.

"The impact peak of the hip adduction moment was significantly increased in women. Results revealed that the gender difference was even more pronounced at 5 m/s than at 3 m/s running speed," the researchers explained.

The doctors also found that, unlike the hip joint, the knee adduction movement at the impact peak and mid-stance peak were not significantly different between the sexes. No general difference was found when comparing entire joint loading. However, a difference existed when comparing gender and speed. The joint impulses in women running at 3 m/s and 4m/s were at the level of men running at 5m/s.

In addition to finding that women's ground contact time was generally shorter than men's, the doctors also discovered notable differences in the joint kinematics of the male and female athletes.

"Female runners showed a significantly more adducted initial and peak hip angle at all running speeds," the study explained. "In contrast, the women's frontal plane knee position at initial contact as well as for peak angle was in general less adducted than that of men."

After evaluating the kinetic and kinematic differences between men and women, the doctors determined that women exhibit increased hip adduction positioning and reduced knee adduction positioning.

"An increase in the hip adduction angle may likely cause an increased lever arm at the knee and hip joint level, which would consequently lead to increased joint adduction moments," the doctors explain. "The results of the present study revealed that female runners exhibit a 4–5° more pronounced adducted hip position at initial ground contact as well as during mid-stance at slow and at fast running speeds than men. This in turn may therefore be an explanatory model of the significantly increased hip adduction moments as well as the trend for increased knee adduction moments in females."

These increased impact adduction joint moments were observed in the female athletes regardless of the speed at which they were running. Increased adduction impulses are often associated with overuse injuries and may be the culprit behind gender-specific injury risk. Further studies are required to pinpoint the reason for gender-specific injuries in running and determine whether the study's results are related to the risk of common overuse injuries.

The study also confirms and extends the results Chumanov et al. obtained in 2008. Running speed and gender differences in frontal plane hip kinematics are independent of each other. The researchers showed that gender differences in frontal plane knee and hip joint kinematics are maintained regardless of distance travelled and running speed.

Conclusions and Lessons

"First, this expands the previously existing knowledge of gender-specific running patterns to runners with a high training volume who are known to suffer the most from overuse injuries," the doctors wrote. "Second, these results support the theory that, independently of running speed and running expertise, gender differences in frontal plane hip and knee kinematics are systematically present."

Despite not finding a direct causation for gender-specific running injuries, the University of Freiburg researchers have made progress in unraveling the knee and hip joint mechanics of men and women. Their extensive study lays the groundwork for a better understanding of gender-specific running patterns and gender-specific injury risk that can help both male and female runners improve their stride. ♦

AOSSM: New President, New Building and Center of Innovation // New Rothman Institute President, Alex Vaccaro, M.D., Talks Major Expansion // Incredible New MRI Form Picks Up "Bruised" Cartilage

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

AOSSM: New President, New Building and Renewed Commitment to Innovation Robert Arciero, M.D. the new president of the American Orthopaedic Society for Sports Medicine (AOSSM), spent 20 years as an Army surgeon and earned a Bronze Star. Now, as he moves forward in his new role as head of AOSSM, he is putting his past to work and is ready to welcome the future. Dr. Arciero, chief, sports medicine division, Department of Orthopaedic Surgery, University of Connecticut Health Center tells *OTW*, "There aren't enough orthopedic surgeons in the military so we rely on each other very much and can only do our work via a team approach to patient care. This solidified in me an attitude of 'let's do this together' and had led me to be very open to other people, ideas, and situations. As president I will essentially be a conductor of great people who are as committed as I am to furthering our mission of education and optimizing sports care."

Robert Arciero, M.D. / Courtesy of the American Orthopaedic Society for Sports Medicine (AOSSM)

"We will soon be moving into a new building, something that is very much needed because the orthopedic learning center of the past needed updating. We are going from 1970s technology to 'Star Wars' as far as the technical capabilities and options with didactic lectures and conferences. For example, if someone has an innovative technique in the surgical care of a torn anterior cruciate ligament (ACL) that surgeon can come in and perform the procedure and it can be webcast to any hospital in the world. We can also archive it and make it available for our membership to review at the time of their choosing."

"As president I will be keeping an eye on how we as a subspecialty devoted to the care of patients with sports injuries are doing as far as proving that our treatment truly makes a positive impact. We are busy caring for patients, but we need to validate those treatments. Intuitively, we surgeons have always believed that our treatments resulted in a positive impact because of our experience and because of older, retrospective studies, but we need prospective randomized trials that prove our interventions and techniques actually work and have a positive impact on the quality of life for our patients."

"Another critical new area is the concept of Physician Performance Standards. We must also be able to show that the members of our subspecialty society meet established performance standards. We all get certified and recertified, but we must be able to demonstrate that we meet every single performance standard out there. This will guarantee that all active patients from the elite athlete to the recreational athlete to the master's level athlete will have access to superior care."

"I am following a lot of giants who have held the post of president…and we have a tremendous staff. I basically don't want to mess up this fine tuned engine. If there is one area in which I hope to make a positive impact in the next years is to improve the quality of sports care for those who cannot pay. I would like to increase our members understanding of how many well deserving, underserved athletes there are in this country. A 16 year old with a severe sports injury isn't just out for the season…they could be 'down' for life. This weakens them, and can affect their future socioeconomic status. There are many financial pressures, of course, and it's easy to not treat people who cannot pay. But there must be a way to increase the number of my colleagues who are dedicating time to these athletes.

Alexander Vaccaro, M.D., Incoming Rothman President, Talks 90% Expansion Alexander Vaccaro, M.D., an academic orthopedic surgeon with 560 peer-reviewed articles to his name, is the newly-minted president of the famed Rothman Institute in Philadelphia. Dr. Vaccaro, also named chairman of orthopedics for Sidney Kimmel Medical College at Thomas Jefferson University, sees a future of strong growth for the Rothman Institute. He told *OTW*, "Our mission at the Rothman Institute is to lead the way for clinical and operational transformation into an era of medicine that demands quality, service and cost effectiveness in every aspect of health care. We expect over the next year to expand our operations into new regions of New Jersey and Pennsylvania based on our mission of academic, clinical and research excellence."

