

Orthopedics This Week

WEEK IN REVIEW

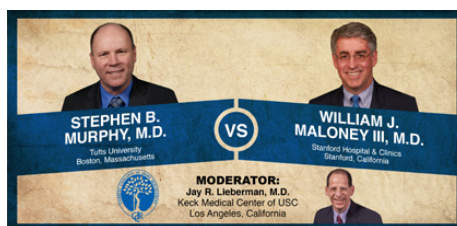
4 New Study: Yoga Builds Bone Mass >> Is yoga an effective way to treat osteoporosis and osteopenia? Standard of care for treating osteoporosis includes exercise—like yoga. A new study attempts to quantify how exercise—specifically yoga—affect bone mass. Loren Fishman, M.D. was principal investigator and his results are summarized here.

8 CMS's 10 Goals for 2016 >> To start the New Year, CMS Acting Commissioner Andy Slavitt gave a major policy speech to the healthcare industry where he laid out CMS's goals for 2016. In a nutshell, CMS wants to be a change agent. And here's how this mammoth bureaucracy plans to do it in 2016.

12 Surprising Study Conclusion: Might Want to Skip PT // Nearly 30% of Residents Are Depressed! // Details on New AAOS Knee OA Guidelines >> New research from the Rothman Institute suggests that formal physical therapy may be unnecessary for THA patients. Meta-analysis reveals that almost 30% of residents are depressed. And the surgeon in charge of the quality and value guidelines at AAOS gives details on the latest recommendations for those undergoing knee OA surgery.



15 Murphy v Maloney: Ceramic on Ceramic THA in Patients <60: A New Standard >> Does a patient's age determine whether to use ceramic-on-ceramic THA? As we saw with the excellent 2013 CCJR debate regarding ceramic-on-ceramic, this is a popular topic. This year Stephen Murphy reminds us that "ceramic-on-ceramic bearings have excellent results" while William Maloney points out that they are not a standard of care and can squeak. Lieberman moderates yet another terrific CCJR debate.



BREAKING NEWS

- 19 **Benvenue Medical Raises \$60 Million**

- 20 **Stryker Caps 2015 With Strong Q4 Sales**

- 21 **Medtech SA: 510(k) From FDA for ROSA Spine Robot**

- 22 **English Junior Docs Strike**

- 24 **Crushable Football Helmet May Prevent Concussions**

- 29 **William N. Levine, M.D. New Editor-in-Chief of JAAOS!**

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Rough start to the year, but there are two important and interesting bright spots. First, orthopedic product sales ended 2015 with vigor and initial reports show that companies will be reporting strong sales and earnings. Second, an under-covered group of small cap orthopedic companies—SeaSpine, Xtant, LDR, Alphatec and Wright Medical—increased in value while the rest of the market fell.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Zimmer Biomet	31.22%	(0.62%)	With the market's sell-off, sales and earnings are doubly important. ZBH is expected to report 14% earnings increase for 2015 full year.
2	3	Stryker	22.94	(2.61)	Stryker pre-announced 2015 results and reported that fourth quarter sales growth accelerated from the third quarter. Strong way to close the year.
3	1	Integra LifeSciences	13.74	(5.03)	IART has consistently exceeded Wall Street's expectations when it comes to earnings reports. The 2015 year-end report should be no different.
4	4	Smith & Nephew	19.66	(3.34)	SNN buys innovative cartilage repair product BST-CarGel from Piramal Healthcare. Important add to SNN's orthopedic portfolio.
5	5	NuVasive	13.35	(6.58)	NUVA pre-announced a solid \$811 million in 2015 sales. With the Ellipse buy, NUVA is clearly a company on the move.
6	6	ConMed	11.10	(6.98)	Analysts are expecting down sales and down earnings for 2015. Then big rebound in 2016.
7	9	Exactech	10.26	6.03	Sells its dental biologics business for an undisclosed amount. Like other small cap ortho equities, EXAC actually INCREASED in value this past month.
8	7	Globus Medical	30.19	(6.95)	GMED pre-announced that sales in the final quarter of 2015 were higher than Wall Street's analysts expected. And management raised 2016 outlook too.
9	8	Medtronic	27.92	(5.45)	MDT, which freed up billions in cash by re-locating to Ireland, announced that it plans to buy back \$5 billion in stock.
10	10	Johnson & Johnson	26.73	(7.84)	It is so interesting that this market sell-off was not across-the-board. Mega-caps like JNJ and MDT plunged. But micro-caps like SPNE, XTANT, LDRH and ATEC rose!

ORTHOPEDICS THIS WEEK PODCASTS LISTEN NOW.

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Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Alphatec Holdings	ATEC	\$0.29	\$29	43.48%
2	MicroPort Scientific	853	\$0.46	\$659	14.69%
3	TiGenix	TIG.BR	\$1.14	\$202	13.55%
4	Exactech	EXAC	\$18.47	\$260	6.03%
5	MiMedx Group	MDXG	\$8.52	\$928	5.19%
6	Orthofix	OFIX	\$39.23	\$741	-0.36%
7	Zimmer Biomet	ZBH	\$101.08	\$20,598	-0.62%
8	Aurora Spine	ASG	\$0.14	\$3	-2.55%
9	Stryker	SYK	\$91.11	\$34,214	-2.61%
10	Smith & Nephew	SNN	\$31.85	\$14,277	-3.34%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	K2M Group Hldgs	KTWO	\$14.47	\$597	-28.68%
2	SeaSpine Hldgs Corp	SPNE	\$14.39	\$160	-11.66%
3	RTI Biologics Inc	RTIX	\$3.34	\$193	-9.73%
4	CryoLife	CRY	\$9.61	\$273	-9.68%
5	Wright Med Grp N.V	WMGI	\$20.82	\$2,137	-9.64%
6	Xtant Medical Hldgs	XTNT	\$2.71	\$32	-9.57%
7	LDR Holding Corp	LDRH	\$20.95	\$608	-8.60%
8	Johnson & Johnson	JNJ	\$97.00	\$268,394	-7.84%
9	ConMed	CNMD	\$39.06	\$1,082	-6.98%
10	Globus Medical	GMED	\$25.32	\$2,411	-6.95%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Exactech	EXAC	\$18.47	\$260	16.60
2	RTI Biologics Inc	RTIX	\$3.34	\$193	16.90
3	Johnson & Johnson	JNJ	\$97.00	\$268,394	16.90
4	Globus Medical	GMED	\$25.32	\$2,411	19.53
5	Stryker	SYK	\$91.11	\$34,214	19.78

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	CryoLife	CRY	\$9.61	\$273	63.06
2	NuVasive	NUVA	\$49.09	\$2,410	56.35
3	MiMedx Group	MDXG	\$8.52	\$928	47.33
4	Smith & Nephew	SNN	\$31.85	\$14,277	28.50
5	Integra LifeSciences	IART	\$62.86	\$2,325	27.63

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	RTI Biologics Inc	RTIX	\$3.34	\$193	1.13
2	Globus Medical	GMED	\$25.32	\$2,411	1.52
3	Smith & Nephew	SNN	\$31.85	\$14,277	1.85
4	Exactech	EXAC	\$18.47	\$260	1.87
5	Zimmer Biomet	ZBH	\$101.08	\$20,598	1.98

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	\$49.09	\$2,410	4.29
2	Medtronic	MDT	\$73.92	\$103,943	3.69
3	Johnson & Johnson	JNJ	\$97.00	\$268,394	3.16
4	MiMedx Group	MDXG	\$8.52	\$928	3.16
5	ConMed	CNMD	\$39.06	\$1,082	2.68

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	\$0.29	\$29	0.14
2	RTI Biologics Inc	RTIX	\$3.34	\$193	0.73
3	Xtant Medical Hldgs	XTNT	\$2.71	\$32	0.91
4	Exactech	EXAC	\$18.47	\$260	1.05
5	SeaSpine Hldgs Corp	SPNE	\$14.39	\$160	1.15

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$1.14	\$202	32.12
2	MiMedx Group	MDXG	\$8.52	\$928	7.85
3	Wright Med Grp N.V	WMGI	\$20.82	\$2,137	6.20
4	Medtronic	MDT	\$73.92	\$103,943	5.13
5	Globus Medical	GMED	\$25.32	\$2,411	5.08

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

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New Study: Yoga Builds Bone Mass

BY WALTER EISNER

In 2005, Loren Fishman, M.D., a physiatrist at Columbia University specializing in rehabilitative medicine, began a small pilot study with 117 patients to determine if a particular form of exercise, yoga, had an effect on bone mass in patients with either osteoporosis or osteopenia.

Four years later, in 2009, the journal *Topics in Geriatric Rehabilitation* published the results of Dr. Fishman's study where he concluded that patients who practiced yoga "gained 0.76 and 0.94 T-scale points for spine and hips, respectively, on the T-scale when compared with controls (P=.01). Five patients with osteopenia were reclassified as normal; 2 patients with osteoporosis are now osteopenic. There were no injuries. The researchers concluded that yoga appears to be an effective way to build bone mineral density after menopause."

The study was small and a number of the patients were not fully compliant with the assigned yoga exercises so Dr. Fishman and his colleagues embarked on a larger study.

The new study, which was also reported in *Topics in Geriatric Rehabilitation* in November 2015, concluded that 12 yoga poses practiced by patients, "appear to be a safe and effective means to reverse bone loss in the spine and the femur and have weaker indications of positive effects on the total hip measurement of the DXA scan. There is qualitative evidence suggesting improved bone quality as a result of the practice of yoga."

More on the specific details of that study below.



Yoga Warrior Pose/Source: Wikimedia Commons and Jessm McIntyre

Impacts of Osteoporosis

In the introduction to his study, Dr. Fishman reminds us that around 200 million people worldwide suffer from osteoporosis and osteopenia. With an aging population, those numbers are likely to go even higher. In the U.S., he cites sources which estimate that the U.S. spends around \$19 billion on more than two million fragility fractures each year. Of those, 700,000 are spinal fractures and more than 300,000 are hip fractures.

He cites evidence that over 55% of everyone over 50 years will have low bone density, and a woman's risk of hip fracture is equal to the combined risk of breast, uterine, and ovarian cancer. Women are as likely to die after a hip fracture as from breast cancer. Men over 50 are more likely to contract hip fracture than prostate cancer. But osteo-

porosis is rarely even mentioned as a chronic disease for men.

According to *WebMD*, osteoporosis can be prevented and treated in a variety of ways. There's calcium and vitamin D supplements and exercise, a critical part of strengthening bone mass. There are also drugs on the market such as bisphosphonates that slow bone loss. They work by inhibiting cells that break down bone and slow bone loss.

