VOLUME 8, ISSUE 11 | APRIL 3, 2012

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: Odds are excellent that the individual mandate will not survive the Supreme Court's review. As that is THE linchpin to the economic viability of the Affordable Care Act (ACA), it makes the whole plan doubtful. But beware of this news as a head fake. Substantive changes from CMS, FDA, BCBS, United, Cigna and Aetna are already occurring—independently of the ACA.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Integra LifeSciences	14.81%	9.78%	No longer the cheapest equity in ortho, it remains #1 on Power Rankings by virtue of a 6% sales growth rate.
2	2	NuVasive	7.26	7.33	15% top line growth in an otherwise tough environment tells you a lot about the team at NUVA.
3	4	Zimmer	24.95	5.81	Watch for a strong earnings report ($1.30 vs. $1.19) this month. Remember, more cash on the books than annual cash flow.
4	3	Conmed	9.65	0.10	CNMD is another ortho company expected to report strong earnings this quarter—$0.44 versus $0.37 last year.
5	5	Orthofix	14.72	(4.16)	With the sell-off, OFIX is officially the cheapest public equity in orthopedics. Quick reminder: OFIX tends to out-perform.
6	7	Stryker	25.23	3.43	BetterInvesting Magazine selected SYK as its "Stock to Study" because of its "growth prospects and reasonable valuation." Absolutely.
7	6	ArthroCare	(0.95)	2.87	This management needs a new growth story—that's the central issue with investors. Where is growth coming from?
8	8	Smith & Nephew	22.80	3.02	The spate of bad news over metal-on-metal keeps being attached to SNN, but there is zero effect on sales and earnings.
9	9	Medtronic	28.63	2.81	Settles Infuse lawsuits for $85 million. Time for new product introductions to start accelerating.
10	10	Johnson & Johnson	26.33	1.35	Second lowest P/E in orthopedics (after MDT), #1 best dividend yield at 3.50%. Still waiting for Godot—er, Synthes.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Kensey Nash	KNSY	$29.26	$254	29.58%
2	Alphatec Holdings	ATEC	$2.37	$212	26.06%
3	TranS1	TSON	$3.67	$100	23.15%
4	Wright Medical	WMGI	$19.32	$759	16.67%
5	Integra LifeSciences	IART	$34.69	$932	9.78%
6	Tornier N.V.	TRNX	$25.70	$1,010	9.36%
7	MAKO Surgical	MAKO	$42.15	$1,788	7.80%
8	NuVasive	NUVA	$16.84	$718	7.33%
9	Zimmer Holdings	ZMH	$64.28	$11,450	5.81%
10	Stryker	SYK	$55.48	$21,153	3.43%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	$2.42	$102	-18.24%
2	Orthofix	OFIX	$37.58	$703	-4.16%
3	CryoLife	CRY	$5.27	$146	-3.30%
4	TiGenix	TIG.BR	$0.88	$80	-3.12%
5	Symmetry Medical	SMA	$7.07	$252	-2.35%
6	Exactech	EXAC	$15.85	$209	-0.25%
7	Synthes	SYST.VX	$173.44	$20,601	-0.06%
8	RTI Biologics Inc	RTIX	$3.70	$206	0.00%
9	Conmed	CNMD	$29.87	$837	0.10%
10	Johnson & Johnson	JNJ	$65.96	$181,065	1.35%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$39.19	$40,781	12.21
2	Johnson & Johnson	JNJ	$65.96	$181,065	13.19
3	Zimmer Holdings	ZMH	$64.28	$11,450	13.36
4	Orthofix	OFIX	$37.58	$703	13.92
5	Stryker	SYK	$55.48	$21,153	14.95

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$19.32	$759	58.55
2	NuVasive	NUVA	$16.84	$718	33.68
3	RTI Biologics Inc	RTIX	$3.70	$206	24.67
4	Symmetry Medical	SMA	$7.07	$252	23.57
5	Exactech	EXAC	$15.85	$209	21.42

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$37.58	$703	0.84
2	Kensey Nash	KNSY	$29.26	$254	0.94
3	Stryker	SYK	$55.48	$21,153	1.39
4	Zimmer Holdings	ZMH	$64.28	$11,450	1.42
5	Integra LifeSciences	IART	$34.69	$932	1.42

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$19.32	$759	6.14
2	NuVasive	NUVA	$16.84	$718	3.76
3	CryoLife	CRY	$5.27	$146	2.28
4	Johnson & Johnson	JNJ	$65.96	$181,065	2.27
5	Smith & Nephew	SNN	$50.50	$9,049	2.17

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$7.07	$252	0.70
2	Exactech	EXAC	$15.85	$209	1.02
3	Alphatec Holdings	ATEC	$2.37	$212	1.07
4	Conmed	CNMD	$29.87	$837	1.15
5	Integra LifeSciences	IART	$34.69	$932	1.20

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.88	$80	69.97
2	MAKO Surgical	MAKO	$42.15	$1,788	21.16
3	TranS1	TSON	$3.67	$100	5.22
4	Synthes	SYST.VX	$173.44	$20,601	5.18
5	Tornier N.V.	TRNX	$25.70	$1,010	3.87

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

Physician-Owned Distribution Companies – The Great Debate

By Walter Eisner

Wikimedia Commons/Image creation by RRY Publications LLC

Should physicians own their own means of implant or instrument distribution?

No other question generates more passionate debate within orthopedics than that one. Many physicians have jumped onto the Physician-Owned Distributor (POD) bandwagon and defend their decisions to do so fiercely. At the same time, many suppliers and distributors are equally adamant that PODs are out of bounds and should be modified or even stopped immediately.

Orthopedics This Week is pleased and honored to invite two of the most articulate and knowledgeable experts in the area of orthopedic product distribution to debate and shed light on the POD controversy—John Steinmann, M.D., founder of the first physician-owned distributor and Bill Kolter, Vice President for government and public affairs and corporate communications for Biomet, Inc.

Biomet, in the person of its CEO Jeffrey Binder, has been an outspoken and very articulate critic of PODs replying to Dr. Steinmanm on a corporate blog on February 21, 2012: *"You are cloaking your argument to doctors in save-the-world*

Bill Kolter
Corporate VP Government Affairs, Public Affairs, and Corporate Communication/Biomet, Inc.

Dr. John Steinmann

self-righteousness while enticing them with the oldest sales pitch in the world: easy money."

Dr. Steinmann commented for *OTW* that having his ethics questioned, "*Is hypocritical from a company who just reported $22 million in fines for suspected violations of the Foreign Corrupt Practices Act*."

So, are physician-owned distributorships legal and ethical and do they reduce overutilization of implants and instruments?

FOR that proposition is Dr. Steinmann and OPPOSING that proposition is Bill Kolter of Biomet. This week we present Part I of this vital and important debate.

Incidentally, while the orthopedics industry is debating PODs internally, the Department of Health and Human Services' Office of Inspector General (OIG) is preparing a report for the U.S. Senate to assess the adequacy of the guidance that has been issued addressing the legality of PODs and other physician-owned entities under the Federal Anti-Kickback Statute.

Dr. Steinmann: The surgeon owned stocking distribution model is legal provided, like any similar arrangement, there exists proper intent, structure, and conduct that is compliant with existing laws.

Proper intent is demonstrated by creating substantial healthcare savings while providing quality products and services. Compliance with existing laws requires transparency, proper disclosure, investment risk, ownership of inventory, written contracts with hospitals and vendors, and never leveraging referrals or favoring the volume or value of referrals.

September 13, 2011 Daniel Levinson, Inspector General of the OIG, confirmed this position in his response to the Senate Finance Committee, stating:

"The legality of any individual physician-owned entity under the Federal Anti-Kickback Statute is highly dependent on each entity's particular characteristics, including the details of its legal structure; its operational safeguards; and importantly, the actual conduct of its investors, management entities, suppliers, and customers during implementation and ongoing operations."

A legally compliant structure for surgeon ownership of distribution is available.

Mr. Kolter: We have yet to encounter a POD that fits within safe harbors, one of which requires 60% of a physician-owned entity's revenue to come from non-investors.

If PODs were able to offer a legitimate distribution business that could attract non-investor surgeon customers, then the model should also attract non-surgeon investors. But PODs depend on surgeon investors switching their

business. POD proponents know it. We know it. This is the essence of a kickback.

If PODs were to tout a pure low cost model without financial incentives to surgeons for using particular products, we would have no issues. We would simply compete.

However, given our understanding of the POD structures that we have reviewed, we believe they run afoul of the Federal Anti-Kickback law (AKL), a concern that OIG has repeatedly and consistently expressed.

The AKL has a "one purpose" test. If even one purpose of a payment to a healthcare provider is to induce referrals or other business, it runs afoul of the AKL.

PODs seem tailor-made to violate the "one-purpose" test by depending on surgeon/investor purchases.

Can manufacturers who supply PODs reasonably argue that generating sales from physician-investors is not one purpose of distributing through PODs? Can physician-investors reasonably argue that financial motivation is not one reason for choosing POD products? Can hospitals that work with PODs reasonably argue that preventing the loss of referrals from surgeon-investors is not one reason for purchasing from a particular POD?

Dr. Steinmann: Biomet maintains that surgeons, hospitals and manufacturers cannot be trusted to act with honorable intent. This is hypocritical for a company who just reported $22 million in fines for suspected violations of the Foreign Corrupt Practices Act.

We do not violate the "one purpose" rule and are fully compliant under the AKL.

Nowhere in Mr. Kolter's response does he propose a solution. Fourteen years ago a hip implant represented less than 30% of the DRG [diagnosis-related group] and now it often exceeds 60%. It is time the industry take responsibility to help develop a solution and stop spending resources to eliminate a viable alternative to overly expensive distribution.