"Every decision I make will be based on the need to keep our three original pillars of excellence standing: academic, educational, and clinical. There are many groups that are busy and profitable, but our institution stands out because in order to join our team you must be talented in all three areas. If you are fast, safe, and great on the clinical side that is still not enough to be part of the Rothman Institute. You must also demonstrate a commitment to research and education. So, for example, if a hospital expresses interest in affiliating with us, they must prove that they will emphasize these things."

"We are walking into a world that has significantly changed in terms of periodic payments, capitation, employee healthcare, etc. In order to make value based decisions we will rely on big data. I want to know every complication that can possibly happen to any of our surgeons in spine, hand, shoulder, etc. We can only track—and rectify—those situations with the help of large databases."

His initial goal? "I would like to strengthen our affiliation with Thomas Jefferson University and work alongside the new president, Stephen Klasko, M.D. I believe that we can create a symbiotic relationship whereby we can together bring excellence in orthopaedic care to the communities in which we serve."
But as he looks out over the Delaware River he sees another goal. "I would like to expand the Rothman Institute into Central New Jersey. Yes, there will be some entities and individuals who will not send out a welcome party, but I believe the community will welcome us. Our goal is not to displace anyone, but to bring to that area the exceptional quality care that Rothman is known for. At this time, we have a total of 105 physicians working throughout southeastern Pennsylvania and New Jersey; I see no reason why we can't grow that to over 200 surgeons going forward."

"I've been asked to chair other orthopedic departments in the past, but none of those situations would have resulted in a perfect role. In the back of my mind there was always the thought, 'It would be fantastic to be chair at Thomas Jefferson.' The committee searched for approximately six months and last week they interviewed all three final candidates. Any one of them could have run a major orthopedic facility. Frankly, I got lucky."

Incredible New MRI Form Picks Up "Bruised" Cartilage It took a West Point graduate and specialist in military intelligence to find key new clues in solving an osteoarthritis (OA) mystery. Constance Chu, M.D. is professor and vice chair of research in the department of Orthopaedic Surgery at Stanford University. Dr. Chu, director of the joint preservation center and chief of sports medicine at the VA Palo Alto, told *OTW*, When I started practice 15 years ago at the University of Pittsburgh, I was seeing young people in their 20s and 30s with end stage OA. What they had in common was that they had suffered anterior cruciate ligament (ACL) tears as teenagers. I was also doing ACL reconstructions and finding that the articular cartilage usually appeared normal at the time of ACL injury. Yet, 10 to 15 years later, the cartilage was gone. I decided to see if there was cartilage damage underneath the surface after ACL tear that we just weren't able to see at arthroscopy or with regular MRI. And, if so, whether these subsurface injuries could heal."

"Conventional wisdom holds that articular cartilage does not heal, and that damaged cartilage inevitably progresses to OA given enough time. Through some amazing imaging technology known as ultrashort echo time (UTE) enhanced T2* mapping, however, we were able to show that articular cartilage and meniscus can heal subsurface injuries after anatomic ACL reconstruction. I began this work by looking into ways to visualize what I termed 'invisible cartilage damage.' I drew upon my time after West Point, where I served in the Army and commanded an image intelligence unit. One of our tasks was to locate weapons or signs of military activity that our adversaries worked hard to hide from us. We used special imaging tools and software to help visualize what was hidden from view to determine what they really had. As a physician, I thought advanced imaging techniques would help us see potentially reversible cartilage damage well before the onset of clinical OA because there is no cure once you hit that stage."

In regular MRI scans, the deep articular cartilage and meniscus can be considered hidden from view. If you look at a regular MRI scan of the deepest layer of articular cartilage, it appears black because you are not picking up the signal due to the very short relaxation time of the tissue. My collaborator, a physicist, worked out a way to acquire very short echo times clinically and we obtained a supplement to my NIH [National Institutes of Health} R01 grant to do bench to bedside studies on the value of UTE acquisitions in uncovering deep subsurface cartilage damage. Those studies were encouraging. About the same time, I learned techniques for anatomic ACL reconstruction from Freddie Fu, M.D. so we began a prospective clinical study on patients receiving anatomic ACL reconstructions. From the beginning, it was clear that we were picking up subsurface cartilage and meniscus injuries that were not evident on regular MRI scans or by arthroscopy. The two-year data was incredible. The abnormally high UTE signal in the deep cartilage and meniscus seen at ACL injury was gone at two years follow-up. Rather, the two year scans were similar to that of uninjured knees."

Of this little-known imaging technology, Dr. Chu says, "UTE is a very specialized technique that is not widely available‹clinically with only a few centers in the world able to scan patients. The University of Pittsburgh, where I did this work, is one. We are in the process of putting procedures in place at Stanford. The image processing to elicit the information from the MRI scans is also not trivial. Because this work is getting traction, I believe that in just a couple of years we will see more facilities with access to UTE."

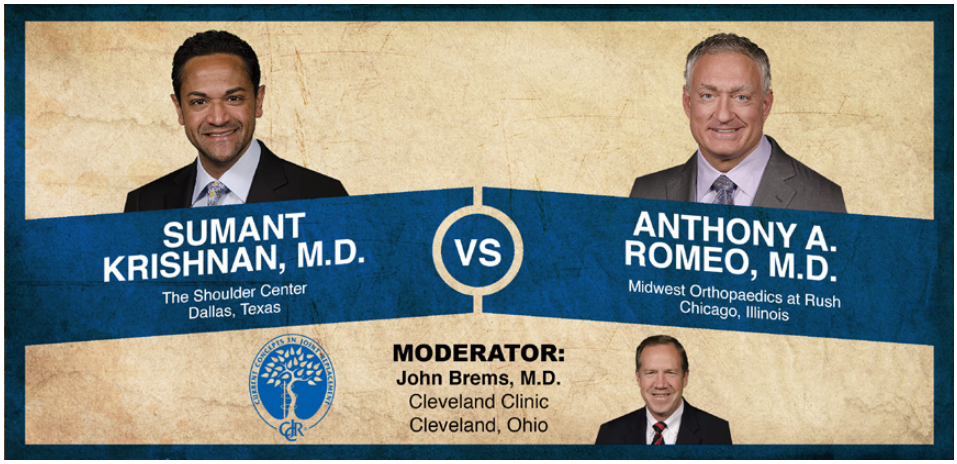
"While it is thrilling to be able to show this early damage, our finding that articular cartilage retaining intact surfaces can heal deep tissue injuries is a major breakthrough in the search for new strategies to prevent or delay the onset of osteoarthritis. I liken the UTE signal change to showing a deep bruise in the articular cartilage. If you suffer a blow to your arm and get a bruise, most people don't keep hitting the same spot because it hurts. If someone did, the skin would probably break open. Articular cartilage doesn't have nerves so when the cartilage has been bruised, patients don't know it. If we are now able to show someone that they have this bruise, and also that the cartilage can recover from the bruise, then they can decide to rest the joint until it improves. To be able to show cartilage damage at a reversible stage and to help patient's understand why they need time to recover their joints is quite an advance in patient care because these steps may help prevent devastating OA later on." ♦