The New York Times reported on December 21, 2015, that those medications "can produce adverse side effects like gastrointestinal distress and fractures of the femur. Indeed, a recent study published in *Clinical Interventions in Aging* found that among 126,188 women found to have osteoporosis, all of whom had Medicare Part D drug coverage, only 28 percent started bone drug therapy within a year of diagnosis many of

those who avoided drugs were trying to avoid gastrointestinal problems.”

In October 2010, the FDA required makers of bisphosphonates to add a warning to their labels describing the risk of atypical fractures of the thigh, known as subtrochanteric and diaphyseal femur fractures, in patients who take bisphosphonates for osteoporosis. Dr. Fishman posited that patients may avoid treatments with such side effect, but may be more inclined to try yoga which “is good for range of motion, strength, coordination and reduces anxiety. All of which contribute to the ability to stay upright and not fall. If you don’t fall, you greatly reduce your risk of a serious fracture.”

Second Study Results

In November 2015, Dr. Fishman and his colleagues reported the results of

the second and larger study, *Twelve-Minute Daily Yoga Regimen Reverses Osteoporotic Bone Loss* by Yi-Hsueh Lu, Ph.D.; Bernard Rosner, Ph.D.; Gregory Chang, M.D., Ph.D.; Loren M. Fishman, M.D., B Phil (oxon.) [Click here for the study.](#)

This is a retrospective, single site, non-randomized study.

The study investigators reviewed data for 741 patients who’d included yoga in their exercise routines between 2005 and 2015. Of that group, 227 were identified as having practiced yoga more than every other-day. Women comprised 202 of these high frequency yoga patients. The average age at the beginning of the study period was 68.2 years. Entry DXA bone scans showed that 174 (83%) of the compliant patients had osteoporosis or osteopenia.

Inclusion criteria were osteopenia or osteoporosis as measured by dual energy x-ray absorptiometry (DEXA) scan, that is, T-scale values below -1.0 for spine or hip, and commitment to two years of daily or near-daily yoga.

Exclusion criteria included history of bone disease, such as osteofibrosis cystica or osteomalacia, or metabolic or endocrine disorders specifically affecting bone, as detected by tests listed below, and current pregnancy.

Fishman and his colleagues wrote:

“In approximately 4 years preceding study entry, 128, 130, and 125 patients presented prestudy DXA scans that revealed a mean monthly decline in BMD of -0.0036 g/cm² for the spine, -0.00008 g/cm² for the hips, and -0.009 for the femora, over a mean 47, 52, and

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Most Recent Changes in BMD Before Yoga vs Those Following Two Years of Yoga								
Location	Pre Yoga	Number	Timing	SD/CI	Post Yoga	Timing	Number	SD/CI
Spine	-0.036	128	47	0.125/0.118	0.048	21.7	71	0.551/0.44
Left Hip	-0.017	130	52	0.117/0.183	0.088	22.0	81	0.103/0.159
Femur	-0.03	125	48	0.317/0.192	0.003	24.0	83	0.129/0.133

Source: Yi-Hsueh Lu, Ph.D.; Bernard Rosner, Ph.D.; Gregory Chang, M.D., Ph.D.; Loren M. Fishman, M.D., B Phil (oxon.)

48 months, respectively; standard deviations/95% confidence intervals = 0.125/0.118, 0.117/0.183, and 0.317/0.192, for spine, hips, and femora, respectively.

After practicing the 12 assigned yoga poses over 22, 22, and 24 months, respectively, 72, 81, and 83 of these subjects reported mean gains of 0.048, 0.088, and 0.0003 g/cm² per month, for spine, hips, and femora; standard deviations/95% confidence intervals = 0.551/0.44, 0.103/0.159,

and 0.129/0.133, respectively.” (See table above.)

Figure 3, 4 and 5 from the study show the mean bone density change/month for the spine, left hip and left femur. (See figures on page 7.)

The study continues:

“Mean rate of improvement in total hip BMD [bone mineral density] increased from baseline by 50% after a mean 23 ± 2 months of yoga,

but wide variation in individual improvement caused the confidence intervals to overlap, thus precluding statistical significance.”

The 12 yoga poses were selected specifically to produce torque and bending of the proximal femur, compression of the pelvis, and twisting of the lumbar vertebral bodies. The choice was determined because these are the most common sites of osteoporotic fractures and the anatomical regions measured by the DXA scan.



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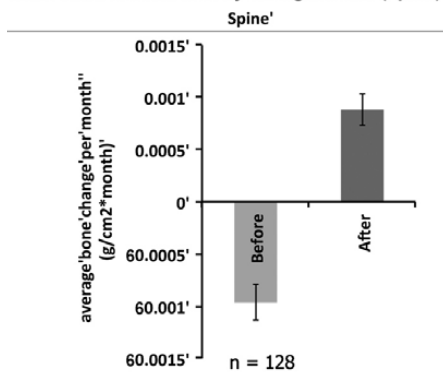
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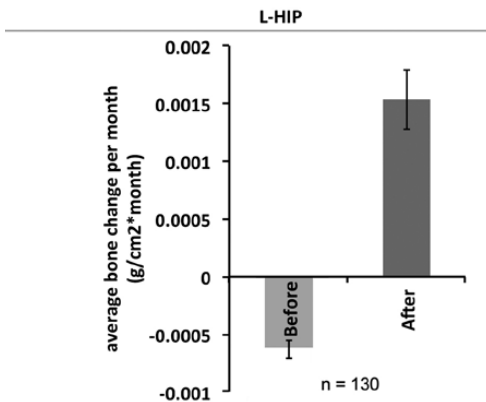


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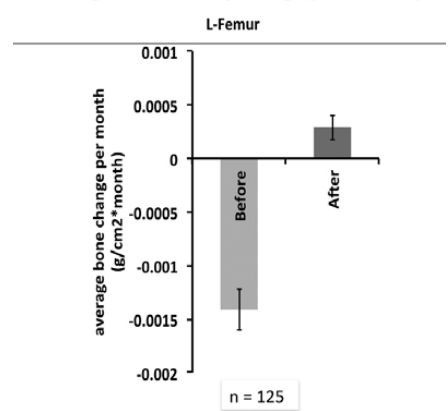
Mean bone mineral density change/month (spine)



Mean bone mineral density change/month (left hip)



Average bone density change (Left-Femur)



Left to Right: Figure 3, Figure 4 and Figure 5

Dr. Fishman wrote that weight-bearing activity, which is often recommended to patients with bone loss, can be accomplished with the yoga poses. “Yoga puts more pressure on bone than gravity does,” he said in *The New York Times* story. “By opposing one group of muscles against another, it stimulates osteocytes, the bone-making cells.”

View From the Yoga Mat

The results of Dr. Fishman’s study are probably not surprising to exercise enthusiasts—whether tennis players, weight lifters, pilates or yoga practitioners. But his data adds to the already large body of evidence that exercise is a key and vital part of an overall treatment plan for osteoporotic patients.

Yoga instructors have noticed the health benefits of this particular form of exercise for years. “Yogis have intuitively known for years about the physical and

psychological health benefits of a daily yoga practice. Having those benefits confirmed through scientific studies helps to encourage older adults to start a yoga practice,” says TC McVey, yoga instructor in Altos del Maria, a mountain community in Panama known for attracting aging gringos.

McVey started her regular yoga practice at age 50 and became an instructor after hundreds of hours of training. Now, 60, McVey says that in her personal experience she has seen improvement in her joint flexibility, stability, balance, overall strength and muscle tone.

Her students (including this writer) are mostly in their 60s and have never done yoga before. Some have had knee or hip replacement surgeries. Using props like bolsters, blocks and straps her students can receive the benefits of yoga. “Being able to explain the yogic purpose of a pose and have that be supported by sci-

ence, brings a validity to the practice for many students.”

One of her most popular classes is yin yoga, which is a slow but powerful form of yoga poses that are held to a point of compression for five minutes or longer while the student consciously relaxes the muscles using their breath allowing more stress on the connective tissue and the bones. “The long-held poses in yin yoga give the bones, especially the lumbar spine, more time to be stressed, thus allowing for a deeper recovery response and stronger bones,” added McVey.

The authors of the study acknowledged many limitations to the study, including the use of self-selected volunteers and the lack of a control group. But the team concluded, the results may lend support to Dr. Fishman’s long-held belief that yoga can be a vital part of an overall treatment plan for patients with osteopenia or osteoporosis. ♦

CMS's 10 Goals for 2016

BY ROBIN YOUNG

This past Tuesday (January 12) acting commission for the Centers for Medicare and Medicaid Services, Andy Slavitt, gave a major policy speech at the 2016 JP Morgan Healthcare conference in San Francisco.

Slavitt (who previously ran United-Healthcare's Ingenix and Optimum data bases and health information systems) described CMS's top goals for 2016. Contextually, Slavitt reminded his audience that 130 million Americans rely on Medicare, Medicaid or CHIP programs for their healthcare. Said Slavitt: "2016 will be an enormous and pivotal year for progress and it's starting off with a bang."

In reverse order, here are CMS's top ten goals for 2016:

Goal 10: Talk regularly to the health care investor community.

Historically, CMS has had an adversarial attitude toward the health care investor community. To the investor community, CMS has often felt opaque and divining CMS's agenda required poring through an often intricate set of regulations like they were Fed minutes. Slavitt promised to change that, beginning with this week's speech.

Goal 9: Implement the next generation ACO model.

Beginning this year, CMS is introducing the second generation ACO model or "Next Gen ACOs." These are provider groups who take full financial responsibility for a patient's care and have innovative options like telemedicine, home



YouTube and Health Data Consortium

visits, and direct consumer incentive and engagement options.

Accountable Care Organizations (ACOs) are groups of doctors, hospitals, and other health care providers who come together voluntarily to give coordinated care to their Medicare patients using a range of payment models (capitation, fee-for-service with asymmetric or symmetric shared savings, etc.). ACOs assume increased levels of responsibility for the quality, appropriateness and efficiency of the health care provided.

In CMS's words; an ACO is "an organization of health care providers that agrees to be accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it."

CMS plans to start with 21 new Next Gen ACOs which will be in addition to

more than 475 ACOs already in place with 30,000 physicians participating around the country.

Approximately 64 current ACOs are two-sided or full risk organizations, up from 19 just last year and of course zero before the Affordable Care Act.

Goal 8: Increase the number of existing ACOs.

In total, 8.9 million Americans receive healthcare services from ACOs in 49 states and the District of Columbia. For 2016, CMS hopes to increase that number by 1.6 million and serve these patients in better, more advanced ACO models.