OTW: Mr. Kolter and Dr. Steinmann, are there ways in which physician participation in a POD is ethical and are there ways in which it is not?

Mr. Kolter: Physicians may gain guidance from the AAOS [American Academy of Orthopaedic Surgeons] and AMA {American Medical Association] Codes of Ethics.

The AAOS Code of Ethics states:

"It is unethical for an orthopaedic surgeon to receive compensation (excluding royalties) from a manufacturer for using a particular device or product."

The AAOS Code of Ethics does allow for dispensing of patient-care items EXCEPT where inconsistent with applicable law, and we clearly believe that the POD model is inconsistent with applicable law.

The AMA Code of Ethics states:

"Physicians may not accept any kind of payment or compensation from a drug company or device manufacturer for prescribing its products. Furthermore, physicians should not be influenced in the prescribing of drugs, devices, or appliances by a direct or indirect financial interest in a firm or other supplier, regardless of whether the firm is a manufacturer, distributor, wholesaler, or repackager of the products involved."

Dr. Steinmann: A properly structured surgeon-owned distribution company will operate entirely consistent with the AMA and AAOS Code of Ethics. Mr. Kolter presents a small subset of the broad Academy Code that supports physician's ethical participation in ancillary services.

Recognizing that pitfalls do exist and desiring to protect the virtues of this model led to the establishment of the American Association of Surgeon Distributors (aasdonline.org), an association that has established comprehensive legal and ethical standards.

Again, I find it hypocritical that Biomet continues to suggest that there exists a "de facto" absence of ethical standards in physicians.

Surgeons by and large are ethical individuals who face various conflicts every day and steadfastly manage these in the best interest of their patients.

While this model does create a conflict of interest, it is no different than the conflict that exists in our fee-for-service reimbursement system or with surgeon ownership in surgery centers. Such conflicts are common in the practice of medicine and are managed through transparency and disclosure to patients, hospitals and colleagues.

While there are some unethical surgeons that have chosen self-interest over patient and societal interest, these deviants can be easily controlled through the adoption of standards such as those published by the American Association of Surgeon Distributors.

Similar to the question of legality, a distributorship structured with transparency and the assurance of high quality products and services is highly ethical and clearly in patients, hospitals and society's best interest.

Mr. Kolter: Surgeons certainly are capable of managing their own ethical behavior. The question is whether the model is ethical.

Dr. Steinmann essentially argues that, because fee-for-service rewards surgeon volume, it is therefore ethical to pay surgeons based on the volume of implants they distribute to themselves. Clearly, the model itself is inherently unethical, as suggested by AAOS and AMA guidelines, and preys upon surgeons' legitimate frustration in the current reimbursement environment.

Those who attempt to sell surgeons on POD models are leading them (and hospitals) into a dangerous trap that runs the risk of federal enforcement.

Dr. Steinmann: The vast majority of surgeons are honorable and ethical individuals that would never operate

on someone for their own personal gain. For the few dishonorable individuals out there, you can be assured that the fee-for-service system has far greater influence on them and hence this model does not introduce an incentive that does not already exist.

A study conducted by Alliance Surgical Distributors analyzed utilization (measured as the ratio of new patient visits to the decision to treat operatively with implants) in five affiliate distributorships. This surgical decision index was calculated for the 12 months prior to the distributorship and up to five years following the distributorship. There was no increase in the decision to treat surgically following the implementation of this model in any of the five distributorships studied.

While it is reasonable to have concern regarding the issue of utilization, currently, there does not exist any evidence to support the allegation that this model introduces a new incentive capable of increasing utilization

Mr. Kolter: While OIG intends to investigate POD utilization, we have never argued that PODs influence surgeons' decisions to operate. But they clearly influence the choice of implants.

It is fallacious to argue that the POD model does not introduce new incentives. Rewarding surgeons financially for using a device distributed by their POD is a new incentive and a new conflict. When the amount paid increases, either directly or indirectly, with the volume of devices used, that also is a new incentive and a new conflict, which we believe is clearly proscribed by AAOS and AMA Codes of Ethics and federal statutes.

OTW: Gentlemen, let's talk for a minute about this issue of overutilization. Does physician involvement in the distribution of implants promote overutilization or reduce it?

Mr. Kolter: Proper utilization can only be determined on a patient-by-patient basis. Mere increases in volume, of which there is some evidence, may or may not be overutilization. Whether or not PODs promote overutilization is immaterial to the fact that the model is problematic under the Anti-Kickback Statute. That said, the OIG, as part of its investigation into PODs, intends to explore this very question, and will undoubtedly question volume increases, whether legitimate or not, that coincide with surgeons' changing their implants to those distributed by their PODs.

Dr. Steinmann: We have found no increase in utilization among the surgeons in our distributorships, nor would I have expected to. Contrary to the suggestions of Mr. Kolter, surgeons do not operate on people because they own a distributorship.

We have voluntarily met with the OIG and showed them how we track utilization and ensure transparency. We also fully support a distributorship registration process to ensure transparency. Finally, I again draw the readership attention to the standards published by the American Association of Surgeon Distributors to see how this and many other concerns are appropriately addressed.

OTW: Gentlemen, so in terms of the larger economic issues, who wins and loses under the current models of physician-owned distributorships? ♦

(The answer to that question and the rest of this debate continues in Part II in an upcoming issue of *OTW.*)

Growing Orthopedic Hospitals in China

By Biloine Young

Courtesy International Spine and Orthopedic Institute China
Caption: First Affiliated Hospital of Soochow University, Suzhou, China

When a Texas-sized idea runs headlong into a China-sized opportunity, watch out! In the middle of March Mike Franz, former CEO of the Texas Back Institute (TBI), flew off on his 54th or 55th trip to China (he has lost count of the number) to celebrate the opening of a prototype that, very probably, will profoundly change how orthopedics is practiced in that country.

As part of a group that took some Chinese companies public between 2003 and 2005, Franz "got to know the landscape in China." He realized that China's population of 1.35 billion people was rapidly aging, that they held western medicine in extremely high regard, and that the affiliations that orthopedic practices had worked out with hospitals in the United States might also work in China. It was, he said, "like a light bulb going off."

Franz's big idea was to establish a network of free standing private orthopedic surgery hospitals in China that specialized in spine, sports medicine and total joints. The patients would be solicited from three groups: wealthy Chinese who would pay a premium to be treated by western surgeons, expatriates, and patrons of medical tourism. The premise undergirding the project was that wealthy patients would pay a premium to be treated in China by western doctors following a western protocol.

Though Franz has a reputation for moving fast to implement his business projects, he knew that, to develop his big idea, he had to slow himself down. "For this venture," he said, "we had to be very deliberate in the beginning to put a foundation, a solid footing in place that was firm." He spent a year and a half in China just developing relationships at the senior orthopedic level with people working in spine, joints, and in orthopedics in general. He wanted to understand the landscape relative to the hospital situation in China and who the players were. He needed to know who was in control in China. At that time foreigners could own up to 70% of private hospitals so Franz knew that he was going in the direction that the government was going to approve. "There was a light breeze at our back," he explained, relative to the government of China's support.

Franz quickly learned that in China, unlike the United States, people select the hospitals where they want their surgery performed. They do not select the doctors. (The exceptions are the few elite surgeons to whom people will travel to patronize.) Therefore the reputation of the hospital is all important. "The hospital is the key," he noted. He also learned that the public hospitals are the dominant institutions and that private hospitals are "just starting to roll out."

By 2009 Franz had developed close relationships in China, felt that he had a good understanding of what was happening in the country and had

Front Door of the First Affiliated Hospital of Soochow University, Suzhou, China

developed a model that he believed made sense. It was time to proceed with Phase 1 of the execution strategy, what he called the "proof of concept" stage, which was to put his orthopedic model in an existing Chinese hospital. He partnered with a public hospital, the Affiliated Hospital of Suzhou University, located about an hour and 20 minute drive from Shanghai that had the required volume, patient flow, reputation and history. There he built a VIP orthopedics ward and clinic where western surgeons could come every six weeks to do spinal surgery. Franz said they focused first on spinal surgery because they wanted to perfect their model in spine. It was also probably significant that the chief of orthopedics in the Suzhou University Hospital was a spine surgeon.

The facility opened in March 2011 and has been a big success. Surgeons from the United States came to Suzhou for a two-week period of work. During the first two and a half days they met patients in the clinics. The remainder of their time was spent doing surgeries.

With the proof of concept demonstrated to be successful in a Chinese public hospital, Franz moved to test it in a private hospital in what he calls Phase 2. "We instituted a joint venture with a Chinese hospital group called Tongren and did a deal with the Tongren Hospital in Kunming which is a 500 bed, full-service private hospital," he said. "We did that deal in December 2011, had a test run with one of the Texas Back surgeons there in the beginning of March 2012 and had the grand opening on March 21." This hospital will specialize in sports medicine and Franz flew off to China for the opening.

Still to come is Phase 3 for which Franz is now in the process of lining up both strategic and hospital partners to build his first free-standing orthopedic surgery center. He expects to have it up and running by the middle of 2013.

The political climate in China is, if anything, accelerating Franz's plans. While he sensed a breeze at his back in 2009, he said that breeze has turned into a powerful wind. "The government has come out with its five-year plan and in the health care reform area they have strongly stated that they encourage foreigners to invest in private hospitals in China. That is a very strong wind that is blowing and we are going in the same direction that the Chinese government wants."

The initial phase of Franz's China project, organized as The International Spine and Orthopedic Institute (ISIO), was funded by individuals. Approximately 65 U.S. orthopedic surgeons

First Affiliated Hospital of Soochow University, Suzhou, China

are investors as are the two institutions, Texas Back Institute for spine and Kerlan Jobe, of California, for sports medicine and total joints.