Krishnan, Romeo Debate Hills-Sachs and Surface Replacement

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

Is the Hills-Sachs lesion best treated with a surface replacement? Sumant Krishnan of The Shoulder Center in Dallas says "yes" while Anthony Romeo of Midwest Orthopaedics at Rush disagrees. Who gets the best of this debate? Read on…

This week's Orthopaedic Crossfire® debate is "The Hill-Sachs Lesion is Best Treated With a Surface Replacement." For the proposition is Sumant Krishnan, M.D. of The Shoulder Center in Dallas, Texas. Against the proposition is Anthony A. Romeo, M.D. of Midwest Orthopaedics at Rush in Chicago, Illinois. Moderating is John Brems, M.D. of the Cleveland Clinic.



Current Concepts in Joint Replacement/RRY Photo Creation

Moderator Brems: "We're debating an actual case today. It is a 32-year-old amateur boxer who has had numerous anterior dislocations; they now occur daily and nocturnally. The clinical exam is consistent with isolated recurrent anterior instability. He has failed to respond to nonoperative management and has had no prior surgery."

Dr. Krishnan: "To be clear, a Hill-Sachs lesion is a posterolateral impression fracture of the humeral head with an anterior subcoracoid dislocation. Fifty years ago Michel Latarjet described the expansion of the glenoid by attaching a corocoid process to that to treat all manner of bone problems around the shoulder. But there are lesions that cannot be treated that way…a significant Hill-Sachs lesion involves the location and size of the lesion and the patient's age."

"There is a contact point as the humerus comes into abduction and external rotation in which it tracks on the glenoid. Nearly a decade ago Yamamoto and Romeo helped popularize the glenoid track, i.e., that the humeral head is a contact point to the glenoid as the arm is moving. If the Hill-Sachs lesion is within that track—generally 18mm medial to the rotator cuff footprint—then it will engage."

"As for size, if you look at the percentage of articular surface involvement, and consider that this surface is half of a sphere, we realize that this is a 50 degree articular surface involvement. But most of the biomechanical studies with regard to engagement of significant Hill-Sachs lesions involve a percentage of the humeral head diameter."

"Patient age is probably the most important component in defining what is significant about a Hill-Sachs lesion. A study in the *British Journal of Radiology* found a positive correlation between the bony defect size and the age of the patient. In a retrospective study of more than 400 consecutive multiple dislocators, researchers found that if the patient was over 29 there was a higher degree of depth and size of lesions on the humeral head compared to patients younger than 29. Perhaps it's related to relative osteopenia or multiple trauma."

"There are complications with regard to grafting defects. A size mismatch can be very ineffective with regard to articular surface restoration. There's fixation failure with screws if you're trying to fix a bulk/sized allograft. Dr. Romeo's partner, Dr. Cole, said that the best grafts are those that are fresh…fresh, frozen osteochondral allografts that are less than 28 days old. With regard to arthroplasty complications, there can be a size mismatch. We do know with surface replacements that if you don't match the radius of curvature (the articular surface to where the rotator cuff inserts) you might engender a cuff difficulty."

"So in our case here the lesion is within the glenoid track. Whether it's a humeral head defect or some type of angular measurement, it's approaching between 30-50% of the articular surface. He is 32 years old, but there is pre-existing dislocation arthropathy. Dr. Bob Samuelson helped us understand a classification for dislocation arthropathy relative to the humeral head and glenoid osteophytes. In this 32 year old there are cartilaginous changes, both on the glenoid and humeral sides. So in this case perhaps it's best to proceed with a surface replacement."

Dr. Romeo: "When we have these individuals with a fairly violent event there can be significant bone lesions on both sides of the joint. The question becomes, 'When is the humeral side important to address?' In the concept of the glenoid track is the fact that the glenoid will fall into that defect. You can address that two ways. You can widen the glenoid per Latarjet or corocoid transfer—or you can fill the defect to avoid the glenoid from hitting into the hole that is created from this injury."

"We know that for the lesion to occur that at some point they all engaged… and we try to understand when this happens—especially below 90 degrees of abduction. We want to know how much this plays a role in recurrent instability."

"How often is this really an issue? A group in Japan felt that it was about 7%. If you take care of a large rugby population that number goes up dramatically. Most of the time our treatment is glenoid-based, but it is occasionally humeral-based as we cannot resolve the entire issue by bone-grafting on the glenoid side when we have a large humeral defect."

"You can't fix all bone lesions with a soft tissue operation. When there is a Hill-Sachs lesion that is less than 15% we manage the glenoid pathology exclusively. When it's 15-25% we will incorporate our management on the arthroscopic side if there's minimal glenoid bone injury. If the glenoid bone problem is significant then we treat it on the glenoid side with a coracoid transfer. If the lesion is more than 25% we must consider the possibility that we won't be successful with just our soft tissue or arthroscopic treatment alone. We try to identify the glenoid track to make sure we understand that the glenoid is going to fall into this defect."

"If it is a smaller lesion you can fill that defect with the soft tissues of the capsule and the infraspinatus and get a good result. This was demonstrated by Pascal Boileau where he looked at 47 patients who were around 29 years of

age, and found that the capsule healed in many of these patients. Boileau provided us with a nice clinical algorithm. If you have a bone lesion we get a CT scan; if you see minimal damage on the glenoid side we can address a significant humeral side lesion (under 25%) with a remplessage."