Said Slavitt: "Many have wondered whether ACOs would succeed or would end up in the dustbin of health care's three-letter acronyms. As a recovering entrepreneur, I can certainly tell you that the execution in the first stage is

often the hardest part. But today's news is strong evidence that ACOs will be part of ushering in the new wave of alternative payment models. They have demonstrated improvements in quality, patient experience and have been certified to reduce costs."

Goal 7: Implement bipartisan MACRA legislation.

MACRA, which stands for Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act, is the legislation passed in 2015 which replaced the sustainable growth rate (SGR) formula with statutorily prescribed physician Medicare payments. It also extended for two years CHIP and reinstated global surgical bundles.

MACRA set up a two-track payment system designed to move patients into risk-based payment models.

In Slavitt's view, MACRA is a program that brings pay for value into the mainstream through something called the Merit-based incentive program.

"The stakes are high for this program," said Slavitt. "As any physician will tell you, physician burden and frustration levels are real. Programs designed to improve often distract. Done poorly, measures are divorced from how physicians practice and add to the cynicism that people who build these programs just don't get it. Over the next several months, we will be rolling out details."

Goal 6: Simplify.

CMS plans to combine, streamline and simplify as many old programs as possible in order to free up physicians to focus where they need to—on their patients.

CMS is working with front-line physicians, tech companies, and practice managers to learn which measures for each specialty work best and how to implement programs most simply.

Slavitt said that CMS is committed to building flexible and adaptable programs that reflect individual practice and patient goals.

Goal 5: End Meaningful Use.

"Meaningful Use" refers to a CMS program which tried to promote the use of electronic health records (HER) through a series of guidelines and incentives.

That's ending.

Now that the vast majority of health-care providers have electronic health records, Meaningful Use becomes, in effect, MACRA.

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CMS laid the groundwork for this switch in late 2015 by consulting with physician organizations like the American Medical Association (AMA) to work out the end of Meaningful Use and the start of MACRA. Slavitt promised to release details over the next few months.

As envisioned by Slavitt, CMS still stop rewarding providers for using technology. Instead it will focus on patient outcomes. Under the new guidelines, providers will be able to customize their goals so tech companies can build around the individual practice needs, not the needs of the government.

Lastly, the new program will encourage technology start-ups and new entrants. CMS plans to require open APIs in order to allow apps, analytic tools, and connected technologies get data in and out of an EHR securely.

Goal 4: Increase interoperability.

Interoperability is the ability of different healthcare information systems and software to communicate, exchange data, and use information regardless of the platform they live on.

Slavitt says he is “deadly serious about interoperability.” CMS is initiating collaborations with physicians and consumers to, for example, close referral loops and engage patients in their own care—which can’t work without interoperability.

And, Slavitt warned: “Technology companies that look for ways to practice ‘data blocking’ in opposition to new regulations will find that it won’t be tolerated.”

Goal 3: Modernize Medicaid coverage.

More than 13.5 million people have entered the Medicaid or CHIP coverage programs in the last couple of years. To handle not only these people but the tens of millions on the way, CMS has to modernize—ASAP.

In 2015, CMS released proposed or final rules to modernize Medicaid’s management, access to care at both the state and CMS level and to manage incentive programs for value-based care with delivery systems.

Slavitt promised that in 2016 CMS would attract innovative companies to invest in the Medicaid IT space. He pointed to CMS’s actions this past December to extend the 90% federal match for Medicaid system investments.



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For 2016, CMS will invest approximately \$5 billion in state Medicaid IT. More than 30 states are currently redesigning their Medicaid IT systems, as a result.

Goal 2: Support private sector technology innovation.

Slavitt promised to make it easier in 2016 for innovative and differentiated technology solutions to get into the Medicaid and Medicare systems. Specifically, Slavitt would like to see greater investment in modular, reusable, and cloud-based solutions.

To make that happen, CMS is launching in 2016 a one-stop-shop program for innovative, disruptive technologies. This new program will offer resources to encourage private sector companies to step into what Slavitt described as a huge opportunity.

The Number One Goal for CMS in 2016: Insure the long term health and stability of the Health Insurance Marketplaces.

The number one goal for CMS in 2016 is the health and long term stability of the Health Insurance Marketplaces.

The Marketplace is still in the early stages. Consumers are getting educated. Health plans are experimenting with products and network designs.

Millions of new patients are signing up.

CMS has studied the data and met regularly with all market players—41% of all new consumers this Open Enrollment are under 35, compared to 38% a year ago. And if past patterns continue

to hold, the percentage of young people will climb throughout the rest of Open Enrollment.

There are also high levels of consumer engagement—as over 60% of Marketplace consumers have made active decisions about their health insurance choices.

But, to move the current health insurance Marketplace from start-up stage to a more mature stage will require adjustments to more fairly compensate for risk and to keep the risk pool stable, balanced and to provide a predictable set of underwriting rules.

If successful, the customer base for health plans will look more attractive with a younger population and high levels of engagement and responsiveness to new offerings.

As Slavitt put it: “There is still a large untapped market to serve.”

Wrap Up

With these goals CMS is signaling that care delivery payments are changing in ways which could reward providers who deliver superior care—as defined by CMS. The other signal is that CMS is increasingly friendly and encouraging to innovative technologies.

Under Slavitt’s leadership CMS is launching a number of start-up activities which makes an improved private sector relationship even more important.

Finally, in his talk Slavitt earnestly pushed a CMS culture of listening and learning. Whether that trickles down the organization is the big question. ♦

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Surprising Study Conclusion: Might Want to Skip PT // Nearly 30% of Residents Are Depressed! // Details on New AAOS Knee OA Guidelines

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

Skip the Formal PT, Says Rothman Study Should hip patients ditch PT? In an effort to get beyond the assumption that all total hip arthroplasty (THA) patients require physical therapy (PT), surgeons at the Rothman Institute in Philadelphia undertook a study stratifying patients to those who received formal PT and non-formal PT. Led by Matthew Austin, M.D., an orthopedic surgeon, the researchers began by looking at the Holy Grail: cost. Dr. Austin told *OTW*, “We knew that post discharge care accounts for a huge percentage of the cost of THA. Our team decided to see whether hip replacement patients actually needed formal PT or whether they would fare just as well doing exercises at home. From the outset we knew that not all patients could conform to a single protocol. Someone who is 80 years old, lives alone, and has heart disease and THEN undergoes THA is vastly different from a 50 year old who was recently very active and has an in-home support system.”



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“We looked at the population of patients who were active to see if they could go home after surgery and do exercises on their own. These patients were randomized to see if they required formal PT or if they could manage self-directed PT (with 60 patients in each group).”

“Our preliminary results show that at four weeks postop and 6-12 months postop there were no differences in the Hip Society scores or the WOMAC scores. At two weeks we offered all patients in the non-formal PT group

the option to switch to the formal PT group. We expected that some patients would cross over from non-formal to formal PT; in fact, more patients crossed from formal to non-formal. These individuals cited copays, time, and inconvenience as the reasons for this move.”

“We were somewhat surprised to find that patients did equally well whether they undertook a formal PT program or stayed home to exercise. It is becoming clear that we need to better define what type of patients need what type of

care. Someone who lives alone and has to navigate a narrow staircase is going to have different needs that someone living in the suburbs in a ranch home with their children in the same neighborhood. We can't treat all patients the same; you may give too much to someone who needs less. Ideally, we need risk stratification for post discharge care.”

“Our future plans are to examine which patients need a rehab facility and which patients should go directly home. We

need to look at what makes a home environment safe. There is a lot of room here to work collaboratively with homecare specialists.”

Almost 30% of Residents Are Depressed A new study from Brigham and Women’s Hospital (BWH) has found that 28.8% of trainees screen positive for depression during their residency. The findings, published in the December 8, 2015 issue of *The Journal of the American Medical Association (JAMA)*, came from a meta-analysis involving 54 studies (17,560 physicians in training). The findings were similar across specialties and countries, say the authors, suggesting that the underlying causes of depression were common to the residency experience.

Corresponding author Douglas A. Mata, M.D., M.P.H., is a resident physician in pathology at Brigham and


Women’s Hospital and clinical fellow at Harvard Medical School. Dr. Mata told OTW, “It’s an open secret that depression is rampant among medical trainees, who devote themselves to medicine at a young age when the end result might be different from their original expectations about the field. Ask anyone in medicine, and they’ll be able to rattle off a list of colleagues who have been through depression. Many of my medical friends have grappled with depression or burnout at some point in their careers. Many doctors will, unfortunately, also have an acquaintance or friend who committed suicide. I’ve known these things to happen to too many people that I know. That’s what led to my interest in the topic.”

“As you are likely aware, becoming a doctor involves studying and deferring gratification for years, taking on thousands of dollars in debt, missing out

on important life events of friends and family due to work obligations, treating critically ill patients, and witnessing trauma and death in person. We’re conducting this study to bring real facts to the table, to show that depression among doctors and residents is not going away and we need to seek solutions. Coming up with a reliable estimate of the prevalence of depression among graduate medical trainees would help us identify causes of resident depression so we can begin to treat or prevent it.”

“We found that as many as 43% of residents screen positive for depression during any given year of their training. This is remarkable, and suggests that it is a near universal experience. We also found that the prevalence of physician depression might be getting worse with time. This is similarly remarkable given efforts by the ACGME [Accreditation

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Council for Graduate Medical Education] and others to ameliorate the problem. But in my opinion what they have tried (e.g., duty hour reforms) is not enough. It misses the fact that we need to fundamentally rethink the way medicine is taught in this country, much like we did when the Flexner report came out so many decades ago. We've got a public health crisis on our hands and it isn't going away anytime soon."

We asked Andreas Gomoll, M.D., an orthopedic surgeon with Brigham and Women's Hospital, what he sees happening with their residents. He told *OTW*, "The first two years are still very stressful, but the work hour restrictions have helped a lot. Also, hiring mid level practitioners has helped. We occasionally see problems these days but less so than in the past."

As for what staff orthopedic surgeons should keep an eye out for, Dr. Gomoll commented to *OTW*, "Changes in resident behavior, lower scores in board exams, tardiness, compromised patient care, increases in patient complaints. All signs of burn out and depression."

New AAOS Guidelines on Knee OA Surgery Thank goodness for the orthopedic surgeons willing to devote their time to clarify things for the rest of the field. David S. Jevsevar, M.D., M.B.A. is Acting Chair and Assistant Professor of Orthopaedic Surgery at the Dartmouth Geisel School of Medicine. Dr. Jevsevar is also Chair of the Committee on Evidence-Based Quality and Value (EBQV) at the American Academy of Orthopaedic Surgeons (AAOS). He tells *OTW*, "Most orthopedic surgeons simply do not have time to read all the literature and evaluate each article for its merits. That's where we come in. Our group refines all of the content so that we can get down to

the best of the literature. The result? Clinical practice guidelines (CPGs)."