The individual investors, besides putting in their money, must agree to participate—play their professional roles, from doing surgery in China to managing the training of Chinese physicians in China or in the U.S. Texas Back Institute and Kerlan Jobe serve as training hubs for doctors from China.

Franz is now in conversations with institutional investors and strategic partners, principally in China, for the financing of Phase 3. "We have had extensive discussions and multiple conversations with firms and we are lining up the capitol funding. The feedback we are getting is that we are coming in at the right time with a model that people really like," he said. Within the next six months Franz expects to have secured a relationship with a strategic partner "with the resources and desire to scale this across China in a fairly rapid manner." Franz plans to perfect his model in the first stand-alone surgery center. "We will do that in conjunction with the strategic investment partner—one who is already in the health care field and wants to be in the service end of it."

So how does it work? As Franz explains, "One very important aspect that we are promoting to the market place is that we have a unique combination of western surgeons and Chinese surgeon partners. The patients understand that when they see a western doctor there is a Chinese partner next to him. When the western doc goes back to the U.S. the Chinese doctor is there and is part of a two-man team. Patients will meet their western and Chinese surgeons at the same time. As the volume grows the Chinese surgeon partners will be doing a lot of the surgery as well. We are deploying a tele-medicine capability that will keep the western surgeon involved in what we call a case-director strategy."

"This is not about taking western practices and forcing them on Chinese patients," Franz insists. "It is about finding the optimum mix or blend of the Chinese culture and how they do things and western practices. We are very sensitive to that. The formula for failure would be to take a model from the outside and force it on China."

Franz is aware that, as time goes on, Chinese surgeons will get better and better. "Our game plan is to recognize the present window of opportunity," he said, "and establish what we need to within that window."

Franz says that he is sensitive to the fact that China is a tremendous market place—that it is a different culture from the U.S. and that people think differently. He says that he "does not go to bed at night worrying. We have been very methodical in putting the foundation in place. The pieces are there. The task now is one of putting them together and executing the strategy that has been laid out." ♦

Malchau Debates Engh Over Highly Cross-Linked Poly

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

"In the mid-term, at least," says Henrik Malchau, "highly cross-linked polyethylene is doing well. "Wait a minute," counters C. Anderson Engh. "Even your own recent data emphasizes that the outcome is not clear, even after a nine year experience."

This week's Orthopaedic Crossfire® debate is, "Cross-Linked Poly 30 Year Hip: We Can All Go Home Now." For the proposition was Henrik Malchau, M.D. from Harvard Medical School. Against the proposition was C. Anderson Engh, Jr., M.D. of Anderson Orthopedic Research Institute; moderating was Thomas S. Thornhill, M.D. of Harvard Medical School.

Wikimedia - KaihsuTai and Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Malchau: "We can all go home… cross-linked poly will solve the problem. I don't have data that confirms 30 year outcomes, but I have an outcome that is superior to the disastrous outcome of some metal-on-metal (MOM) total hips and let the patient move around in silence in contrast to ceramic-on-ceramic (COC)."

"Registries: from Australia, they have 173,591 total hips with primary diagnosis of osteoarthritis. MOM has the highest revision rate; ceramic on conventional poly is number two, and metal on conventional poly is number three, then ceramic on highly cross-linked poly (HCLP), followed by ceramic-on-ceramic, then metal on HCLP, finally ceramicised metal on HCLP. So HCLP is doing good at ten years."

"The first study was at Mass General (MGH)…a multicenter study looking into conventional head sizes. Another study looked at larger head sizes (>32mm). The Longevity/Durasul has been used in more than two million patients, and the clinical outcome is excellent."

"There are three analysis methods—confusing. You can do linear wear rates (postop versus the most recent); you can do group regression where you use all the data; or you can do individual regression where you have a minimum of three points required. I still don't know which is better. MGH had 241 hips…we have not revised any components due to wear; we have no indication of osteolysis, and we have done CTs on a number without identifying osteolysis. There is no wear…at ten years, same story."

"The multicenter study: we have 278 hips with close to 4,000 film comparisons where we have very high quality criteria. You have a flat curve. None of the three methods show any difference between the head sizes or any increased head penetration…no wear detected and no increase in femoral head penetration in the late versus the early period."

"Finally, the large head study…three centers with 486 patients. We found a significant difference in median linear wear. The steady state linear wear and individual regression analysis didn't show any difference. So the low femoral head penetration rate we previously reported is still—up to 12 years—showing very good results. The large head shows a possible increase in penetration rate, but significantly reduced wear rates."

"I know what my opponent is going to tell me…because we did explant analy-

sis and we found that implants that have been in a patient then put on the shelf for a number of months or years—something happened there—maybe cyclic load or absorbed lipids. So we looked at fresh explants and implants and we found some oxidation, but very low still…and I doubt that it would really affect long-term outcome."

"There are more concerns about the sequential, irradiated material that have a lot of free radicals. In an example of a four year X3 retrieval…the oxidation levels are up to 1, which is white banding, and there might be clinical problems associated to this. Therefore, vitamin E where you add an antioxidant in your poly, blocking your free radicals might be better than the first generation highly melted."

"So based on multicenter radiographic studies, and the nearly 175,000 Australian patients mid-term results are extremely encouraging. Why wouldn't it last another 15 years? Thank you."

Dr. Engh: "The literature on cross-linked polyethylene looks good…and I use it daily. All of the reported wear rates [.05, .003, .088, .04, .031, .03 mm/year] are with 28mm heads…not many of us are still using 28mm femoral heads."

"To make a reliable prediction for a 30 year hip there should be no unexplained occurrences, no lingering questions, and we should be using them in appropriate patients. First of all, oxidation. We know that it leads to mechanical failure by way of embrittlement; it may lead to increased wear because of decreased cross-linking."

"In an article from Dartmouth, 22% of cases had measurable oxidation on retrievals that was at similar levels to gamma inert retrievals at the same time; the oxidation appeared to be correlated with the time in vivo. Another article looked at retrievals and measured oxidation immediately upon retrieval and after storage in air. There was minimal oxidation in these explants at removal, but when the explanted polyethylene was put on the shelf oxidation levels increased."

"Looking at an article from Boston, there was no difference comparing the 28mm and the 32mm, but there appeared to be a slight trend for the 32mm to be greater. In another article—by Lachiewicz—they looked at 36mm and 40mm heads and actually saw greater volumetric wear. They advised caution using larger femoral heads in younger, active patients. So they combined theirs: 534 hips, two techniques (a dual radiographic technique looking at the

one year film and the follow-up film and then a group regression)."

"In the dual radiographic technique the large heads had significantly increased linear and volumetric penetration. But when they analyzed it differently they had no significant difference. They concluded that the differing statistical analysis makes interpretation difficult."

"Component position: An award winning article indicated that as many as 50% of hips that are put in are outside of the target range, potentially leading to edge loading and cracks at the edge of the polyethylene."

"Patients who are focused on function are not too concerned about longevity, and are pushing the limits of total hip. Lastly, taper corrosion. We've seen a bit of that with MOM, and I believe it is reappearing with metal on polyethylene."

"Lastly, I want to point out an article from Henrik in 2011 on the introduction of innovations. The case studied was that of heavily cross-linked polyethylene. He indicated that the clinical experience to date, although it generally supported the use, recent data emphasizes that the outcome is not clear, even after nine years. Thank you."

Moderator Thornhill: "That's harsh, Andy. Let's pick on Seth! I have patients who want the 30 year knee based upon laboratory testing. Can you extrapolate it out to 30 years?"

Dr. Malchau: "Hard to predict, and I don't know how many of our hips will still be working in 30 years. But I don't think that the current literature on explants contradicts a good long-term result. Despite the fact that we found oxidation in the sequential irradiated polys, Crossfire and X3, we still have to get the clinical failures. The paper you quoted, Andy, from Dartmouth—there's really no control there at all of how those explants are stored. Most of the oxidation in that paper is probably happening after explantation."

Moderator Thornhill: "Hips are failing with dislocation, with periprosthetic fracture, etc. What do you tell a patient?"

Dr. Engh: "I think this poly is good—I use it all the time. What I'm trying to do is avoid the 36/38/40mm heads."

Moderator Thornhill: "Yes, but how long is my hip going to last, Dr. Engh?"

Dr. Engh: "You're going to take yours with you."

Moderator Thornhill: "We have a bioethics course here at noon. Anyway, so what is your preferred head size?"

Dr. Engh: "32mm"

Moderator Thornhill: "Henrik?"

Dr. Malchau: "32mm"

Moderator Thornhill: "Henrik, do you still use metal-on-metal?"

Dr. Malchau: "I do."

Moderator Thornhill: "What percentage of your practice is resurfacing?"

Dr. Malchau: "Around 5%. My only problem with resurfacing is that I did two or three females and they come back now with a contralateral hip and ask me to do that, but I won't do it. But the big males they're doing great."

Moderator Thornhill: "So minimal thickness of poly in a hip, in the dome and in the periphery…"

Dr. Malchau: "Dogma says that it needs to be 6mm, but I don't believe that's needed with the modern highly cross-linked polys. I think we can go thinner, which means we can have more conservative bone resection on the acetabular side. I would go 36mm in elderly patients with dislocation risks, but in a younger patient I would stay at 32mm."

Moderator Thornhill: "What's the minimal thickness of polyethylene that you would accept at the dome and at the periphery?"

Dr. Malchau: "At the dome, four; at the periphery, two."

Moderator Thornhill: "Two at the periphery, even though in something that's a little vertical the edge wear…"

Dr. Malchau: "Even the edge loading, that's fine."

Moderator Thornhill: "You have a robust revision practice as well."

Dr. Malchau: "I get all the patients from Brigham, yes."