"We use fresh osteochondral grafts and we have a lot of experience with this around the shoulder. These are not frozen or preserved. They are tested and after 14 days they are allowed to be placed into your patient by 28 days. If you are in the shoulder, the cartilage will survive at a very high rate. So we're doing a biological restoration of the shoulder. We can match these defects very well, and it's important to try to match them so we don't distort the overall anatomy. I typically address the glenoid side arthroscopically in the lateral decubitus position. Then we make a split posteriorly in the same position (arm out of traction) and we can address that Hill-Sachs lesion with an osteochondral graft that is fresh with live cartilage. We check to ensure that's it is tracking well, we move it back and forth, and we will sink the screw. Our healing rates approach 100%."

"The best study yet is from Canada… the 30% defect model from George Athwal and his group; their work on remplessage, osteochondral graft or partial replacement is outstanding. Joint stiffness is reproduced normally with the two techniques of the bone as well as the graft and surface replacement, but not so well with the remplessage. With the osteochondral graft we get all the benefits and we restore anatomy. The one problem we have with partial resurfacing is while it looks good and does a lot of nice things, we can't match it up perfectly with the normal anatomy."

Moderator Brems: "This was a real case. If this person was 60 years old would that change what you do?"

Dr. Romeo: "A 60 year old would make us think more along the lines of joint replacement, either complete surface replacement—not partial—or hemiarthroplasty. Because you get dislocation arthropathy, if we lower that number to 40 and below then I would stick with my argument."

Moderator Brems: "Sumant, if this patient had a surface replacement would you let him return to boxing?"

Dr. Krishnan: "J.P. Warner has probably done the best study on anatomic replacement on the humeral side with just a hemiarthroplasty. He demonstrated that the contact point of the glenoid—if it's truly anatomic—is no different from a natural shoulder. And

the glenoid wear that they have started to demonstrate over 5-10 years has not been the 'one in four develop glenoid arthritis. So I would let him return to boxing."

Moderator Brems: "Tony?"

Dr. Romeo: "From the beginning I would assume that he is returning to boxing. So the graft would be part of that."

Moderator Brems: "What about the timing of his return?"

Dr. Krishnan: "As soon as the cup can stabilize that humeral head—three to six months."

Dr. Romeo: "We are treating most of these patients on the glenoid side, so for a boxer I would let him back to drills and shadow boxing at three months… six months until he could compete."

Moderator Brems: "Do imaging techniques adequately allow you to assess graft incorporation?"

Dr. Romeo: "Yes, but be patient. If you take a picture of these at three months you often see the gap and there is some osteopenia. You shouldn't interpret that as a nonunion because the patients are clinically stable…if you follow them long enough you will see that all incorporate."

Dr. Krishnan: "We agree that the most effective advanced imaging both preop and postop is a 3D CT for this implant."

Moderator Brems: "At what point would you convert to a stemmed humeral implant from a surface replacement?"

Dr. Romeo: "In my algorithm I rarely use a surface replacement. I use a limited or smaller stemmed replacement. But if there was enough deformity of the humeral head such that the surface replacement cannot sit anatomically with a nice mechanical fit then I would convert."

Moderator Brems: "Cement or non cement?"

Dr. Romeo: "Uncemented."

Dr. Krishnan: "Uncemented."

Moderator Brems: "Thank you both." ♦

Please visit www.CCJR.com to register for the 2014 CCJR Winter Meeting, December 10 – 13 in Orlando.

COMPANY

Bacterin Garners $6.5 Million in Stock Offering

Bacterin International Holdings, Inc. has raised $6.5 million in a common stock offering.

The company announced on August 6, 2014 that the successful public offering of 1.143 million shares at $5.70 has been completed. The funds will be used to expand the sales force and the increasing inventory needed to meet expected market demand.

Bacterin was founded in 1998 as a spinout of the Center for Biofilm Engineering at Montana State University. Revenues were historically derived from testing services and milestone payments from collaborative product development agreements with various blue chip medical manufacturers. Today, the company generates revenue from a number of sources including:

- sales from products developed and manufactured by the company
- sales of products manufactured by a third party and sold and distributed by the company
- contract revenue from analytical testing and development services provided to medical device manufacturer clients, which tailor Bacterin's coating process to the client's specific product/medical application.

Bacterin International Holdings, Inc.

Bacterin Products

The company, located in Belgrade, Montana, develops bioactive coatings for medical applications and bone graft material, processes and markets biologic allografts for transplantation. Bacterin's biologic scaffolds, OsteoSponge, OsteoSponge SC and OsteoWrap, are made from demineralized bone that is malleable and flexible, which enables efficient and precise handling. It also markets BacFast and OsteoLock, which are used in spine surgery, designed to minimize graft back-out, and increase osteoinductivity. Bacterin's latest allograft, OsteoSelect DBM Putty is distributed as a sterile product, with osteoinductivity testing completed on every lot after terminal sterilization.

Bacterin's Medical Device and Coatings Division focuses on the development of bioactive coating technologies for implantable devices. Its core competency is anti-microbial coatings designed to reduce potential infections associated with implants. This division also manages surgical kits necessary to support implantation of products processed by Bacterin's Biologics Division. Bacterin operates a 32,000 sq. ft., state-of-the-art, fully compliant and FDA registered facility, equipped with five "Class 100" clean rooms. — *WE*

LEGAL

Ortho Pair Plead Guilty to $800k Fraud

Two former Integra LifeSciences Holding Corp. employees have pled guilty to defrauding hospitals of more than $800,000.

Image created by RRY Publications, LLC

Dan Metz was a Northeast regional manager for Integra LifeSciences until he was terminated in April 2013. Charles Carey, Jr. reported to Metz as a product specialist until he resigned in April 2011.

On August 12, 2014, the pair pled guilty to conspiracy to commit wire fraud.

Fraudulent Billing

The New Jersey U.S. Attorney, Paul Fishman, said Metz admitted to using various fraudulent methods to overcharge hospitals and surgery centers. He would sometimes charge for a greater quantity or a more expensive product than was actually used, increasing his compensation and improving his employment evaluations. Metz and Carey admitted that after Metz became regional manager, he taught at least some of the fraudulent methods to product specialists working for him, including Carey, who sometimes employed those methods.

They caused medical facilities to pay more than $800,000 in inflated bills.

Metz worked at Integra from July 2005 until his termination in April 2013, first as a product specialist (also referred to as a sales representative) and then as Northeast regional manager, supervising 16 product specialists and assistant sales representatives in Massachusetts, New Jersey, New York, and Pennsylvania. Carey was a product specialist, reporting to Metz, from January 2009 until he resigned.