"The most recent CPGs are related to adults undergoing surgery for knee osteoarthritis. At times, the evidence we find is contradictory to what we are doing in practice. Our work group consists of 12 people willing to have difficult conversations where the lines are blurred between evidence and practice. One of the things we struggle with is how to present that in a way that is appropriate."

"An example of something that goes against what people are doing in practice is the routine use of postoperative drains. There are always patients who are different than other patients and for whom a drain may be necessary. The guidelines are aimed at 80% of patients. Another controversial recommendation is that the routine use of surgical navigation is not supported by current evidence. That doesn't necessarily apply to all patients, and the workgroup discusses possible exceptions in the rationale for that recommendation. When we do CPGs we first look at what outcomes are important to patients. So with navigation, for example, it is hard to find in first two years after surgery a related outcome that is important to patients."

"In doing this CPG we started out with over 10,000 articles and pared it down to roughly 200. The workgroup composes the rationale for each recommendation after reviewing the evidence, and the resulting document is sent out for peer review (to interested parties or specialty societies), and then have a phone meeting to go through criticisms of peer-review concerns. Following this we send the CPG out for public comment, then the EBQV and Council on Research and Quality approve the CPG;

finally, the AAOS Board of Directors reviews the document."

"There are few organizations that invite patients into the process. We actually allow patients to ask questions that are important to them and integrate that information into the CPG. For this particular CPG, patients had specific questions about the types of knee implants, unicompartmental versus total knee, and continuous passive motion machines."

"These are guidelines and not rules. First, use the best evidence available. Second, surgeons should consider their clinical expertise and experience. Third, take into account the patient's unique values or social situation." ♦

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Murphy v Maloney: Ceramic on Ceramic THA in Patients <60: A New Standard

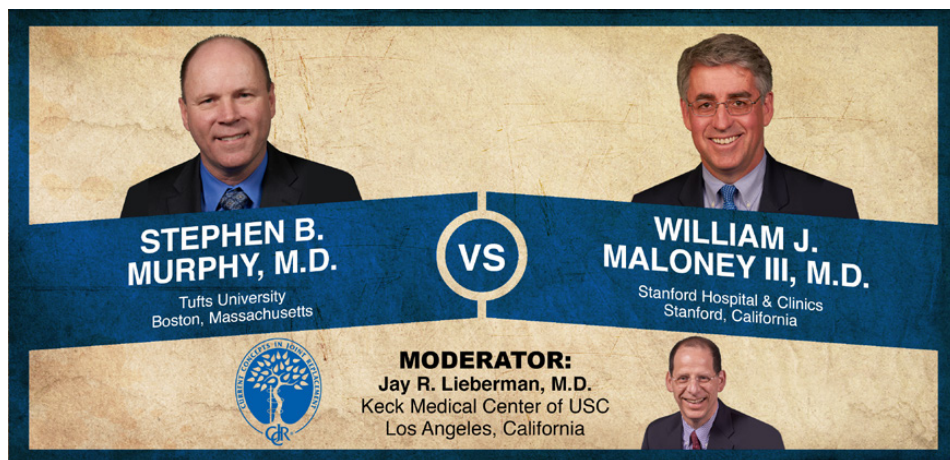
BY OTW STAFF

This week's Orthopaedic Crossfire® debate was part of the 16th Annual Current Concepts in Joint Replacement® (CCJR) – Spring meeting, which took place in Las Vegas this past May. This week's topic is "Ceramic on Ceramic THA in Patients <60: A New Standard." For the proposition is Stephen B. Murphy, M.D., Tufts University, Boston, Massachusetts. William J. Maloney III, M.D., Stanford Hospital & Clinics, Stanford, California is opposing. Moderating is Jay R. Lieberman, M.D., Keck Medical Center of USC, Los Angeles, California.

Dr. Murphy: So my job is to argue in favor of ceramic-ceramic total hip arthroplasty in patients under the age of 60 years.

To begin I'd like to review our 18 years of experience with ceramic-ceramic bearings. We have previously published in patients under 50, starting in 1997 and then uncemented in 1999, 307 hips in total with 262 having a minimum of two-year follow-up with an average age of 42; more males than females. This study was initially part of a prospective IDE study with the FDA. The acetabular cup design utilized was flush-mounted with an 18-degree taper. Seventeen percent of these patients had previous surgery and a number of them were relatively complex. Surgical techniques all were posterior capsular preserving whether it be transgluteal, trochanteric slide, or more recently through the superior hip approach.

In terms of component positioning before 2001 I did them all freehand.



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From 2001 to 2008 we used traditional navigation and from 2008 to now we've used smart mechanical navigation. Our survivorship at 14 years is 97% for these patients and that's survivorship with any reason for revision.

What about < 60, instead of < 50? We recalculated a similar series of our patients over a similar time course starting in 1999; 243, average age 46. Follow-up average 8.1 years out to 15. Again, a preponderance of men and 17% bilateral. Six patients revised. We had a couple of fractures with high energy trauma and one atraumatic liner fracture in the presence of a trochanteric non-union. Three components did not osseointegrate. The 11 year survivorship was 97.8% with revision for any reason. In terms of dislocations, there weren't any. No revisions for infection. And no cases of osteolysis.

This is similar to a previously published study (Hsu JE, et al, Semin Arthroplasty 2011) where they showed equally

high survivorship for alumina ceramic-ceramic bearings.

Why is it that we don't really recognize the superiority of these bearings? Is it cost? Is it the squeaking? Registry dislocation? Well, cost I don't think is a significant issue. Many of the available polyethylene bearings with porous coatings are actually more expensive than the implants that I use. In terms of squeaking, that's clearly related to a particular design utilizing an elevated rim. What about registry data? Well, in Australia in particular, a lot of the latter components were used and that would explain the higher failure rate in Australia. If you could filter out just for the flush-mounted, 18-degree taper liners, I think it would show clear superiority.

What about dislocation? Well, I think dislocation is a function of soft tissue preservation and component positioning. There weren't any dislocations in this series.

What about concerns for polyethylene? Well, my concerns are that polyethylene

changes all the time. There are a million products out there. The products that were used 10 years ago are not the same ones that are used now. There are no long-term studies of any of the current ones that people use with high frequency. Certainly there are mechanical problems with decreased tensile stress, strength, edge loading leading to fracture; sub-surface oxidation; and reports of osteolysis.

I think another big, big problem right now is liner dissociation. There will be a number of studies coming out in the next year about this and this really relates to the mechanical integrity of the plastics, so not only can it break, but it can dislodge from the metal shell. And in terms of some of the newer ones, certainly there are concerns about in vitro wear and, again, I just point out that we don't have any long-term follow-up on these components.

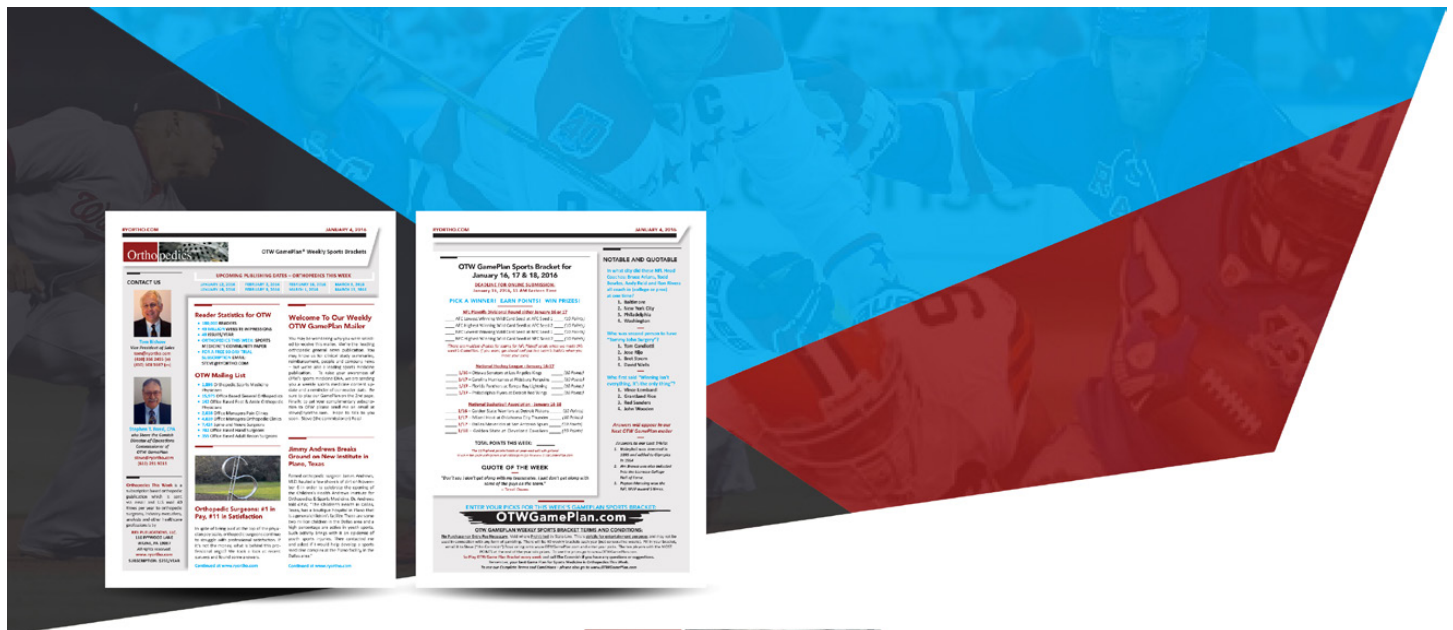
So in summary, I would say that I hope that these polyethylene bearings turn out to be good bearings. I think that removing cobalt chromium and polyethylene from the total hip construct is really the best thing for long-term outcomes. But I know based on clinical outcomes at more than a decade that alumina ceramic-ceramic bearings have excellent results.

Dr. Maloney: The question is: 'Is this a standard?' Well, a standard is something established by authority, custom or general consent. And it's clearly not true for ceramic-ceramic total hip replacement. There's a better question. 'Is there any indication for a ceramic-ceramic total hip replacement in 2015?'

Well, why the interest in ceramic-ceramic? First, the low wear rates. Clearly it does have a low wear rate. But is that relevant in today's bearing surface? I think the answer is probably not.