Moderator Thornhill: "Andy, same question."

Dr. Engh: "I would say 4mm and 4mm. The rim…that's the area that's exposed to the joint fluid…the area that if it's going to oxidize and if the oxidation is going to be important then we'll see it there. It needs to be a good modern design; if that 4mm is captured within the metal and supported it's OK, but a lot of these designs are getting that 4mm by lateralizing the poly 2mm and 4mm. I'm cautious about using the first polyethylene that I can use with a larger head size, in other words that 36mm and a 52/54mm because they have to get the edge by lateralizing that polyethylene…that puts load."

Dr. Malchau: "You mean the poly needs to be supported by metal or cement? You need to support it; you can't build up the rim. It's going to fail."

Moderator Thornhill: "When you're talking about your minimal thickness you're talking about something that's got low wear, good mechanical properties, and is oxidatively stable."

Dr. Malchau: "The Swedish randomized trial showed a blip from five to seven [years], but when they got follow up at 10 years that blip disappeared. What we did to get that answer was to initiate a multicenter U.S. study where we couldn't reproduce that finding. The Swedes have since addressed it and there is no increase anymore."

Moderator Thornhill: "I'm trying to find areas of disagreement."

Dr. Malchau: "We did have 500 patients in the large head multicenter study and we have a slight increase in linear wear rates. Of course that will translate to a higher volumetric wear rate, but it's still unclear what is the best way to calculate volumetric wear. So there are indications in one of the analyses we did that 36mm is associated to a slightly increased linear wear rate. But still, there are a number of statistical issues… we have three statisticians fighting for a year over which way to go. And I still don't know. Two or three methods show no significant difference."

Moderator Thornhill: "Andy, last word."

Dr. Engh: "I think we agree on more than we disagree. There are concerns, and we still need to look at the explants."

Moderator Thornhill: "Henrik, a question from the audience. 'Will vitamin E be the solution to the melt/annealing property and maintaining oxidative resistance without losing mechanical properties?'"

Dr. Malchau: "No doubt that vitamin E in the lab tests has a mechanical toughness that's the best we have seen so far. Will the vitamin E stay in the poly? We're trying to do anything to chase it out—boil it in lipid solvents—we can't get it out. But we need to collect data; so far it looks good, but it's early."

Moderator Thornhill: "Thank you." ♦

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

"You may now view content from the CCJR Meetings on the CCJR Mobile™ App. Please scan the QR code to download the CCJR Mobile App to your Android or iOS mobile device, or visit www.ccjrmobile.com."

From left to right, Dr. Freddie H. Fu, Special Guest Speaker at the Congress and Chairman of Orthopaedic Surgery at the University of Pittsburgh; Christopher D. Murawski, research fellow for Dr. Kennedy; Dr. John G. Kennedy, Co-Chairman of the Congress and Foot and Ankle Surgeon at Hospital for Special Surgery; Prof. C. Niek van Dijk, Co-Chairman of the Congress, President of ESSKA and Orthopaedic Head at the Academic Medical Center, University of Amsterdam.

On (and Off) the Record

By Elizabeth Hofheinz

$44K CMS Bounty and How to Get It…Bundling to Increase Income? …Most Commonly Injured Joint Diagnosis Being Standardized…the "Bible" of Orthopedic Oncology Surgery Released…Previous NIH Grant Winner Does it Again!…and more.

$44,000 CMS Bounty for EHR: What You Need to Know For ten years, Herb Alexander, M.D., a retired captain in the U.S. Navy, has been asked by AAOS (American Academy of Orthopaedic Surgeons) to give lectures on the importance of electronic health records (EHR). Dr. Alexander, who is president of the Society of Medical Consultants to the Armed Forces, tells *OTW*, "Regardless of how we feel about it, paper is on the way out of medical offices. Efficiency aside, the major incentive for converting to EHR is the fact that Medicare will begin penalizing us if we don't use it. I've had time to get used to it…and I love it. My interest in EHR goes back to when I was in the Navy. There were different computer systems for different functions…one for appointments, another for lab tests, one to register for X-ray and none of them 'talked to' each other. I swore that if I ever got into practice I'd have one system that handled everything. In 2002 I did just that…

and ended up being an early adopter of the electronic office, something that has increased my efficiency by leaps and bounds.

"How to do this? Begin by contacting different vendors and doing an RFP. There are programs with lots of bells and whistles, but if it's not what you need then it's not helpful. Something important to recognize is that if a vendor is not focused on educating you about their program then they are probably selling you a bill of goods. Any legitimate vendor should be willing to send you a demo so you can try their system. Equally as critical is to ensure that this vendor will stand by you for 'meaningful use.' CMS [Centers for Medicare and Medicaid Services] will pay doctors up to $44,000 if they convert to EHR, but to get that money the software has to be certified for 'meaningful use.' Ease of use is also important…you don't want it to slow you down such that it takes time away from patients. The most efficient systems use voice recognition and templating. And my experience has been that patients feel more comfortable knowing that all of their information is in an EHR. They are impressed when they can leave my office with a paper copy of everything I just did."

First in Ten Years: Oncology "Bible"

James C. Wittig, M.D., along with Martin Malawar, M.D. and Jacob Bickels, M.D., have co-authored "Operative Techniques in Orthopedic Surgical Oncology," the first book of its kind in ten years. Dr. Wittig, Chief of Orthopedic Oncology at Mount Sinai Medical Center in New York, tells *OTW*, "My co-authors and I have tremendous experience in treating these types of patients. We have also developed surgical techniques that have been proven to be reliable and safe methods of dealing with different types of tumors. With

this book, residents, fellows and practicing orthopedists have step-by-step instructions to treating any and all type of tumor. Also making this book special are the hundreds of color illustrations demonstrating what amounts to 10 to 20 years of surgical techniques…not to mention the videos that correlate with the specific procedures.

"Most orthopedists don't see many tumors, and are understandably less informed about how to handle certain situations. This book shows you how to 'stay out of trouble,' especially with biopsies—something that is so important that done wrong, can result in unnecessary amputation. Each step for each kind of tumor in each anatomic location…that is what we have laid out."

Most Commonly Injured Joint Diagnosis Being Standardized – Finally!

John Kennedy, M.D., is an assistant attending orthopedic surgeon at Hospital for Special Surgery (HSS). He recently co chaired the International Congress on Cartilage Repair of the Ankle in Dublin, Ireland, with Drs. Rick Ferkel and Niek van Dijk. Dr. Kennedy tells *OTW*, "We brought together a panel of 25 surgeons and scientists as well as over 200 attendees from the U.S., Europe, Asia and Australia to establish a foundation for international collaboration and innovation regarding ankle cartilage care. One of the topics we tackled was whether to repair or replace cartilage defects…the debate was, 'Should we consider microfracture repair in lesions below 1.5cm or reduce that size knowing that when we repair there will be degradation of the repaired fibrocartilage after ten years?' We haven't answered that question conclusively yet but we do know that we should not ignore these lesions regardless of size. The fact is that every time we treat an ankle fracture we are potentially walking away from the table with the job half done. Why? Because we know that the cartilage has been damaged—and that may be a good reason to at least look inside the joint when you are fixing the fracture.

"Perhaps the most important thing we did was tackle this longstanding controversy: how to standardize the diagnosis of an osteochondral lesion of the talus (OCL). We have the luxury of an MRI here in the U.S., whereas in the rest of the world this technology is not always readily available. In areas where CT scan is used as a diagnostic tool it measures the bony defect but not the cartilage defect either at the initial diagnosis or at follow up. Ideally a combination of MRI and CT scan would give us the best imaging of this challenging lesion. At some point MRI with T2 mapping will become more universally available. This will really give us the information we are looking for as it can tell us the quality of the reparative tissue as well as the quantity of the tissue repair.

"Over the next six months or so the participants will attempt to standardize the issues of diagnosis, treatment and follow up of talar OCLs. The AO Foundation did this for fracture fixation four decades ago and it has made a huge difference for patients and surgeons. The exciting thing is the progress we've made so far in this field in a short period of time. Ten years ago this event could not have happened as there was little interest in ankle cartilage. Amazing, really…given that the ankle is the

most commonly injured joint in an athlete. It's now considered to be 'sexy' and that's good for all of us."

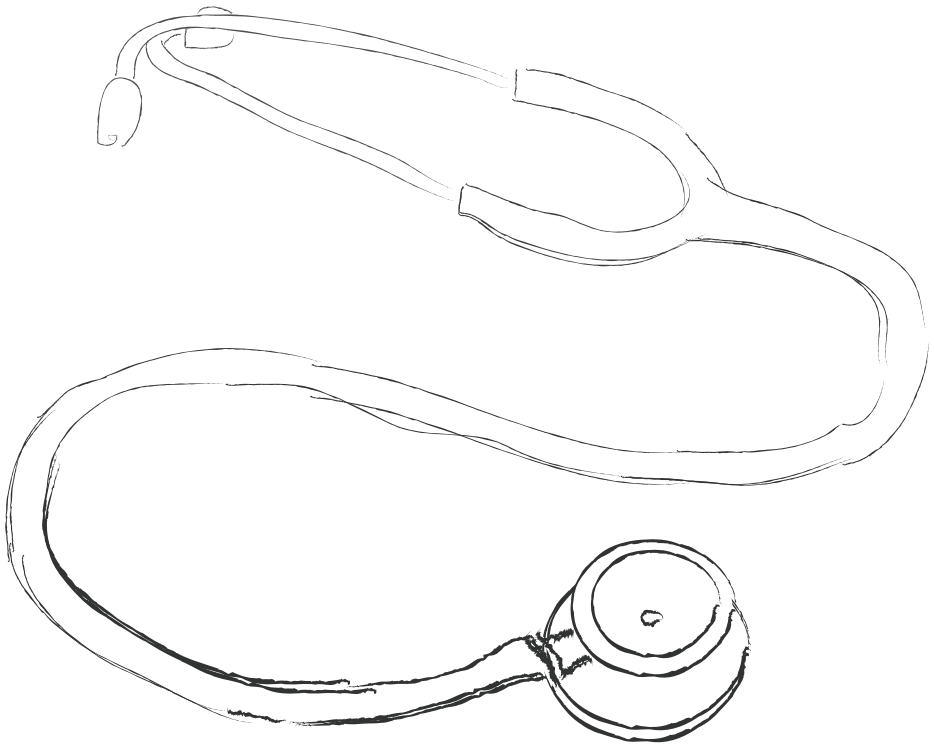
Bundling to Increase Reimbursement? A Horizon Blue Cross Blue Shield program in New Jersey just might be a snapshot of what's coming your way. Richard Popiel, M.D., M.B.A., president and chief operating officer of Horizon Healthcare Innovations tells *OTW*, "We launched our Joint Replacement Episode of Care Program in January 2011, and we now have more than 30 joint replacement surgeons participating in this initiative. By paying one sum for episodes of care we are helping to not only meet the national agenda to reduce healthcare costs, but the effort to improve quality as well.