Sentencing and Penalties

The count of conspiracy to commit wire fraud to which Metz and Carey pleaded guilty carries a maximum potential penalty of 20 years in prison and a $250,000 fine, or twice the gross gain or loss from the offense. Metz and Carey also agreed to forfeit $100,000 and $77,000, respectively, representing the amounts of money they personally made through the fraud scheme.

Sentencing is scheduled for January 20, 2015.

The defrauded hospitals have been reimbursed by Integra for the fraudulent charges.

Christie Successor Record

Fishman, who succeeded Chris Christie as New Jersey U.S. Attorney, reorganized the health care fraud practice shortly after taking office, including creating a stand-alone Health Care and Government Fraud Unit to handle both criminal and civil investigations and prosecutions of health care fraud offenses. Since 2010, the office has recovered more than $540 million in health care fraud and government fraud settlements, judgments, fines, restitution and forfeiture under the False Claims Act, the Food, Drug and Cosmetic Act and other statutes. — *WE*

Physician Complaint Shuts Down CMS Open Payment Site

A complaint from a physician about inaccurate payment information reported by device makers shut down the CMS (Centers for Medicare and Medicaid Services) Open Payment System temporarily in early August.

The Open Payments System website is where healthcare manufacturers report payments to physicians. The system was taken offline on August 3 to resolve a technical issue. A full investigation into a physician complaint found that manufacturers and group purchasing organizations (GPOs) submitted intermingled data, such as the wrong state license number or national provider identifier (NPI), for physicians with the same last and first names. This erroneously linked physician data in the Open Payments system.

Review Time Extended

So CMS extended the time for physicians to register, review and, as needed, dispute financial payment information received from device makers.

CMS announced on August 15, 2014 that it was extending the time for physicians and teaching hospitals to review their Open Payment System records to September 8, 2014. The public will have access to the data on September 30, 2014.

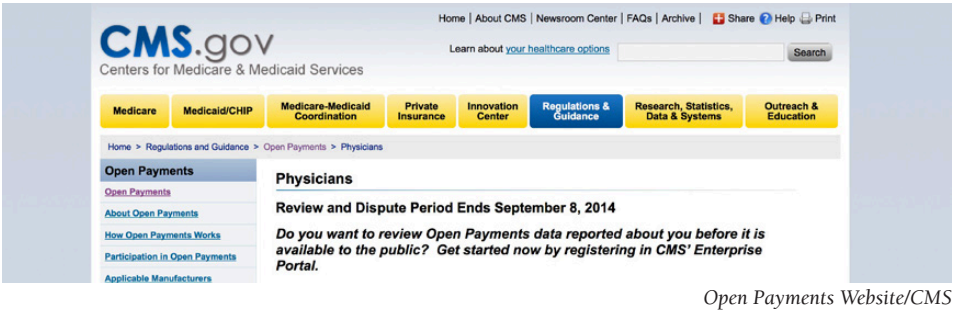
The agency says it has implemented system fixes to resolve the issue, and revalidated all data in the system to verify that the physician identifiers used by the applicable manufacturer or GPO are accurate, and that all payment records are attributed to a single physician. Incorrect payment transactions have been removed from the current review and dispute process and this data will not be published.

"CMS takes data integrity very seriously and took swift action after a physician reported a problem," said CMS Deputy Administrator and Director of the Center for Program Integrity Shantanu Agrawal, M.D. "We have identified the root cause of the problem and have instituted a system fix to prevent similar errors. We strongly encourage physicians to review their records before the deadline and before the data are posted publically to identify any discrepancies."

Check Your Data!

If you have any concerns about the data's accuracy, this is the time to dispute and correct the data submitted by industry. Physicians and teaching hospitals can register in Open Payments to review their payments.

For tutorials, information and a quick reference guide, visit: http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Physicians.html. — *WE*



Open Payments Website/CMS

BIOLOGICS

Subjects Needed For Stem Cell Trial

Chicago orthopedic surgeon, Mitchell Sheinkop, M.D., in collaboration with Regenerative Sciences, Inc., is seeking qualified candidates in Illinois, Wisconsin, Indiana, and Michigan for a clinical trial comparing the efficacy of stem cell therapy to traditional treatments for degenerative knee conditions. Regenerative Sciences, Inc. is a Colorado-based company that specializes in regenerative orthopedic medicine. Sheinkop is a board certified orthopedic surgeon, former director of the joint replacement program and professor emeritus at Rush University Medical Center.

Knee osteoarthritis is one of the most common degenerative joint conditions in the United States, affecting millions of individuals and resulting in 700,000 knee replacements a year, according to the release by Rosner Public Relations. In the study the Regenexx stem cell therapy will be compared and measured against the treatments given to a control group of patients undergoing exercise therapy and other non-surgical modalities, as well as historical results of those who have had knee replacement surgery.

The study will focus on patients, 18 to 70 years old with injuries, arthritis and other degenerative conditions of the knee. Those who qualify will receive the treatment at no cost to the patient, but they must agree to a periodic assessment protocol over a two year period.

"Regenerative Sciences continues to be at the forefront of regenerative orthopedic medicine in the United States and Europe. I have seen the ability of these new biological treatments help heal injuries and degenerative conditions without surgery and I believe they will soon become the new-normal for treating many orthopedic conditions," said Sheinkop. — *BY*

Regenexx SCP™

Courtesy of Regenerative Sciences, Inc.

LARGE JOINTS

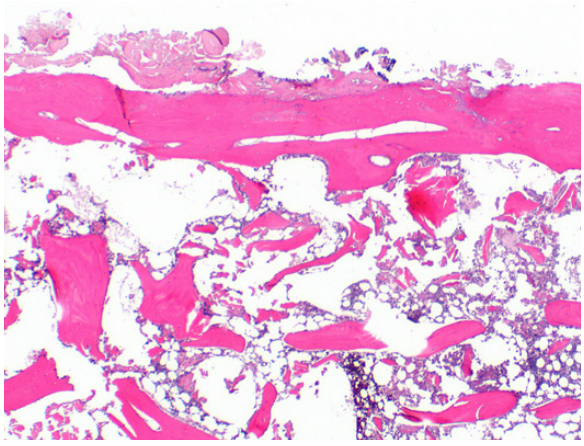
UK Scientists: Metabolic Disease Key to OA?