You cannot tell a difference in wear of ceramic versus cobalt chrome femoral heads on highly cross-linked polyethylene. Highly cross-linked polyethylene is very difficult to make wear under any condition. In fact, we did a study looking at the wear of conventional versus highly cross-linked polyethylene with retrieved femoral heads. We took retrieved heads from revision surgery with various degrees of roughness, and on conventional polyethylene there was direct correlation between the surface roughness and wear. Taking clinically relevant rough heads, it was even difficult to make the highly cross-linked polyethylene wear at 5 million cycles. Very low wear despite the rough femoral heads.

What about the negatives related to ceramic-ceramic? Well, Steve did a good job of telling you about the negatives and I think they are real. First,



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there's cost. If you'll look at the cost, it's substantially more at most institutions and it's simply not cost effective. They are more expensive and we'd have to have a substantial reduction in revision to justify that cost. The risk of complication data in the United States, from all payers, looking at metal and plastic and ceramic, ceramic-ceramic does not produce a substantial reduction in revision. When we looked at the revision rate for metal- plastic and ceramic- ceramic for several thousand hips in the United States, there was no significant difference. They were essentially identical.

In the Australian registry data, metal-highly cross-linked polyethylene is the most reliable bearing, which includes ceramic- ceramic. When reviewing femoral head sizes less than or equal to 28mm, adjusted for age, which is a surrogate for activity; and gender, a surrogate for bone quality, metal- highly cross-linked polyethylene is the most reliable bearing surface. Further, for larger heads, those greater than 28mm, again metal-highly cross-linked polyethylene is the most reliable bearing surface.

And if you're going to use ceramic-ceramic, it's probably better to use a larger femoral head because they do a little bit better than the smaller femoral heads. With the larger heads you do have a few more options. Breakage is probably no longer a significant issue. Certainly, I think delta ceramic is significantly better. The fracture rate with delta ceramic is quite low. There have been a couple of reported fractures, but I don't think that's the main issue going forward. It's not going to be zero.

What about the squeaking? Well, for those patients who squeak, they're fairly upset. I saw a nurse in the clinic who had bilateral ceramic- ceramic total hip replacements. Both were squeaking. One fractured and she was worried

the second one was going to fracture because of the squeaking. When you have it, it's not a trivial issue. And there are various types of squeaking. Some are like an old door hinge. Others "chirp". Some squeak like a cat. Most people tolerate the squeaking fine, but for some patients it's obviously a problem and occasionally you need to revise for squeaking.

I think in summary, ceramic- ceramic hip replacement is clearly not a new standard and any use is based on the long-term theoretical advantage which is yet to be proven.

Moderator Lieberman: Steve, so who in your practice gets a ceramic- ceramic hip?

Dr. Murphy: I use alumina ceramic bearings on people well into their 60s and sometimes in their early 70s. I think Bill makes a good point that the results of some highly cross-linked polyethylenes have been okay, but the long-term results are always shorter than what ceramic-ceramic has and the polyethylene's are changing all the time. So when you advocate for a highly cross-linked polyethylene, you're using in vitro studies instead of long-term clinical results to justify it and I think there is a big difference, as we all know, when you actually operate on patients and look at them in the long term.

Moderator Lieberman: So you use ceramic- ceramic on a 70-year-old?

Dr. Murphy: Yeah, and I think they're proven.

Moderator Lieberman: So how about the head sizes, Steve, you want to briefly comment on that?

Dr. Murphy: With alumina ceramic, there are 28mm, 32mm, 36mm and with delta-delta the sizes are 28mm

and 36mm. I use 28mm bearings with some frequency in dysplasia patients. Again, I think in that clinical study there were no dislocations. Hip joint stability is a function of surgical technique, soft tissue preservation and component alignment, and if using bearing diameter to back that up, that's fine, but you shouldn't need it.

Moderator Lieberman: I think that the data would clearly show that the larger the head the more stable the hip. Bill, what are your feelings about ceramic heads against highly cross-linked polyethylene?

Dr. Maloney: I think clinically they're indistinguishable. I think the data would suggest that's the case in multiple registries. We're doing it more currently on a gut reaction over concerns with taper corrosion. In our own study at our own institution we've yet to identify a significant taper corrosion case.

Moderator Lieberman: Steve made a very good point about concerns about the biomechanics of highly cross-linked polyethylene and looking at things like vitamin E to reduce in vivo oxidation. Can you give the audience some perspective on where you think we are with that and what the future will hold?

Dr. Maloney: I think it's going to be impossible to prove that any new released polyethylene, highly cross-linked polyethylene, or enhanced polyethylene would be better than the one I've been using since late 1998. I've yet to see a case of lysis on my own practice—we follow those patients under 50. If you're looking at 10+ year data with no lysis, it's hard to prove anything's better. We have not seen a fracture in those as well, so I don't think it's a real issue.

Moderator Lieberman: Steve, you're a real advocate for ceramic- ceramic.

Are there any patients for whom you wouldn't use a ceramic liner because you were concerned about stability or any other issue?

Dr. Murphy: There aren't young patients that I would not use a ceramic-ceramic bearing in because of a technical issue unless it were somebody with polio or something I really felt that it was a small cup that needed a big bearing. I haven't been in that situation in the past decade. But I might consider something else in a circumstance like that. That would be about it and I have a lot of confidence in those bearings, obviously, and they've been around for a long time so there are no secrets. I do have concerns about the polyethylene disassociation problems that we're seeing now and the fractures and the fact that I think those will become more commonly recognized in the near

future. Whereas when I use ceramic-ceramic bearings, I know exactly what I'm going to get. They're not going to disassociate. They wouldn't fracture typically unless someone fell from a height and it saves them from some other injury. No osteolysis. I just think they're incredibly, incredibly reliable bearings.

Moderator Lieberman: What about concerns about the chip fractures, or even people just having some difficulty with smaller incisions when impacting a ceramic component and getting a good fit?

Dr. Murphy: Well, the 18-degree taper components are really easy to put in. You put them in by hand you just let them go in themselves and you just help them. If you try to force one in at the wrong angle it will get stuck, so you just don't do that. The delta ones

that are a 10-degree taper are a little bit trickier, but you need to use the same technique to put it in. They go in quite well and you can tell when they're seated. It's not a big deal.

Moderator Lieberman: Bill, finally how about any concerns about elevated lip liners? Or lateralized liners with the new highly cross-linked polyethylene?

Dr. Maloney: We don't use lateralized liners in general. Occasionally we use elevated lip liners. Again, it goes back to what Steve said. If a surgery is done well, it's not an issue.

Moderator Lieberman: Well, gentlemen, thank you for a very envisioned discussion. Excellent presentations. ♦

Please visit www.CCJR.com to register for the 2016 CCJR Spring Meeting, May 22 - 25 in Las Vegas, Nevada.

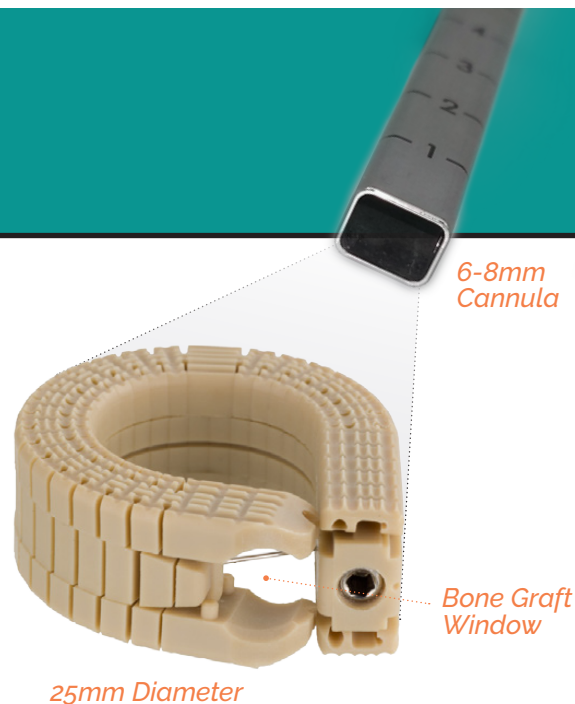
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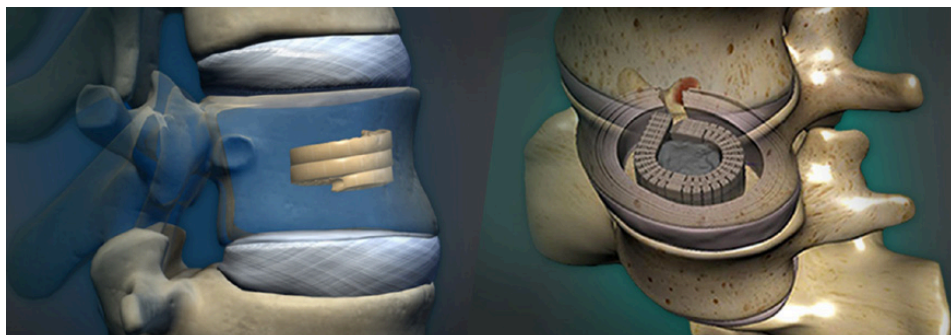
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Benvenue Medical Raises \$60 Million

Benvenue Medical, Inc. announced on January 6, 2016 that it has completed a \$60 million round of financing.

The spine company said it will use the funds to accelerate U.S. commercialization activities for its two minimally invasive products—the Luna 3D Interbody Fusion System for treating degenerative disc disease and the Kiva VCF Treatment System for treating vertebral compression fractures (VCFs).

The financing consists of \$23 million in equity and \$37 million in debt. The equity was provided by DeNovo Ventures, Domain Associates, Esquilme Partners, InterWest Partners, Technology Partners and Versant Ventures. The debt was provided by CRG. Donald Miller, co-founder and managing director of Versant Ventures will join Benvenue's board of directors.



Kiva VCF/Luna 3D Interbody Systems

Interbody Fusion and VCF Treatment Systems

The company says the Luna 3D Interbody Fusion System is designed to provide the “least minimally invasive approach” to lumbar spinal fusion while “providing spine surgeons control and flexibility in implantation.” The system was cleared by the FDA in November 2014. The system features a small profile PEEK implant designed to expand in three dimensions within the disc space “allowing surgeons to restore height via a posterior approach while providing the stability of a larger construct more often associated with an anterior approach.”

The Kiva VCF Treatment System, a cylindrical implant for spinal fractures, uses expandable technology to create structural support for the vertebral body and a reservoir to direct and contain bone cement. The Kiva system was also cleared by the FDA in 2014. The system, says the company, was proven in a randomized, controlled study published in *Spine* “to restore kyphotic angle and reduce the rate of adjacent level fractures vs. balloon kyphoplasty—with added economic benefits.”