"Surgeons are surgeons because they like to be in the OR…we asked these practices to think differently. We asked them to think about costs as related to the period prior to surgery, the period after surgery, the post discharge period (up to 90 days), as well as the time the patient is in the hospital. Did the patient get the appropriate prophylaxis for DVT [deep vein thrombosis]? Cost… the major cost is the inpatient experience and the key driver there is cost of the implant. Discharge—we had to understand where someone was being discharged to and the relative advantages of skilled nursing/rehab/homecare. To ferret through all this we used a technology called Prometheus, which groups all the pieces of an episode.

"In our preliminary results we are seeing 100% compliance with prophylaxis, and every case is getting the appropriate preop antibiotics…great quality outcomes. *As for reimbursement, this has the potential to increase compensation for doctors and/or hospitals because in some cases hospitals and doctors are partnering.* We want to provide rewards for eliminating things that add no value like extra days in a post acute facility. *But a fundamental point here is that there are safeguards to ensure that we don't create any perverse incentives to cut corners. A physician cannot access additional compensation unless he or she triggers certain quality parameters."*

Melissa Kacena, Ph.D. Awarded Second NIH R01 Grant Melissa Kacena, Ph.D. is Assistant Professor of Orthopaedic Surgery Indiana University School of Medicine…and she is now the recipient of two NIH R01 [National Institutes of Health] grants. This latest grant will fund research on how the protein thrombopoietin can enhance bone healing in mice. Dr. Kacena was only awarded her first R01 this past fall–Regulation of Osteoblast Function by Megakaryocytes: Key Signaling Proteins. Dr. Kacena received her Ph.D. in Aerospace Engineering from the University of Colorado, Boulder in collaboration with Harvard Medical School and NASA Ames Research Center in 1999. She then began her postdoctoral training in the Department of Orthopaedics and Rehabilitation at Yale University School of Medicine. In 2002, she was promoted to research faculty at Yale and was subsequently promoted to Assistant Professor in 2005. Dr. Kacena was recruited to IU in 2007.

Her past honors include the American Society for Bone and Mineral Research Young Investigator Award, the Advances in Mineral Metabolism/American Society for Bone and Mineral Research Young Investigator Award, the National Society for Histotechnology Diamond Cover Award, the Sun Valley Workshop on Skeletal Tissue Biology, Alice L. Jee Memorial Young Investigator Award, and the US Bone and Joint Decade Young Investigators Initiative. ♦



company

Biomet Pays to Defer Bribery Prosecution

U.S. Attorney's Office/Wikimedia.com

The U.S. Department of Justice's Criminal Division (DOJ) announced on March 26, that Biomet, Inc. has entered into a deferred prosecution agreement (DPA) with the government to, "resolve improper payments by the company and its subsidiaries in violation of the Foreign Corrupt Practices Act (FCPA)."

Biomet agreed to pay over $22 million to avoid prosecution and resolve charges brought by the DOJ under the FCPA.

Bribery Investigation

According to the announcement, the matter is part of an investigation into bribery by medical device companies of health care providers and administrators employed by government institutions. Previously, Johnson & Johnson and Smith & Nephew Inc. have agreed to pay criminal penalties and entered into deferred prosecution agreements related to the ongoing investigation. The resolution was reached after the company agreed to enter into a Deferred Prosecution Agreement.

According to the criminal information filed on March 26 in U.S. District Court in the District of Columbia, Biomet, its subsidiaries, employees and agents, "made various improper payments from approximately 2000 to 2008 to publicly-employed health care providers in Argentina, Brazil and China to secure lucrative business with hospitals. During this time, more than $1.5 million in direct and indirect corrupt payments were made. In addition, at the end of each fiscal year, Biomet, its executives, employees and agents falsely recorded the payments on its books and records as 'commissions,' 'royalties,' 'consulting fees' and 'scientific incentives' to conceal the true nature of the payments."

In China, a "Kind Word"

Sales in China, according to published reports, were made through a distributor who was known to provide publicly employed doctors with money and travel. In 2001, he sent an e-mail to Biomet that said:

"[Doctor] is the department head of [public hospital]. [Doctor] uses about 10 hips and knees a month and it's on an uptrend, as he told us over dinner a week ago. …Many key surgeons in Shanghai are buddies of his. A kind word on Biomet from him goes a long way for us. Dinner has been set for the evening of the 24th. It will be nice. But dinner aside, I've got to send him to Switzerland to visit his daughter."

Compliance Monitor

Under the DPA, the DOJ agrees not to prosecute Biomet, provided the company satisfies its obligations under the agreement over the next three years. The DPA calls for the appointment of an independent external compliance monitor to review the company's compliance with the DPA, particularly in relation to Biomet's international sales practices, for at least the first 18 months of the three year term of the DPA.

Biomet agrees to pay a $17,280,000 penalty to resolve the DOJ charges. The company also agreed in a Consent Agreement to "disgorge profits and pay prejudgment interest" in the aggregate amount of $5,575,731 to settle civil claims with the SEC (Securities and Exchange Commission).

Biomet's President and Chief Executive Officer, Jeff Binder, stated: "Biomet has long been committed to upholding the highest standards of ethical and legal conduct both in the United States and abroad. Over the past several years, we have significantly enhanced our global compliance procedures and financial controls, and we fully intend to work with the independent monitor and the Department of Justice and Securities and Exchange Commission to bolster our FCPA compliance practices and procedures. Moving forward, we intend to continue to adhere to our enhanced

global compliance procedures, and to promote the Company's commitment to the highest ethical standards in all the markets that we serve."

Biomet Cooperation

The DOJ press release stated the agreement, "recognizes Biomet's cooperation with the department's investigation; thorough and wide-reaching self-investigation of the underlying conduct; and the remedial efforts and compliance improvements undertaken by the company. In addition, Biomet received a reduction in its penalty as a result of its cooperation in the ongoing investigation of other companies and individuals."

—WE (March 27, 2012)

legal

FDA Issues De Novo Guidance

When you go to the FDA for premarket approval (PMA) to market a Class III medical device, the petitioner can make the case that a substantially equivalent (SE) product already exists and should be allowed to go through the less expensive and time-consuming 510 (k) clearance route.

But what if your device is a novel, low- to moderate-risk device without a previously approved SE, or predicate, device?

If you could make the low risk argument, you could petition the FDA to allow your device to get to market through the de novo process, which is also less time consuming and expensive. But how does the FDA weigh the benefits against risks of your device? Up until now, there had not been a common framework for benefit-risk determination.

Benefit-Risk Determinations for De Novo Classifications

On March 28, the FDA released its long promised, "Guidance for Industry and Food and Drug Administration Staff - Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications."

The guidance document includes a worksheet that a reviewer will use in making the benefit-risk determinations as part of the premarket review process.

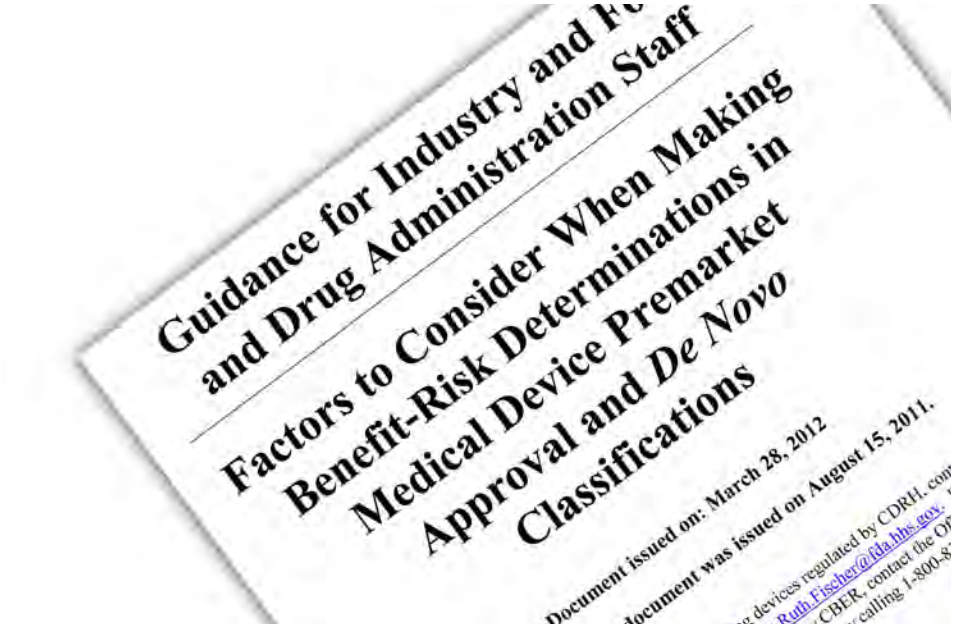
The FDA says, the worksheet incorporates the principal factors that influence benefit-risk determinations, such as the type, magnitude and duration of a risk or benefit, the probability that a patient will experience the risk, patient tolerance for risk, availability of alternative treatments, and the value the patient places on treatment.