Professor Alan Boyde and colleagues from Queen Mary University of London have identified a new mechanism of joint destruction that is caused by a material that grinds down healthy cartilage and makes painful osteoarthritis (OA) even worse.

Initially, the team looked at the hip of a man with alkaptonuria (AKU). According to the news release, this is a metabolic disease in which a substance called homogentisic acid accumulates in joint cartilage, causing changes to its physical properties. The researchers found high density mineralized protrusions (HDMP), which had previously only been seen in horses. "These protrusions are caused as the body acts to fill in cracks in joint cartilage and can snap off, leading to sharp, dense particles in the joint which grind against healthy tissue. To confirm the findings, the team studied eight hips donated for research by people with osteoarthritis and found the same results as in the alkaptonuria patient."

Professor Jim Gallagher led the study in Liverpool. In the August 11, 2014 news release he said, "There is no cure for osteoarthritis, but it is one of the leading causes of disability, causing immense pain and difficulty of movement to sufferers. The discovery of HDMP in humans means that for the first time we are seeing an important mechanism in the process which causes the disease. In effect these small, sharp particles could act like an abrasive powder scouring the surfaces of the joint."

The authors, whose work was published in the *Journal of Anatomy*, recommend that searching for these HDMPs should now be included in the study of patients with osteoarthritis. — *EH*



Wikimedia Commons and Nephron

Biomet UK Withdraws Flawed Hip Shell

Biomet UK Ltd wants hospitals that have the Mallory-Head 6 Hole Shell HA/PC implant used in hip replacements to discontinue using the shell due to a manufacturing error.

In an August 1, 2014 "Field Safety Correction Action," Richard Castaneda, UK Quality and Regulatory Compliance Director for Biomet UK, wrote that following a complaint, Biomet UK initiated an investigation that revealed that certain shells "have been manufactured without the pre-defined HA coating."

The notice says that a customer who is not familiar with the HA Coated Mallory-Head Shell would not easily recognize that the implant has been manufactured without the required HA coating.

"No adverse health outcome is expected as the shells have the required porous coating for fixation," stated the notice.

The Mallory Head HA/PC acetabular shell is intended to be used as an uncemented acetabular component used as part of a total hip replacement. The HA coating is intended to enhance the bone growth into the porous coat layer of the acetabular implant.

The company is telling hospitals to alert their staffs, make sure all implants have been identified and removed, complete and return a "Response Form" and return the defective shells.

Hip Replacement/Wikipedia Commons and NIH

"Please accept our apologies for any inconvenience caused by this action," concluded the notice.

Read the notice here: http://www.mhra.gov.uk/home/groups/fsn/documents/fieldsafetynotice/con444301.pdf — *WE*

TRAUMA

Would Congress Let Traumatic Brain Injury Care for Vets Expire?

With time quickly running out before Congress' month-long recess in August, lawmakers were able to keep a small but critical program to help veterans with traumatic brain injuries (TBI) funded.

Sadly, this critical program was already on life-support and Congress was about to let it expire. The recent scandals regarding the Veterans Administration (VA) treatment of veterans gave Congress and the President the political will to find funds to try to repair what's broken at the VA.

Two legislators, in particular, grabbed the opportunity to slip in a provision that would keep this incredibly important TBI program funded. When this bill is signed into law, veterans living with TBI will be able to maintain their current level of care. The bill itself intends to better the VA health care system by expanding veteran access to private health care and by increasing the number of hospitals and medical staff who will treat the wounded warriors.

One of the invisible wounds of war, traumatic brain injury has affected more than 300,000 American service members since 2000, according to Department of Defense reports. As improvised explosive devices detonated along roads and caught vehicle and foot patrols in their deadly fire, the head trauma experienced by wounded service men and women became the grim signature of the wars in Iraq and Afghanistan. To remedy the troubled Department of Veterans Affairs, Congress passed a bill to reform the VA and make efforts to rehabilitate veterans with TBI.

Wikimedia Commons and SSgt Robert Dea

On Wednesday, July 30, the House of Representatives passed the VA reform bill with a 420-5 vote. The Senate passed the bill late on Thursday, July 31 with a 91-3 vote. President Obama signed the bill into law on Thursday, July 7 during an event at Fort Belvoir, Virginia. Although the main focus of the bill is the $16.3 billion VA overhaul, the bill also includes measures to aid veterans living with TBI.

The additional measure, sponsored by Senators Cory Booker, D-N.J. and Dean Heller, R-Nev., extends a VA pilot program for veterans with TBI an additional three years. The pilot program provides assisted living and therapy to veterans who suffer from moderate and severe TBI. In 2011 when the program began at the behest of Congress, the VA committed 20 certified residential brain injury providers to make services available at 150 sites across the nation.

"It is about giving [veterans] their practical skills that they need to return to their communities and live independently," Booker said in support of the bill. "That is what is so special about this program."

The pilot program has helped veterans receive 24-hour team-based care at these facilities. The staff rehabilitates the wounded warriors both physically, by helping them walk independently, and mentally, by assisting them with speech therapy and improving their memory. Although this program has helped countless veterans, it was to expire in October if Congress could not gather enough support. — *SB*

Voluntary Amputation: When is it the Right Decision?

It was morning on September 9, 2012 when Corporal Alan Fernandez was hit by an hidden improvised explosive device (IED). His commander, Sgt. Lee Davidson, also in the vehicle, died.

Caption: Corporal Alan Fernandez, member of the Light Dragoons, during a homecoming parade through Dereham Source: EDP24 and Matthew Usher

Fernandez survived but with massive injuries which required more than two years of intensive rehabilitation. At 33 years old, after all the surgeries, all the rehab, he was faced with a monumental decision. Should he ask his doctors to amputate his still grievously deformed leg?

The blast happened when Fernandez and Davidson were driving along a dirt road in the Nahr-e Saraj district of the Helmand Province in Afghanistan. The two men had been assigned to a police advisory team and were

driving the last Ridgeback with the Afghan Uniform Police. A team of American bomb-expert engineers had cleared the road about an hour before. But somehow, someone slipped a new IED into the hidden crevasses along the road. As the two men drove by it blew with ferocious intensity, killing Davidson and changing Fernandez's life forever.