The company, founded in 2004, is privately held and funded by the venture capitalists noted above. — WE

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Stryker Caps 2015 With Strong Q4 Sales

On the eve of the JP Morgan Health-care conference in San Francisco this week, Stryker pre-announced its sales results for the 2015 fourth quarter and full year. Stryker's fourth quarter sales were \$2.7 billion which is +6.4% higher than the same period last year and a sequential growth rate acceleration compared to the third quarter when overall sales rose 5.5% from Q3 2014.

The key to Stryker's fine end-of-the-year sales report was a surging robotics business (31 MAKO robots sold in the fourth quarter compared to 17 in the third quarter) and a reinvigorated Neuro & Spine business (up 9.9%). MedSurg, which is Stryker's medical equipment business, rose 5.6% excluding currency effects.

Q4 Segment Details

MedSurg sales were \$1.1 billion (up 3.0%; up 5.6% ex-FX) which was a slight sequential growth rate improvement from 3Q15 (sales that quarter were up 0.6%; up 4.1% ex-FX).

Stryker's Orthopedics sales were \$1.1 billion (up 3.3%; up 7.1% ex-FX) included sales of 31 MAKO robots (versus 17 in 3Q15; 13 in 2Q15; 9 in 1Q15).



Courtesy of CNBC and YouTube

Neurotechnology and Spine sales were \$483 million (up 6.5%; up 9.9% ex-FX).

Stryker's management also announced that the company had repurchased \$700 million worth of common stock. Looking ahead, Stryker also let it be known that it plans to reinvest the majority of the MedTech tax benefit (\$0.13 in 2015).

Wall Street's Assessment

Wells Fargo's Take:

"We see the results as positive for SYK and note that SYK continues to grow at the high end of the large cap medical device names."

BMO Capital Market's Take:

"While we will have to wait for its earnings call to gain further clarity

on the quarter, we expect a number of topics to be addressed, including: 1) hospital capital equipment purchasing trends; 2) the orthopaedic landscape, including the usual conversation on volumes and price, but also the competitive landscape; 3) emerging markets (as macroeconomic issues in China and Brazil began to weigh on the MedSurg segment in 2Q, and affected Orthopaedic sales in Q also); 4) new product launches, including MAKO applications in Recon and the 1588 camera platform in Endoscopy (launched at the end of 2015); 5) operating leverage; and 6) 2016 guidance."

RBC Capital Market's Take:

"Overall, SYK reported largely in-line 4Q15 results. SYK raised the bottom end of its 2015 cash EPS guid-

ance range to \$5.09-\$5.12 (from \$5.07-\$5.12). This implies 4Q15 cash EPS of \$1.53-\$1.56 (RBC's: \$1.56, FCF: \$1.55)." — RRY

STRYKER Sales 4Q and Full Year 2015			
Sales Divisions	4Q 2015	Full Year 2015	Year-Over-Year Growth Rate (with currency effects)
Orthopaedic	\$1.1 billion	\$4.2 billion	1.7%
MedSurg	\$1.1 billion	\$3.9 billion	3.0%
Neurotechnology & Spine	\$483.0 million	\$1.8 billion	5.0%
TOTAL	\$2.7 billion	\$9.9 billion	2.8%

Source: Stryker Corporation

LEGAL

Medtech SA: 510(k) From FDA for ROSA Spine Robot

Medtech SA has recently announced that it has received 510(k) clearance from the FDA to market the ROSA Spine robot in the United States.

Bertin Nahum, CEO and Founder of Medtech, said in the January 5, 2016 news release, “We are thrilled to have FDA approval for ROSA Spine. Building on the success that ROSA™ Brain has encountered on the American market, this new key regulatory milestone will allow us to strengthen our position in the world’s leading market for spine surgery. In addition, the FDA approval again reflects our capacity to respect the commitments we made at the time of our IPO, growing as a company while offering innovative robotic technology.”

According to the news release, “ROSA Spine received the CE Mark in 2014 and is currently being used in minimally invasive spine surgery. The first commercial procedure in Europe was performed in December 2014 at the Neurosurgery Department of Amiens-Picardy University Hospital to treat a patient with a degenerative spine disorder through a lumbar fusion with a posterior approach. The ROSA platform was previously approved in the U.S. for brain surgery in 2012. There are currently 27 ROSA Brain systems installed in American facilities.”

Nahum told OTW, “Development of the ROSA Spine robot, devoted to spine surgery, began in 2012. ROSA™ Spine is capable of performing minimally invasive spine surgery. Authorization to sell the device on the European market

(CE mark) was obtained in July 2014 and the first surgical operation was performed in November 2014. Clearance for the American market (FDA approval) was granted in January 2016. In developing the latest generation of surgical assistance robots, Medtech’s ambition is to establish surgical procedures which are less-invasive and safer for the patient, and to offer surgeons greater accuracy and safety.”

“Thanks to our robots, surgery is changing, moving from an open approach to a minimally invasive approach, and surgeons no longer need to make large incisions to operate. As for the patients, the recovery time is shortened and the risk of infection is reduced. The ROSA device is innovative in two ways. From a technological viewpoint, ROSA has a robot arm whose architecture imitates the movements of a human arm, conferring great dexterity to the surgeon’s movements and complete freedom in the choice of trajectory. ROSA also gives them the possibility of guiding the instruments by hand, within the limits established during the planning stage, while giving him all the advantages of robotic movement. This new platform allows real-time monitoring of patient movements and compensates for these movements without the necessity to stabilize the robot using the surrounding vertebrae.”

“Minimally invasive spine surgery shares the same difficulties as brain surgery, such as reduced visual field, but includes added complications like the inability to fully immo-

bilize the patient. Accurate intraoperative planning is obtained with ROSA Spine. During surgery, patients need to breathe, and when the surgeon operates he exerts pressure on the patient causing the spine to move. To overcome this movement, surgeons operating without robot-assistant systems have to compensate for the body’s movement, decreasing surgical accuracy. Previously developed robots for spine surgery assistance were designed to be bone-mounted but, due to its weight and stability, the ROSA Spine robotic arm offers firm, accurate instrument guidance. Moreover, it has a dynamic guidance system that tracks and responds to patient movement in real time, providing compensation for the body’s movements without the additional risk of clamping onto the spine.” — EH



Courtesy of Medtech SA

English Junior Docs Strike

English junior doctors, who work for the National Health Service (NHS) went on a one-day strike on January 12, 2016 to protest a new employment contract offered by the government.

While unheard of in the U.S., physicians in Europe will take to the picket lines. German physicians went on strike in 2006 and 2010. Then Moscow physicians struck in 2015. Now, according to *Reuters*, English junior physicians are striking for the first time in 40 years.

Junior doctors are physicians in training who make up just over half of all physicians in the state-funded NHS.

Ninety-eight percent of more than 37,000 junior doctors in England voted

for strikes in protest against the new contract proposed by Health Secretary Jeremy Hunt. Physicians in the rest of Britain are not involved.

The government says the new contract will deliver more consistent service seven days a week. *Reuters* reports that studies have shown that mortality rates are higher on weekends when staffing is reduced. The new deal would see the junior physicians given a pay rise but some anti-social hours for which they are currently paid a premium would be considered to be standard.

The doctors' union the British Medical Association said the contract does not provide proper safeguards against doctors working dangerously long hours.



Doctors on Strike/Al Jazeera and RRY Publications

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The Telegraph reports that trainee doctors currently have a starting salary of £22,636 (\$24,630 roughly USD), rising with experience to reach £30,000 (\$32,644 USD) within four years. Doctors in specialist training receive a salary of between £30,002 and £47,175 (\$51,333 USD), while those who make the grade can earn up to £69,325 (\$75,436 USD) (£1 = \$1.44).

Public Support

According to an Ipsos MORI poll for BBC Newsnight and the *Health Service Journal*, most people in England are supportive of the strikes, as long as emergency care is still provided. The survey of 869 adults in England found 66% were supportive, with 41% strongly supportive. Only 16% were against the strikes.

The physicians said they would only provide emergency services during the 24-hour walkout. They are planning a 48-hour stoppage later in January with a full withdrawal of labor, including emergency care, for nine hours on February 10, 2016.

The government expects some 4,000 non-emergency operations to be canceled during the stoppage.

One junior doctor, Dr. Lamia Zafrani of the Stepping Hill Hospital in the norther city of Stockport, told the *Al Jazeera* news outlet that the government was taking advantage of junior doctors because they were locked in training programs that could last up to 10 years.

“As junior doctors, we work hard, we work unsociable hours and we work weekends...staying behind after work to make sure things are safe. The NHS runs on the goodwill of its staff,” Zafrani said. — WE

EXTREMITIES

Vitamin D Supplements Just Expensive Urine?

Another popular belief is dashed. A study in Switzerland—published online in *JAMA Internal Medicine*—has found that higher doses of vitamin D were no more effective than lower doses in improving lower leg functioning. They were even associated with a higher risk of falls. What’s an elderly person to do?

Researchers divided 200 participants, ages 70 and older into three treatment groups. One group received 24,000 IU of vitamin D3 monthly. Another group received 60,000 IU and the third group received 24,000 IU plus calcifediol.

After one year, groups two and three were more likely than the first group to reach a serum vitamin D level of at least 30 ng/mL ($P=0.001$), reported Heike Bischoff-Ferrari, M.D., Ph.D., of the University Hospital Zurich in Switzerland, and colleagues. They found that supplements were not more effective in improving lower extremity function, which was the same among all the groups.

All of the participants in the study had had a low-trauma fall in the previous 12 months and lived at home. To be included, participants had to be able to walk, use public transportation to attend clinical visits, and be willing to discontinue other calcium and vitamin D supplementation. They also had to score at least a 27 on the Mini-Mental State Examination to show that they understood the procedures and give their consent. The average age of the participants was 78 and 67% were female.

The number of falls varied significantly among treatment groups, with the highest incidence in the 60,000 IU group and in the 24,000 IU plus calcifediol group. “High monthly doses of vitamin D or a combination with calcifediol may not be warranted in seniors with a prior fall because of a potentially deleterious effect on falls,” the authors stated.

There is little evidence that supplementation to achieve 30 ng/mL works, so “it is prudent to get recommended intakes of vitamin D and other vitamins from a balanced diet with foods that naturally contain what is manufactured into supplements,” wrote Steven Cummings, M.D., of the California Pacific Medical Center Research Institute in San Francisco, and colleagues in an accompanying editorial.