In addition, the guidance:

- Outlines the systematic approach FDA device reviewers take when making benefit-risk determinations during the premarket review process
- Provides manufacturers a helpful tool that explains the various principal factors considered by the agency during the review of PMA applications, the regulatory pathway for high-risk medical devices, and de novo petitions, a regulatory pathway available for novel, low- to moderate-risk devices
- Describes an approach that takes into account patients' tolerance for risks and perspectives on benefits, as well as the novelty of the device.

Shuren: "More Clarity, Predictability, Consistency and Transparency"

"This guidance clarifies this process for industry, which will provide manufacturers with greater predictability, consistency and transparency in FDA decision-making while allowing man-



U.S. FDA

ufacturers and the FDA to use a common framework for benefit-risk determinations," said Jeffrey Shuren, M.D., director of FDA's Center for Devices and Radiological Health (CDRH).

The FDA will also increase the transparency of the decision-making processes by describing the worksheet analysis in the Summary of Safety and Effectiveness Data for PMAs and the decision summary review memos for de novo decisions.

"In addition to bringing clarity to our decision making for industry, this guidance will provide our reviewers with uniform and consistent guidelines to assess probable benefits and risks," said Shuren.

CDRH will train medical officers, review staff managers and device reviewers on the guidance to assure the guidance is applied consistently to submissions and petitions. CDRH reviewers will begin applying the guidance to incoming PMA and de novo submissions and to submissions already under review with decisions beginning on May 1.

The FDA is also developing external training modules to help industry and device sponsors understand how CRDH will apply the guidance.

To view the new guidance document, **click here:**

—WE (March 30, 2012)

FDA Calls Special Metal-on-Metal Meeting

The FDA says a recent study noting an increased failure rate of metal-on-metal (MoM) hip systems that utilize large-diameter femoral heads has "added to the agency's existing concerns." In response the agency announced on March 29, that it will convene its Orthopaedic and Rehabilitation Devices Panel on June 27-28, 2012.

OTW reported on a call by the British Hip Society to ban the devices as well as a study based on data from the National Joint Registry of England and Wales. We asked whether American surgeons would heed their British counterpart's warnings. Looks like the FDA was watching.

The British study found that MoM total hip replacements failed at "high rates." Failure, wrote the authors, was related to head size, with larger heads failing earlier (3.2% cumulative incidence of revision [95% CI 2.5—4.1] for 28 mm and 5.1% [4.2—6.2] for 52 mm head at five years in men aged 60 years).

The agency will seek the panel's expert scientific and clinical advice on the risks and benefits of MoM hip systems as well as potential patient and practitioner recommendations on the use of MoM hip systems and the management of patients implanted with such devices.

Two categories of systems will be considered:

1. Metal-on-metal total hip replacement systems consisting of a metal ball (femoral head), a metal femoral stem in the thighbone, and a metal cup in the hip bone (acetabular component)
2. Metal-on-metal hip resurfacing systems consisting of a trimmed femoral head capped with a metal covering and a metal cup in the hip bone (acetabular component).

In May 2011, the agency issued an order for manufacturers of MoM hip systems to conduct post-market surveillance studies to collect more safety data on these devices, including data related to metal ion concentrations in the bloodstream.

In February 2012, the United Kingdom's FDA counterpart, the MHRA, (Medicines and Healthcare [products] Regulatory Agency) published a Medical Device Alert with updated advice on the management and monitoring of patients implanted with MoM hip systems recommending more aggressive follow-up of patients with larger total hip systems (.36 mm).

In December 2011, the American Academy of Orthopaedic Surgeons (AAOS) published an overview on MoM hip systems. The AAOS overview provides a summary of clinical outcomes in patients with MoM hip systems.

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

The agency is currently considering whether to make MoM hip systems subject to more rigorous testing and premarket review requirements.

"We are asking outside scientific and medical experts to discuss recent information on these devices so that the agency can continue to make reliable safety recommendations to patients and their health care providers," said William Maisel, M.D., M.P.H., deputy director of science at FDA's Center for Devices and Radiological Health (CDRH).

Experts on CDRH's Orthopedic Devices Panel will discuss:

- Failure rates and modes
- Metal ion testing
- Imaging methods
- Local and systemic complications
- Patient risk factors
- Considerations for follow-up after surgery.

The location of the meeting is yet to be determined. For full details of the meeting, **click this link** to the Federal Register:

—WE (March 30, 2012)

Justices Question Mandate

After listening to the first two days of hearings before the Supreme Court over the constitutionality of the Affordable Care Act, we think opponents of the law have every reason to be optimistic that the Court will strike down the law in June.

On day one, March 26, the Justices seemed to indicate through their questioning of an independent constitutional expert, that they had the power (jurisdiction) to decide and the law was "ripe" for a court decision.

On day two, March 27, the Justices focused on the Mandate requiring people to purchase health insurance.

Justice Kennedy is widely regarded as a swing vote between four liberal and four conservative Justices. Here's what he had to say to the government lawyer defending the law:

"The reason this [the Mandate] is concerning, is because it requires the individual to do an affirmative act. In the law of torts our tradition, our law, has been that you don't have the duty to rescue someone if that person is in danger. The blind man is walking in front of a car and you do not have a duty to stop him absent some relation between you. And there are some severe moral criticisms of that rule, but that's generally the rule.

"And here the government is saying that the Federal Government has a duty to tell the individual citizen that it must act, and that is different from what we have [said] in previous cases and that changes the relationship of the Federal Government to the individual in [a] very fundamental way."

Chief Justice Roberts expressed concern over the government's position that because everyone is in a health care "market," it can regulate it. "But next year, they can decide everybody's in [a particular] market, we're [the government] going to look at a different problem now, and this is how we're going to regulate it. And we can compel people to do things—purchase insurance, in this case. Something else in the next case, because you've—we've accepted the argument that this is a market in which everybody participates."

On the third day of the Court session, the Justices will hear arguments over whether or not the rest of the law can stand without the Mandate and if the law imposes a burden on states by expanding Medicaid.

While the questioning seemed to indicate Justices had problems with the law, court prognosticators have been notoriously bad at predicting the Court's ultimate decision based on their questions.

—WE (March 27, 2012)

Supreme Court

biologics

Stem Cells Mimic Anti-Rejection Drugs

Morguefile and DSC03798_w.jpg

The fact that mesenchymal stem cells can differentiate into bone, cartilage, fat and other body tissues is no longer news. But a new finding from a transplant study led by scientists from the Diabetes Research Institute at the Miller School and a DRI Federation center at Xiamen University in China showed that mesenchymal stem cells may also replace a powerful anti-rejection drug in transplant recipients.

The study involved kidney transplant patients and the results are published in the March 21 issue of the *Journal of the American Medical Association*. Reviewers suggest that the results of the study may fundamentally transform the future of clinical transplantation.

As outlined by *Health Canal.com*, patients undergoing a transplant routinely receive a regimen of immunosuppressive therapy to block the body's immune system from rejecting the donor organ or cells. While these drugs improve graft function and minimize rejection episodes, they increase the risk of dangerous side effects, including infections and organ toxicity.

To eliminate these adverse effects, scientists at the Diabetes Research Institute have been investigating safer methods for preventing transplant rejection. They turned to naturally occurring cells in the body that have immunomodulatory properties, like mesenchymal stem cells. They found that stem cells also have the ability to modulate the immune system by inhibiting T-cell proliferation, eliminating graft-versus-host disease, limiting cytotoxic inflammation and stimulating vascularization.

In the study, patients with end-stage renal disease received infusions of bone marrow-derived autologous mesenchymal stem cells together with either standard-dose or low-dose calcineurin inhibitors. The control group received an immunosuppression regimen consisting of anti-IL-2 receptor antibody plus standard-dose calcineurin inhibitors.

After one-year post-transplant the use of autologous mesenchymal stem cells (compared with the standard immunosuppressive therapy) resulted in lower incidence of acute organ rejection, decreased risk of infection and better kidney function.

"We reported on the first 12 months follow-up, which showed no adverse events associated with mesenchymal stem cell therapy," said Antonello Pileggi, M.D., Ph.D., director of the Preclinical Cell Processing and Translational Models Program the Cell Transplant Center of the DRI. "We will continue monitoring the patients in the study to assess the long-term effects on kidney transplant function and survival, as well as the safety of stem cell transplantation in this setting. Should long-term safety be confirmed, it may be valuable for improving transplantation outcomes while reducing the risks associated with anti-rejection drugs."

"This study represents a first, important step toward the definition of cell-based strategies that will one day allow for transplantation without the need for life-long anti-rejection drugs," said Camillo Ricordi, M.D., director of the University of Miami Diabetes Research Institute and Cell Transplant Center, the Stacy Joy Goodman Professor of Surgery, Distinguished Professor of Medicine and professor of biomedical engineering, and microbiology and immunology. The study was supported in part by grants from the Key Science Research Project and the Key Laboratory, both of Fujian Province, China

large joints

Diagnosing Knee OA? Use Tomosynthesis!