Sgt. Lee Davidson was the 427th member of the UK forces to have died in Afghanistan since operations began in 2001. News at the time focused on Davidson whose wife was seven months pregnant. Fernandez, who has a wife and two daughters, returned to England to begin healing from his devastating wounds.

"It broke my right fibia and tibia, with the tibia coming out through the skin. My left ankle was shattered, I'd also had a calcaneus fracture under my heel, my back was broken, my left shoulder was dislocated, my left hand was broken, as was my coccyx, and I had tissue damage," said Fernandez.

Fernandez was treated at the Defense Medical Rehabilitation Center at Headley Court, near Leatherhead in Surrey. There he spent months in rehabilitation learning how to walk and engage in everyday activities again.

"Headley Court was fantastic—I wouldn't have been walking so quickly if it wasn't for them—and the regimental association," Fernandez said. "You don't realize how much support there is out there until you are injured—I've been overwhelmed."

Despite the advances he has made, Fernandez was frustrated with his lack of movement and walking with a stick. He would often sit at home, depressed, not taking part in social activities.

"I found it quite hard to adapt to a civilian life and had job after job after job. I didn't fit. It just didn't feel right," Fernandez said. "I still get angry when I'm in pain and I know I'll never be back to how I was. It frustrates me not being able to do what I could do."

Two years down the line, Fernandez made a momentous and courageous decision. He asked the doctors to take off his leg.

Why? Because, Fernandez said, amputee-soldiers seemed to be able to return to an active lifestyle faster than soldiers with extensive leg injuries. His injuries forced him to use a walking stick and prevented him from participating in many active physical activities including running. Amputees had no such limitations.

"Two years on [my leg] still doesn't work very well. Walking on it is a pain. I have good days and bad days, but I think it's time," Fernandez said. "I've seen lads who were in at the same time as me who lost limbs and were running round—but I can't. And amputees are fantastic when you see them doing Paralympic sport."

Fernandez hopes the amputation of his left foot and ankle, which is currently held together by metal pins, will help him run again. His wife, Gemma, and two daughters, Leah and Allana, nine and seven, support his decision.

"My wife thinks it's the best thing to do because I will be more active," Fernandez says. "And the kids are behind it because they think their dad's gonna have a foot like Iron Man." — *SB*

SPINE

Crowdfunding for Spinal Technology

Poets, politicians, and public servants have been lamenting the fickle crowd since before Roman times. With new crowdsourcing and crowdfunding websites, like Kickstarter and Indiegogo, entrepreneurs and inventors can now harness the support and whims of the crowd.

Wikimedia Commons and epSos.de

A well-known example of crowdfunding is the infamous potato salad Kickstarter project where a man from Columbus, Ohio, raised $55,492 for the expressed purpose of making potato salad.

Despite some seemingly strange or failed projects, Apollo Implants, LLC is reaching out to two crowdfunding websites with the hopes of raising enough money to make their minimally invasive spine surgery technique a reality.

Apollo Implants, based in Canton, Ohio, has been developing a minimally invasive procedure to help deteriorating backs. The new technique works by injecting a nano-polymer into the disc

space, thereby creating a new spinal disc. Spinal fusion, the current standard of care for the most severe degenerative disc disease cases, has significant risks associated with it including recurring back pain and adjacent segment disease.

In addition to being a minimally invasive procedure, Apollo Implants' technique will also allow for a greater range of motion in the treated spine segment.

To help fund the innovative new spinal technology, Apollo Implants has reached out to two crowdfunding websites, Kickstarter and Indiegogo. Crowdfunding helps companies gather "backers" or supporters who can contribute any sum of money, from $1 to thousands of dollars. The company puts out incentives for people to chip in, with more impressive incentives for those who contribute at higher levels. Crowdfunding has become increasingly popular for small companies or entrepreneurs who lack the resources to apply for more traditional funding sources.

While it may be unlikely that Kickstarter and Indiegogo alone can deliver the necessary funding to make Apollo Implants a major player in the spine device market, these approaches could serve as a first step in refining the product and pulling in potential larger investors.

Crowdfunding for a medical device development differs substantially from most pet projects or local artists on Kickstarter. Eric VonGuten, D.C., founder and CEO of Apollo Implants, hopes that enough people have an interest in treatments for back pain. After all, a majority of people experience back aches or know someone suffering from chronic back pain. The company's goal is to first reach $250,000, to do the initial stress study and implant lab testing, then raise $500,000 to conduct hematological assays and investigate volunteer trials.

Dr. VonGuten and his staff do not intend to collect salaries or pay from the study funding and any additional funds would go toward a grant proposal to treat military veterans with spinal injuries.

Contributions can be made via the Apollo Disc Injectable Disc Project Kickstarter page or the Apollo Disc Injectable Prosthetic Disc Indiegogo page.

Kickstarter: https://www.kickstarter.com/projects/apolloimplantsllc/apollo-disc-injectable-disc-project

Indiegogo: https://www.indiegogo.com/projects/apollo-disc-injectable-prosthetic-disc. — *SB*

Bacterin Bone Putty Effective For Fusion

OsteoSelect works as well as autologous bone in a rabbit posterolateral spinal fusion model.

Gregory Juda, chief scientific officer for Bacterin International Holdings, Inc., the maker of OsteoSelect said a study, published in *The Spine Journal*, completed at the Integrated Spine Research Department at the Hospital for Special Surgery in New York, has, "shown equivalency in this preclinical model to autograft, the gold standard in bone grafting materials. We expect subsequent clinical research to further validate these findings."

In an August 12, 2014 press release, the company said, "The study compared the efficacy of autologous bone, frequently referred to as the gold standard for achieving fusion, and Bacterin's OsteoSelect DBM Putty in a commonly utilized animal model used to assess spinal fusion. The results showed equivalence between the two groups, based on biomechanical, radiographic and histological analyses, with the OsteoSelect group producing more mature fusion masses relative to autograft. These results may support a surgeon's selection of OsteoSelect DBM Putty as an effective grafting material during spinal arthrodesis procedures, of which there are over 325,000 annually in the United States."

The putty is a malleable bone grafting material comprised of demineralized bone matrix (DBM) allograft combined with a polymer carrier material. The company said the product was engineered using feedback from key opinion leaders in several orthopedic specialties. The bone forming potential of every lot of OsteoSelect is confirmed after sterilization in an animal model thus providing surgeons with a bone grafting solution that is "both safe and confirmed to be biologically active."