Cummings added, “Clinicians should not recommend vitamin D supplements for other putative health benefits. There is no evidence from meta-analyses of randomized clinical trials that vitamin D supplementation reduces the risk of cardiovascular disease or cancer.”

The editorialists stated that until supplementation “is supported by randomized trials with updated meta-analyses, it would be prudent to follow recommendations from the Institute of Medicine that people 70 years or older have a total daily intake of 800 IU of vitamin D without routine measurement of serum 25D levels.” — BY



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SPORTS MEDICINE

Crushable Football Helmet May Prevent Concussions

The University of Washington (UW) and its affiliated Seattle-based start-up company, Vicis, Inc., have invented and introduced a crushable football helmet that may well be the best technology yet developed which can reduce the rate of concussions in football.

This new helmet design is the outcome of research conducted at the University of Washington and, more specifically, from faculty members Samuel Browd, M.D., Ph.D., Jonathan Posner, Ph.D. and Per Reinhall and their faculty and student colleagues at the University.

Samuel Browd is associate professor of neurological surgery, attending neurosurgeon, medical director of the Seattle Children's Sports Concussion Program. Jonathan Posner is associate professor of mechanical engineering at UW and Per Reinhall is a professor and department chair of mechanical engineering at UW. In addition to their academic work, the team also has a strong working relationship with the Seattle

Seahawks professional football team. Dr. Browd covers concussion management on the sidelines as an unaffiliated neurologic consultant.

The key to their new helmet is that it absorbs force by crumbling upon impact—like the front bumper of a car. But unlike the car's bumper, this helmet also bounces back to its original shape.

Starting Over With Helmets

Football helmets were originally designed to prevent skull fractures. The hard shell design for today's football helmet was introduced around 1935 with the Michigan State Wing helmet.

The hard-shell design effectively prevented skull fractures, but did not stop concussions from becoming a devastating side effect of playing the game.

According to the Center for Disease Control and Prevention 1.6 million to 3.8 million sports-related concussions occur annually in the U.S., and those numbers are conservative—as many as 50% of concussions go unreported.

The University of Washington team decided to start over with helmet designs. With the help of CoMotion (a University of Washington technology commercialization incubator) the team defined the problem as creating a helmet that would reduce linear and rotational acceleration to the football player's brain—the forces, in other words, likely to cause concussion.

The UW helmet project received early funding from

the UW Center for Commercialization (C4C) and the Coulter Foundation. When the team helped to form a company called Vicis, Inc. to continue development and eventual commercialization, it then received investments from Seattle-based Alliance of Angels and the W-Fund, a venture capital fund that provides early-stage investment to accelerate the success of Washington's most promising technology-based startup companies originating from research institutions and students across the state.

A video at the end of this article shows how the helmet works.

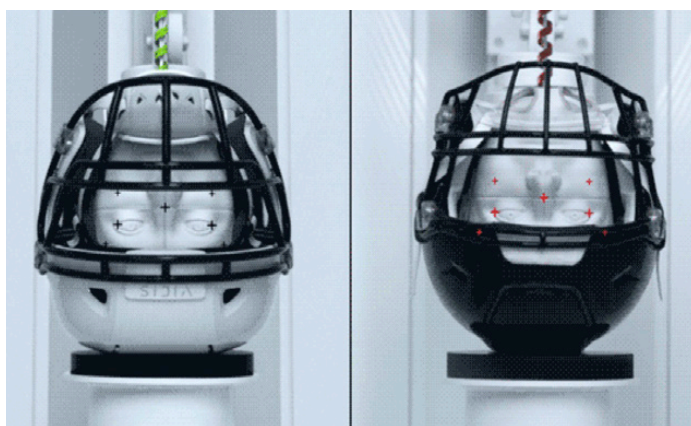
Winner of the Head Health Challenge II Award

The team at UW along with the UW start-up Vicis, Inc., was named one of the winners of the 2014 National Football League, GE and Under Armour funded Head Health Challenge II. The purpose of the award is to support solutions that help prevent, measure and detect brain injury.

More than 500 proposals from 19 countries were submitted for the 2014 Head Health Challenge. (Visit www.headhealthchallenge.com to learn more.)

Dave Marver, CEO of Vicis said: "Our win validates this helmet's promise as a significant breakthrough in the protection of young athletes against brain injury."

UW professor and co-founder of Vicis Jonathan Posner said: "Every engineering design project starts with the users or stakeholders. What do they need? For football helmets, it's obvious: They need something to protect their heads. But there are other aspects, too. How you clean the helmet, service it, and take it off of someone's injured head.



Courtesy of Vicis, Inc.

What it looks like. All of those aspects feed into how the helmet is designed and developed.”

UW professor, Engineering Department Head and Vicis co-founder Per Reinhall said: “UW Mechanical Engineering is full of bright and talented people who are eager to solve the problem of sports-related concussion. Our selection as a grant recipient demonstrates the potential of our helmet.”

UW professor and neurosurgeon Samuel Browd, who initially formed the Vicis team and co-invented the technology with Reinhall, said: “UW Neurological Surgery and our partners throughout UW Medicine and Seattle Children’s are at the forefront of concussion research, diagnosis, prevention, treatment and advocacy. We are confident this new helmet will help diminish the risk of concussion among young athletes.”

Here is the video which demonstrates how the new helmet design works and why it is such a promising new approach to preventing concussions in football. https://www.youtube.com/watch?v=4bMOMf3S_EA — RRY

Orthopedist Calls Hoverboard Craze “Epidemic”

Hoverboards are a hazard. When Asif Ilyas’s (M.D., FACS) children told him about them he did not know what they were talking about. But when he went to work at the Orthopaedic Trauma Service at Thomas Jefferson University Hospital in Philadelphia where he was on call Christmas night he soon learned.

Ilyas is a trauma and fracture care surgeon at Rothman Institute and an associate professor of Orthopedic Surgery at the Sidney Kimmel Medical College at Jefferson. He spent much of that night taking care of patients who had fallen from hoverboards.

“Christmas night alone we witnessed displaced fractures of the wrist, shoulder, ankle, and hip” he



Courtesy of YouTube

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wrote. “That night, my Orthopaedic team and partners in the emergency department evaluated a number of patients of all age groups presenting with falls off of hoverboards resulting in a variety of fractures, some even requiring surgery.”

Ilyas urges anyone attempting to ride a hoverboard to wear protective equipment and have a spotter—someone standing next to the rider providing support and, in the event of a fall, to catch him.

Ilyas warns riders that if they are not experienced with hoverboards or are unfamiliar with riding, they can accelerate very quickly resulting in the rider falling forcefully. Ilyas no longer refers to the hoverboard craze as a phenomenon. He calls it an “epidemic.” — BY

Sports Injuries Up for Youngest Athletes

How often are kids between the ages of 5 and 18 treated in emergency rooms for sports-related injuries? A study conducted by Indiana University School of Medicine in Indianapolis found that between 2001 and 2013, there were 485,514 injuries reported by 100 emergency departments, which amounts to about 16,000,000 sports-related injuries among children showing up at emergency departments nationally, according to Kathryn Doyle, writing for *Reuters Health*.

The study found that the number of injuries in this age group increased yearly.


Three-quarters of those injuries were related to football, soccer, baseball or basketball. However, the proportion related to baseball and basketball dropped over the study period which was 2001 to 2013.

Senior author Teresa Maria Bell reported that the annual increase of injuries may be explained by the fact that more




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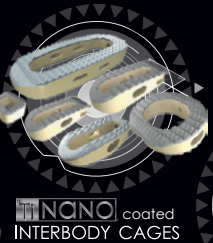
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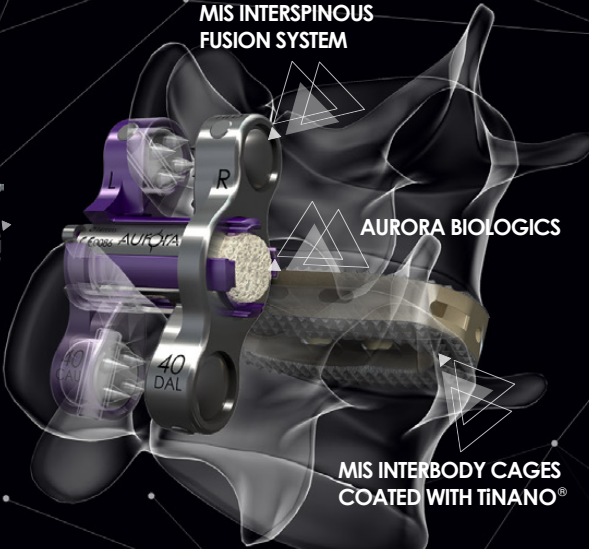
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children were participating in sports each year of the study period. “We don’t know whether people are playing more sports or if people are becoming more competitive and injuring themselves more,” Bell told *Reuters Health*.

The researchers used data from the U.S. Consumer Product Safety Commission’s National Electronic Injury Surveillance System of 100 hospital emergency departments. The study reported on youth injured in 21 different sports, including football, basketball, soccer, baseball, softball and ice hockey.

Injuries from basketball, baseball and golf decreased during the study period and increased for football, soccer and cheerleading.

According to Doyle, one-third of the injuries were strains or sprains. Internal organ injury increased from 2.5% to almost 6.0% by 2013. Concussion diagnoses also increased from 2.0% to 4.6% of injuries.

Bell told Doyle that the study revealed that doctors were seeing more severe injuries in the youngest age group. “One thing that might explain that is sports becoming more competitive and less emphasis on injury prevention,” she said.

Doyle quoted Andrew W. Gottschalk, M.D., a sports medicine expert at Ochsner Health System in Harahan, Louisiana, who also commented on the study. He said, “We know that more kids are vying for scholarships or starting younger. For the most part, increasing trends in sports injury correspond with increasing trends in American sports participation, and that is a very good thing. The best medicine is education, and for more athletes and parents to be aware of sports injuries—and appropriate treatment of those injuries.” — BY

SPINE

International Osteoporosis Foundation: No Automatic Drug “Holiday!”