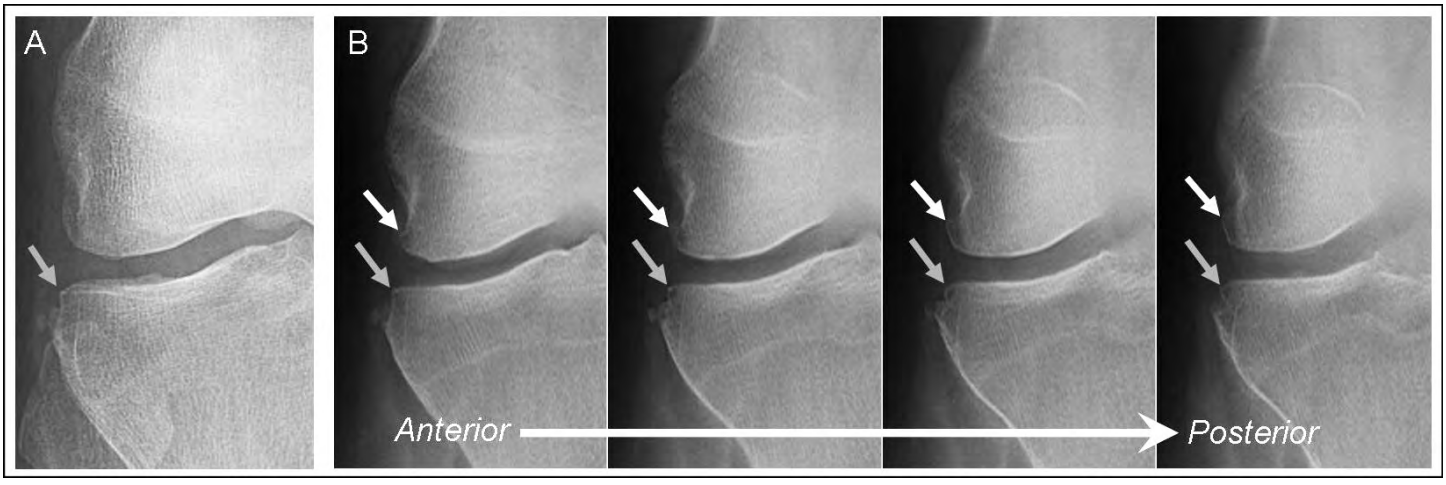
A team from Boston University School of Medicine (BUSM) has found that tomosynthesis may be more beneficial in diagnosing knee osteoarthritis than X-ray imaging. Daichi Hayashi, M.D., Ph.D., research instructor at the Quantitative Imaging Center in the department of radiology at BUSM, is the lead author of the study. The research was led by Ali Guermazi, M.D., Ph.D., professor of radiology at BUSM and chief of musculoskeletal radiology at Boston Medical Center.

They found that tomosynthesis, compared to X-ray, improves the detection of osteophytes in the knee joint in patients with or without osteoarthritis. The sensitivity for detecting osteophytes increased by five to 29% with tomosynthesis compared to X-ray. The sensitivity for detection of subchondral cysts in the knee joint increased by 11 to 50% with tomosynthesis compared to X-ray. Also, those with tomosynthesis-detected osteophytes and cysts were more likely to feel pain than those without the lesions.

When asked what would prevent tomosynthesis from being widely used for knee OA, Dr. Hayashi told *OTW*, "There needs to be a study (or analysis) to assess the cost-effectiveness of the tomosynthesis in comparison to conventional X-ray. It is known that MRI is the current best imaging modality for visualizing features of knee OA, but because MRI is expensive, it cannot be used in routine clinical practice. If tomosynthesis's improved sensitivity for knee OA features makes economical sense, then it can be recommended for wide spread use. Another important consideration is its clinical relevance and how it can change the current medical practice, which is largely dependent on conventional radiography. Our study showed tomosynthesis can detect small bony lesions that radiography may miss, but those lesions that are missed may not be clinically important. Again, MRI can show various pathological features of knee OA that conventional radiography (or tomosynthesis) cannot. However, management of knee OA patients is essentially clinical, i.e., based on symptoms and NOT dependent on the imaging features themselves. Some patients may be completely asymptomatic with lots of pathological findings on MRI. Conversely, some patients may have knee pain despite no obvious pathological features on radiography or MRI. In these cases, patients with pain will be treated, and asymptomatic patients may not even realize they have knee OA in the first place. The same discussion will apply to tomosynthesis as well."

Dr. Hayashi also commented to *OTW*, "The beauty of tomosynthesis is that it can acquire tomographic images (i.e., slices) when the patient is standing. This is not possible with CT or MRI. Thus, perhaps tomosynthesis can be applied to imaging of lower limb pathologies in which weight-bearing is an important aspect. I personally think tomosynthesis also has a potential to be used in imaging of musculoskeletal pathologies other than OA, but research studies looking at musculoskeletal imaging using tomosynthesis are limited to date."

—EH (March 28, 2012)



BUSM

Overeager Runners Injure Their Knees

It may be the fault of the early spring, but runners in the upper Midwest, in their eagerness to hit the road, appear to be falling all over themselves. Staff members of the Regions Hospital Rehabilitation Institute, located at Regions Hospital, Saint Paul, Minnesota, have seen an 86% increase in the number of people needing physical therapy for a running injury. And that is just since 2011, according to physical therapist Lisa Zeman, the compiler of the statistics.

Sixty percent of the injured runners are female, which suggests that many may be participating in the sport for the first time. The majority of the injuries—45%—center on the runners' knees.

Zeman cautions runners not to increase their distance too rapidly, saying that a 10% increase in mileage per week is the limit. Many people are running too far and it is this overtraining that is damaging their knees, she says.

After overtraining, the two most common causes of injury are improper technique when running and improperly fitted shoes. To diagnose problems relating to technique, the Institute tapes runners while running to see how they land on their feet, if their pelvises are level and how they move their legs. The busiest time for the Rehabilitation Institute will be in May when hundreds of runners begin training for marathons.

—BY (March 25, 2012

Wikimedia Commons and Pil Kang

extremities

Symmetry Enhances BOOKWALTER System

Lighter and now with reusable radiolucent blades…Symmetry Medical Inc. has announced the launch of 12 new line enhancements to the BOOKWALTER Retractor System through its hospital direct surgical instrumentation division, Symmetry Surgical.

These product enhancements reduce the overall tray weight of a complete BOOKWALTER table mounted retractor system while providing increased usability. Another new feature is the introduction of reusable radiolucent blades for use in procedures where an intra-operative X-ray is used as part of the surgical intervention. In support of meeting the challenges of surgical intervention on the obese patient population, an expanded ring system has been added to increase surgical exposure and also enhance the benefits of Symmetry Surgical's OPTI-LENGTH surgical instruments.

"Good exposure is the key to good surgery," said John Bookwalter, M.D., inventor of the BOOKWALTER system, in the March 23, 2012 news release. "We have managed to maintain the integrity and stability of the BOOKWALTER Retractor System, while reducing the overall weight of the system. This is important to the Nurses and Technicians who have to lift and move these sets throughout the day."

Thomas J. Sullivan, President and Chief Executive Officer of Symmetry Medi-

Symmetry Medical Inc.

cal, added, "These innovative enhancements to the BOOKWALTER portfolio align perfectly with our strategy of bringing innovation to the marketplace with proprietary, IP-backed technology. We are thrilled to provide products that will expand and enhance usability for our clinician base and assist them in serving the needs of their valued patients."

Dr. Bookwalter told *OTW*, "The orthopaedic environment provides unique challenges due to joint mobilization. We are working hard to provide cost effective solutions to these challenges. I am confident that one great option is the recently launched Radiolucent Titanium BOOKWALTER Blades. These 10 blades are fully reusable, have very little to no artifact and are fully backwards compatible with all of our retractor components. This allows a hospital to utilize the BOOKWALTER System that they already own in procedures that require the use of intraoperative imaging."

—EH (March 30, 2012)

Buz Burkhead, M.D.: YouTube Singing Sensation

He doesn't sport his gold lamé coat in the OR, but he does regale those present with a superb Joe Cocker imitation. Dr. Buz Burkhead, a former president of the American Shoulder and Elbow Surgeons association, says that his mother didn't want him to be a doctor…she wanted a musician for a son. She got both.

Dr. Burkhead, known for the creation of modular replacement for the shoulder, as well as for the development of advanced techniques for rotator cuff repair, tells *OTW*, "My mom—not so supportive of my doctor aspirations—thought that if something couldn't be cured with aloe vera or scotch then it wasn't worth curing. My dad was thrilled to support my medical career, however, because he thought I'd be on the dole with him forever."

Charles A. Rockwood, Jr., M.D., Professor and Chairman Emeritus, Orthopaedic Department, Director, Shoulder Service at the University of Texas Health Science Center. "I trained Buz Burkhead, who for years has been a very close personal friend. I consider him

Buz Burkhead, M.D.

elbow surgeons in the universe but a very talented musician. He is a fun loving character who once made a video of me that he presented to the audience at a national meeting. In the video he's got me dressed as a golfer carrying clubs into the OR. Buz always brings his band—Dr. Buz and the Medications—to our national meeting and performs in that gold lamé coat of his. And yet, he is a highly respected shoulder surgeon… gotta love that."

A graduate of Southern Methodist University, Dr. Burkhead attended University of Texas Medical branch in Galveston, followed by an orthopedic surgery residency at Parkland Hospital. During this time Buz Burkhead received a guitar as a gift—and starting writing songs on progress note paper at 4 a.m. while waiting for another trauma case to roll in.

Many have benefitted from Dr. Burkhead's musical talents. "My friends and I—by way of our band, Doctor, Doctor—have raised more than a million dollars for the Arthritis Foundation. I started something that has evolved into a nationwide annual event. It's called the 'Bone Bash,' and every Halloween there are many such costume charity balls around the country. And of course, my four doctor friends and I are on hand to bring in the funk/rock/Cajun/etc."