The news of the study comes just a week after *The Journal of Foot and Ankle Surgery* published clinical results of Bacterin's OsteoSponge SC Allograft that showed positive clinical outcomes at two years post-op. — *WE*

OsteoSelect DBM Putty
Bacterin International Holdings, Inc.

LDR Applauds UHC Cervical Disc Coverage

The spine gurus at LDR are celebrating an event that should make a real difference in the lives of patients… UnitedHealthcare (UHC) is now covering one and two-level cervical disc replacement. As indicated by LDR, this move, which affects those with degenerative cervical disc disease, follows compelling clinical data in support of cervical arthroplasty and the volume of information available from a multitude of studies supports the safety and efficacy of these procedures. UHC's positive coverage decision further validates cervical disc replacement for both one and two-level surgery as a standard treatment option for indicated patients.

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Joe Ross, executive vice president of Global Marketing for LDR, told *OTW*, "This is a significant payor coverage milestone in support of coverage for cervical disc replacement. It is a reflection of the expansive body of Level I evidence demonstrating the short and long-term safety and efficacy of the procedure. We look forward to other payor reviews and their consideration of broader coverage. We are pleased that large, national payors such as UHC are taking a leadership role in providing their members access to cutting edge treatment options which have demonstrated clinical benefits in rigorous, controlled trials."

"This decision facilitates a more straightforward pathway for coverage for UnitedHealthcare patients. A published policy establishes clear and objective criteria for physicians to reference and follow."

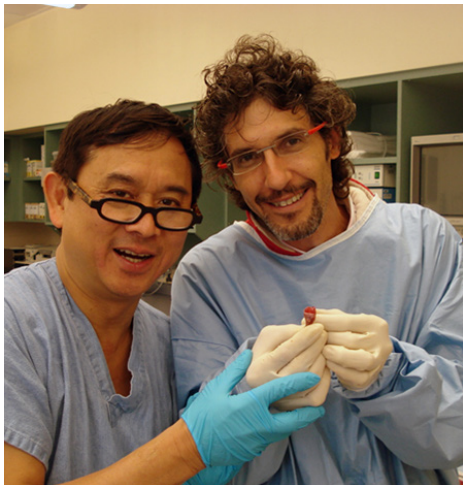
UnitedHealthcare is an operating division of UnitedHealth Group, the largest single health carrier in the United States. — *EH*

PEOPLE

Pau Golanó, Famed Orthopedic Anatomist Passes Too Soon

He surely had much more work to do and life to live.

Pau Golanó, professor of Pathology and Experimental Therapeutics at the University of Barcelona, died on July 23, 2014 of a massive stroke. Dr. Golanó, who was also a part of the University of Pittsburgh adjunct faculty, was only 49 years old. Visitation was held on July 24, and the funeral was the following day at Tanatorio Les Corts, Avinguda de Joan XXIII.



Dr. Freddie Fu and Dr. Pau Golanó
Source: University of Pittsburgh and Dr. Freddie Fu

Niek van Dijk, president of the ESSKA Ankle & Foot Associates, wrote the following in memory and honor of Pau Golanó, "…His exceptional anatomical dissection skills and passion for education was quickly recognized by the orthopaedic surgeons surrounding him. And it did not take long before his skills were recognized worldwide and he became the leading expert on orthopaedic anatomy of the last decade. He

devoted his career and life to the education of orthopaedic surgeons, making them better doctors by teaching anatomy in the finest details…Over the years he has written many inspiring papers on orthopaedic surgical anatomy. A great number of them were the result of the collaboration between Pau and our department. Once every two years we organized in Barcelona a dissection course for all the residents of our Department. We practiced all the open surgical approaches. Pau Golanó was our teacher. But Pau was a teacher for all orthopaedic surgeons. Together with the love of his life Celine, he enjoyed travelling the world, meeting friends and sharing his knowledge…"

A statement from the European Society of Sports Traumatology, Knee Surgery, and Arthroscopy read, "We are deeply saddened to inform you of the untimely passing of Professor Pau Golanó on the 23rd of July 2014. His funeral service was held today [July 25] in Barcelona… In addition to being a dear friend to many of us, and an extremely creative and thoughtful scientist, Pau Golanó was a very talented anatomist who helped shape and advance orthopaedic surgery. He was considered by many to be the best musculoskeletal anatomist in the world. A member of ESSKA and ESSKA-AFAS since 2010, he was honoured with the ESSKA reward for service for the Most Dedicated Individual Member at our 16th Congress in Amsterdam last May. At the ESSKA Congress 2012 in Geneva, Professor Golanó also won the KSSTA Best Paper Award for 'Anatomy of the Ankle Ligaments: a Pictorial Essay.'"

The University of Pittsburgh commented, "It is with great sadness that we learned that Dr. Pau Golanó passed away yesterday. A great surgeon, friend, and family member to all, he was well known for his irreplaceable skills to anatomical dissection and passion for education…He is a world famous surgical anatomist, photographer, and illustrator…His legacy, genius, and talents have blessed our very own in Pittsburgh. After visiting in the summer of 2008, he continued to collaborate with our department and provided musculoskeletal anatomy lectures to our residents, fellows and medical students. In August 2011, he returned to Pittsburgh to participate in the Panther Global Summit as a Keynote Speaker. We are grateful to experience his genius and enthusiasm which have passed down to the residents and faculty of our institution."

Freddie Fu, M.D., David Silver Professor and Chairman of the Department of Orthopaedic Surgery, University of Pittsburgh School of Medicine, will miss his friend and colleague. He noted, "Pau was an inspiration to all of us who wanted to learn anatomy. He was an exceptional teacher, mentor, researcher, artist and a fun and loving person. He will be missed dearly in our field."

Prof. Stefano Zaffagnini, M.D., associate professor of orthopaedics at the University of Bologna Italy commented, "He was a great man, great friend, great scientist, great anatomist, and a great artist. All the scientific community will lose the chance to learn new views and insight from anatomical pictures performed with extreme precision and love. The best anatomical preparation ever that in his hands truly became art. He was also a great friend. All persons like me that had the chance to spend some time with him had the possibilities to admire his kindness and humanity and how he enjoyed life and friends. Ciao Pau." — *EH*

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