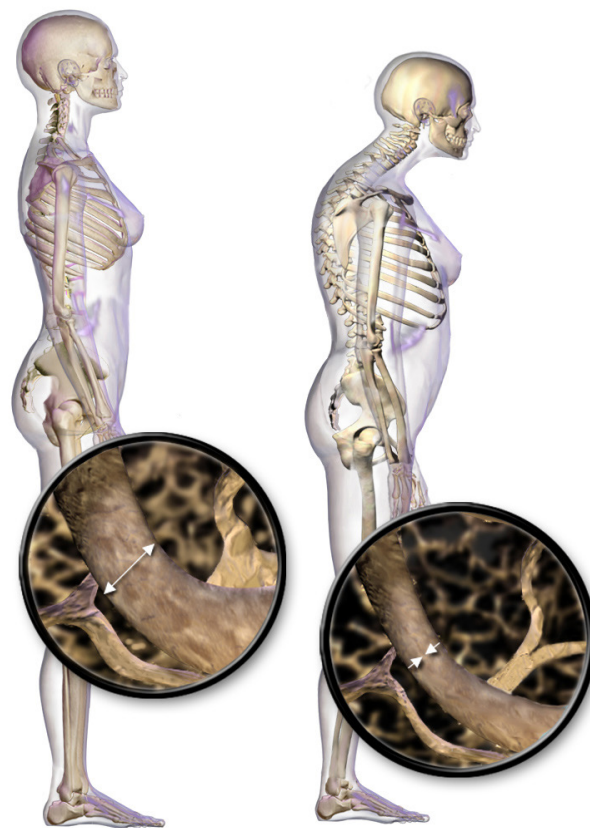
The International Osteoporosis Foundation (IOF) Working Group has just released a new editorial urging physicians to individualize treatment based on patients’ fracture risk, as opposed to automatically interrupting or stopping bisphosphonate therapy after five or three years.

As indicated in the January 4, 2016 news release, “The concept of a bisphosphonate ‘holiday’ arose following concerns about osteonecrosis of the jaw (ONJ) and atypical femoral fracture (AFF), rare events which have recently been linked to long-term use of bisphosphonates.”

Lead author Professor Stuart Silverman, M.D., Cedars-Sinai Medical Center and Professor of Medicine, University of California, Los Angeles (UCLA) noted in the news release, “... In the meantime we want to remind physicians and patients alike that while the incidence of AFF and ONJ are very rare, hip and spinal fractures in high risk patients are, in contrast, far more common and a major cause of disability, loss of quality of life and early death. The ben-

efits of bisphosphonate therapy with regard to reduced fracture incidence in moderate and high risk women clearly outweigh the risk of rare adverse events.”

Professor Silverman told OTW, “The editorial began as a response to what I was seeing in my own practice as a rheumatologist and osteoporosis clinician and what other members of the IOF working group were also seeing in their practices. We were seeing patients who were at high risk of further fracture (based on bone density or history of fracture) who had been on oral bisphosphonate therapy for three to five years and who had stopped their medication and were now on bisphosphonate holiday. Some of these patients were being placed on bisphosphonate holiday by their doctors but others stopped the medication on their



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own without consulting a doctor due to media coverage of side effects such as osteonecrosis of the jaw (ONJ) or atypical femoral fracture. These side effects are rare in comparison to the benefits of reducing fracture risk and fracture complications. The physicians and patients were not considering their fracture risk when stopping the medication and their need for continued therapy.”

“When clinicians began to see patients on bisphosphonate holiday who then began to fracture after several years off therapies, we became even more concerned. Then, when we began to see patients who were at high risk of fracture who refused osteoporosis medications, not only bisphosphonates, because they perceived the medications as dangerous, we realized that the concerns about bisphosphonates being picked up by the media were frightening patients to stop their therapies on their own or to not take them at all. The patients were not understanding that the risks are very small in comparison to the large benefits of risk reduction of fracture. As we know, fractures are associated with considerable morbidity and mortality.”

“To address these concerns, a proposal was made to the IOF working group to do an international survey of the current clinical management of bisphosphonate holidays. The results of the survey showed that the members of the IOF working group did agree that patients at high risk needed to continue therapy, although there was disagreement on the exact definition of high risk. The IOF working group then chose to use the results of the survey to develop an editorial to address the need to continue to treat patients with osteoporosis at high risk of fracture.” — EH

New Study: Exercise Prevents Back Pain

A new literature review published online by *JAMA Internal Medicine* hints that exercise may reduce the risk of low back pain (LBP). The work was led by Daniel Steffens, Ph.D., of the University of Sydney, Australia.

Dr. Steffens and his co-authors identified 23 published reports (on 21 different randomized clinical trials including 30,850 participants). As indicated in the January 11, 2016 news release, “Although our review found evidence for both exercise alone (35% risk reduction for an LBP episode and 78% risk reduction for sick leave) and for exercise and education (45% risk reduction for an LBP episode) for the prevention of LBP up to one year, we also found the effect size reduced (exercise and education) or disappeared (exercise alone) in the longer term (> 1 year). This finding raises the important issue that, for exercise to remain protective against future LBP, it is likely that ongoing exercise is required.”

Dr. Steffens told OTW, “Back pain is a leading cause of disease burden globally. At present, a variety of

interventions, such as exercise, education, back belts and shoe insoles, are commonly prescribed to prevent an episode of low back pain. Guidelines lack clear recommendations for prevention of low back pain and the effectiveness of the range of possible prevention strategies for low back pain is not clear. Our study aimed to investigate the effectiveness of these interventions for prevention of low back pain. We found that exercise alone, or in combination with education, is effective for preventing back pain. In contrast, we also found that education alone, back belts, shoe insoles and ergonomic interventions do not prevent back pain or sick leave due to back pain.”

“It is important that surgeons understand the approach to exercise that was used in the trials so they can best advise their patients. There was some variation but in general trials included exercises to improve strength, flexibility, skill and aerobic fitness. The exercises did not just focus on the spine but included upper and lower limb exercises as well. Typically participants did 2-3 sessions per week at the clinic and agreed to do home exercise as well. The program duration ranged from 12 weeks to 18 months.” — EH



Exercise and back pain/Pixabay, Flickr and Erik Ogan

PEOPLE

**William N. Levine,
M.D. New Editor-in-
Chief of JAAOS!**

William N. Levine, M.D. has been named the new editor-in-chief of the *Journal of the American Academy of Orthopaedic Surgeons (JAAOS)*, the orthopedic journal of the American Academy of Orthopaedic Surgeons. Dr. Levine replaces Jeffrey S. Fischgrund, M.D., who served as JAAOS editor-in-chief from 2009 through 2015.



William N. Levine, M.D., courtesy of Columbia University Medical Center

Dr. Levine is a professor and chair of the Department of Orthopedic Surgery at the Columbia University College of Physicians and Surgeons. He also serves as chief orthopedic surgeon at New York-Presbyterian/Columbia University Medical Center.

Dr. Levine received a bachelor's degree in human biology from Stanford University and his medical degree from Case Western Reserve University. He completed a residency in orthopedic surgery at Tufts Medical Center and held fellowships in elbow and elbow

surgery at Columbia-Presbyterian Medical Center and sports medicine at the University of Maryland.

"I am humbled and honored to have been named the fifth editor-in-chief of JAAOS," said Dr. Levine in the January 14, 2016 news release. "I have grown up with the 'yellow journal' and am excited to build upon what my predecessors created before me. I look forward to taking the journal to even greater heights in the future."

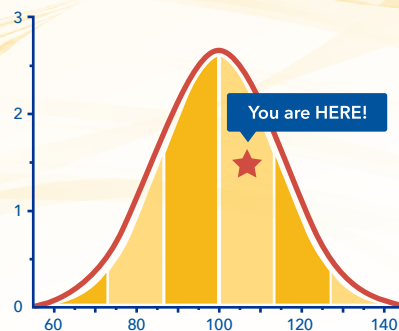
Dr. Levine has served in various leadership roles at the AAOS, including deputy editor of JAAOS from 2007-2014. He previously served on the Board of Directors of the American Orthopaedic Society for Sports Medicine (AOSSM) and is a past director of the American Board of Orthopaedic Surgery (ABOS). Dr. Levine currently is on the executive committee for the American Orthopaedic Association

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(AOA). He is author or co-author to more than 150 peer-reviewed articles and 50 book chapters and has edited 11 textbooks and monographs.

Dr. Levine told *OTW*, “My vision is for *JAAOS* to be the ‘go to’ resource for all musculoskeletal practitioners including orthopedic surgeons, non-operative musculoskeletal physicians, athletic trainers, physical therapists, and nurse practitioners/physician assistants.”

Asked about how he will proceed, Dr. Levine noted, “Despite the push for technology, people still like their journals so we will continue to provide the readers with what they value at *JAAOS*—timely, nonbiased readable reviews of topics that impact their daily lives in helping to take care of patients in the most efficient, evidence-based fashion. At the same time, I will be working with the *JAAOS* staff to ensure that we are employing all appropriate electronic technology to satisfy the needs of our broad users.”

“My colleagues can expect me to continue in my predecessors’ footsteps of creating the premier musculoskeletal journal in the world and expanding the reach and impact as we move forward.” — *EH*

Paul G. Echols, M.D. New CMO at UNM Sandoval

Paul G. Echols, M.D., has been named chief medical officer for the University of New Mexico (UNM) Sandoval Regional Medical Center (SRMC). Dr. Echols, a long-time UNM orthopedic surgeon and military veteran, brings more than 40 years of physician experience to this role.

Jamie Silva-Steele, SRMC president and CEO said in the January 7, 2016 news release, “In addition to his work within the UNM Health System, Echols has extensive clinical and administrative experience in venues including the Albuquerque Veterans Administration Medical Center, as well as military facilities and community hospitals. We are excited to have Dr. Echols join the UNM SRMC team.”

Dr. Echols completed residency training in orthopedic surgery at UNM in 1978. His career at UNM started in 1992 with the UNM Department of Orthopaedics and Rehabilitation. In 2005, he received an academic promotion to professor, and was vice chair of clinical services from 2006-2011. He arrived at UNM SRMC in June 2012 as the Orthopaedic Site Director, and served in that capacity until July 2015, retiring as professor emeritus during the same time.

He served in the U.S. Air Force as a flight surgeon and was an active duty orthopedic surgeon during Operation Desert Shield/Desert Storm and Operation Iraqi Freedom, as well as Operation Noble Eagle/Operation Enduring Freedom. Dr. Echols retired from the USAF in 2003 with the rank of colonel.

Dr. Echols told *OTW*, “Stepping into a leadership role with a team so diverse,

yet so professional and passionate about what they do and how they do it, makes the hair on the back of my neck stand up.”

Dr. Echols added, “SRMC is a University of New Mexico Health System hospital that serves the diverse population of Sandoval County, New Mexico. We have a community academic hospital foot-print with 72-bed capacity, but well over 500 providers participating in an open staff model blending University Faculty with private community clinicians. We’re excited with our progress into our fourth year of operation, and energized about our prospects for the future.” — *EH*



Paul G. Echols, M.D., UNM Sandoval Regional Medical Center



Courtesy of University of New Mexico Sandoval Regional Medical Center



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