When asked how the music side of his life connects with the surgeon side, Dr. Burkhead says, "It seems simple, but it's important. Patients sometimes come in with terrible pain and the fact that they can say, 'Hey doc, how's the band going?' actually helps. It humanizes our contact. I used to tell my patients, 'I'll *give* you my CD if you get better and stop complaining.' Then, with all of the different reductions in reimbursements, I am using my musical career to finance my Medicare hobby. Now I just tell patients that if they buy five CDs they can be seen at 8:30am."

Seriously though…Dr. Burkhead says that his favorite surgery is rotator cuff repair. "Each one is a little different and it's exciting that we now have more offer patients in the way of grafts and improved techniques."

Asked if he has any presurgical routines, Dr. Burkhead tells *OTW*, "I occasionally go into my Joe Cocker routine."

Check out Dr. Burkhead singing, "I'd Get Fat to Feel Better" on YouTube:

http://www.youtube.com/watch?v=w4wodh2Kqe4

—EH (March 23, 2012)

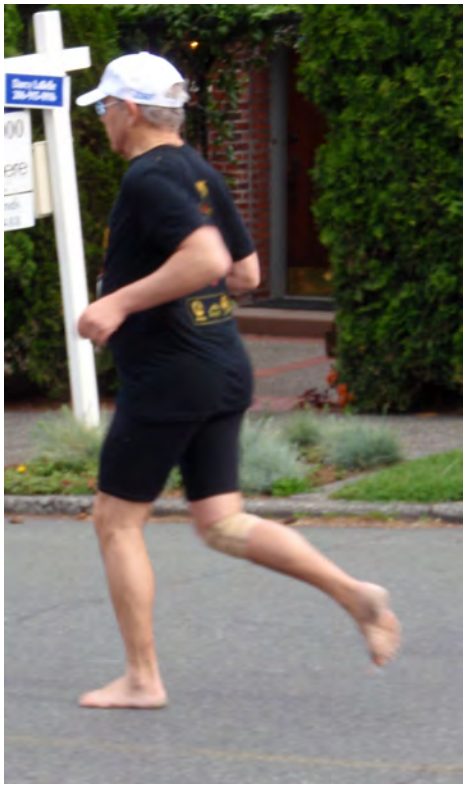
Shoes or No Shoes – The Runners Dilemma

Running barefoot or shod—the debate goes on with proponents on both sides. Advocates of barefoot running claim it is a way to avoid running injuries and gain increased efficiency. They note that wearing shoes forces a runner to carry extra weight on his feet. Studies conducted over the years have found that for every 100 grams of weight a runner adds to his feet, he consumes roughly 1% more energy when he runs. That could be significant as a typical running shoe weighs about 300 grams.

But wait a minute. Now a study by Physiologist Rodger Kram and his colleagues at the University of Colorado's Locomotion Lab has found that runners wearing shoes actually consume less energy than do their counterparts who are running barefoot.

As reported March 18 by Alex Hutchinson of Canada's *Globe and Mail*, researchers measured oxygen consumption, which indicates how much energy runners are burning, while the runners ran either barefoot or in shoes. To vary the amount of weight the runners were carrying they added small strips of lead to the runners' feet.

As expected, adding weight to the runners' feet made them burn more energy—about 1% per 100 grams added—whether they were wearing shoes or not. But surprisingly, for any given amount of weight on their feet, the runners burned 3% to 4% less energy in shoes than when running barefoot. As a result, when all the weights were removed, running in lightweight shoes was found to be more efficient than running barefoot. The shoes conferred an advantage that outweighed the disadvantage of their weight. The shoes



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used in the test were Nike Mayflys, which weight 135.6 grams in a men's size nine.

A possible explanation for this energy savings, Kram said, is that runners use their leg muscles to cushion their bodies from the impacts of running. If the cushioning in the shoes absorbs some of this impact energy, the muscles do not have to work as hard. He added that, for most running shoes on the market, the benefits of cushioning are outweighed by their excess weight. Only ultralight trainers such as the Mayflys offer a net benefit.

As Hutchinson noted, the findings will not put an end to the debate about the ideal running shoe. But they do offer a plausible explanation for why shoes have been so widely adopted: They make running feel a bit easier.

—BY (March 25, 2012)

trauma

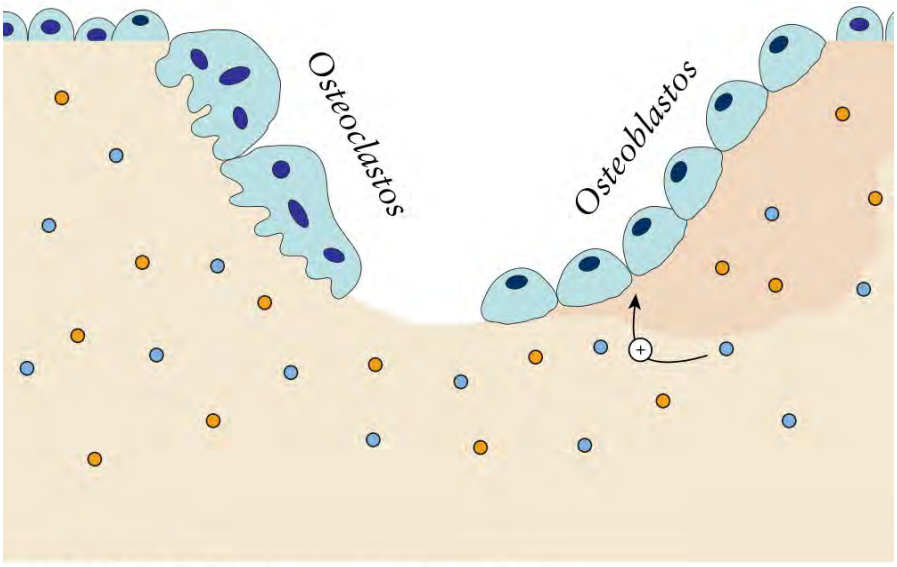
Bone Metabolism and Catch-Up Growth

New research from China has gone where few other studies have… they have looked at the effect of catch-up growth (CUG) on bone metabolism, focusing on adults. In the March 2012 issue of *Experimental Biology and Medicine* the researchers describe the first study to describe the effects of CUG, with different diets, on bone status and the role of resveratrol in CUG models. Dr. Suxing Wang is with the Department of Endocrinology, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China. She told *OTW,* "In our study, we found that bone parameters (bone mineral density, bone mineral content and skeleton area) in resveratrol intervention groups were significantly increased compared with their respective control groups. Studies have demonstrated that resveratrol could stimulate the proliferation and differentiation of osteoblasts. Currently, the bone protective effects of resveratrol have been demonstrated in several osteoporosis models. We also showed that resveratrol could effectively protect bone health in catch-up growth rats. However, we are uncertain its impact on orthopedic patients. We speculate that it also can increase bone density then increases bone strength of orthopedic patients."

The authors note that resveratrol has a protective effect on bone status during the period of CUG, but the exertion of this protective role depends on sufficient nutrition supply. Serum TNF-α levels and body weight also seem to play an important role in regulating bone parameters. Resveratrol has anti-inflammatory effects, increases bone formation but inhibits excessive weight gain. The researchers note that this can be used as a template for synthesizing new drugs, providing a large potential for treatment of overweight and osteoporosis groups.

In the March 7, 2012 news release, Steven R. Goodman, Ph.D., editor-in-chief of *Experimental Biology and Medicine* said, "Wang and colleagues have demonstrated that re-feeding with a normal diet showed a larger improvement in bone mineral density than a high-fat diet. Resveratrol has also been demonstrated to have a protective effect on bone status during the period of catch up growth. As serum TNF-α levels and body weight also appear to play a role in regulating bone parameters this study may have important implications for the treatment of obesity and osteoporosis."

—EH (March 27, 2012)



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spine

Adolescents and Back Pain: New Data

Youth is the beginning of many things…including the body's breakdown. Filling a gap in the literature, Finnish researchers set out to evaluate the role of physical workload in low back pain among adolescents. They found that the duration of work exposure was associated with lower back pain (LBP) in adolescents without LBP at baseline during a time course of two years. Those adolescents—males and females—with high exposure to awkward trunk postures or an overall physically demanding job had a higher likelihood of LBP.

The team studied 1,984 members of the Northern Finland Birth Cohort. Results: 753 (75%) of subjects without LBP at 16 years of age had been working during the two-year follow-up period. The average duration of work was 6.2 months. In adolescent girls, working regularly or irregularly and duration of work exposure were associated with incident LBP. Of specific physical workload factors, only awkward trunk postures were associated with incident LBP in both genders.

When asked what led the team to undertake this research, Professor Jaro Karppinen of the Institute of Clinical Sciences, Department of Physical and Rehabilitation Medicine, University of Oulu, told *OTW*, "We found several studies including a couple of systematic reviews stating that manual material handling, awkward postures and whole-body vibration increase the risk of LBP. Yet, this is still a matter of controversy as the some recent reviews claim that mechanical factors do not have a major pathogenic role. We were impressed that heavy physical job and awkward postures were associated with LBP in both genders irrespective how we analyzed them (either as specific self-reported work tasks or as natural clusters of work tasks). To our surprise the associations were visible only in those with no LBP at 16 years (so-called 'incident' cases). This has not been reported before."

Wikimedia Commons and Robert Michael

Professor Karppinen also commented to *OTW*, "These findings should assist in designing jobs for the adolescents and young adults—their spines do not tolerate abnormal stresses (though this is valid for adults as well). Furthermore, we are interested to know why workload did not associate with LBP among those with LBP at 16 years—it may be that these 'persistent' cases have genetic or other early lifetime factors which render them more vulnerable for persistent pain."

—EH (March 26, 2012)


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