

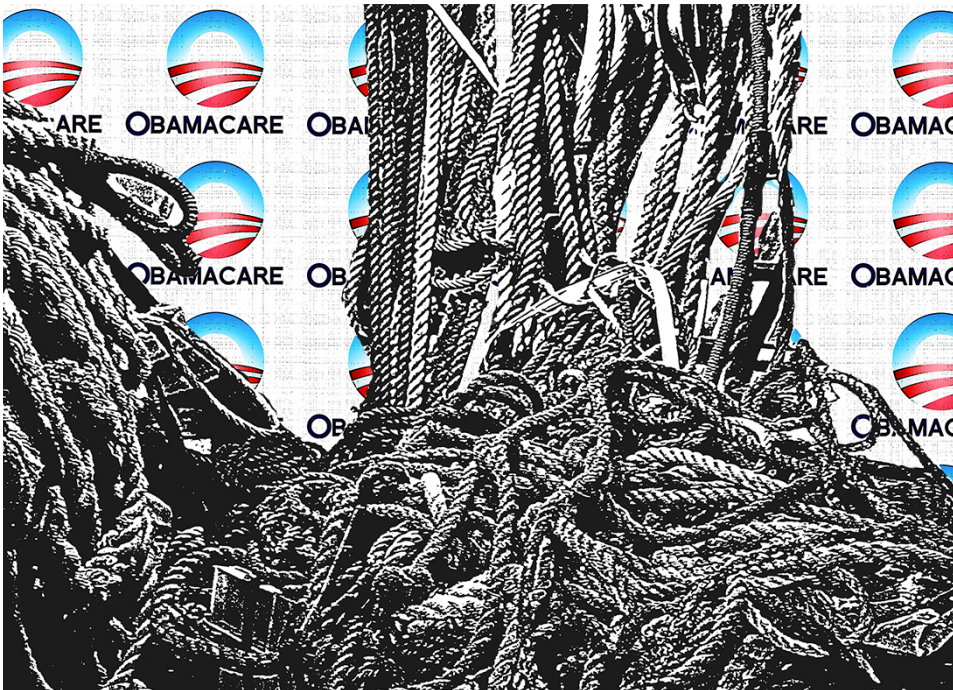
Orthopedics • This Week

WEEK IN REVIEW

4 Is the Marketplace Unraveling Obamacare? >> The head of America's largest insurance company dropped a bombshell recently when he said his company can't make money on insurance policies offered through Obamacare exchanges. After failed political and constitutional challenges to the Affordable Care Act, the marketplace is finally having the final word. Read it here.

8 Trauma Training Must Change for Global Care // Rothman's Bensalem Hospital: Best for VBP // Neel Anand, M.D. Wins SMISS Award >> Trauma kills more people than AIDS, malaria and tuberculosis combined. But we are mis-training the surgeons who can help. Andy Pollak, M.D. and colleagues are advancing a strong solution. Rothman Orthopaedic Hospital in Bensalem, Pennsylvania "crowned" best hospital for Value Based Purchasing! And Neel Anand, M.D. wins Best Paper Award at SMISS.

11 Floating Vessel of Hope Seeking Volunteer Surgeons // NYU Langone's Launching Pad for Researchers! // Rush's Fracture Liaison Service Ramping Up >> "All hands on deck" could be the motto for the surgeons willing to donate their time caring for the world's poor. Budding orthopedic researchers have a new way to start their careers: at NYU Langone. Rush University Medical Center is flagging patients at risk with their Fracture Liaison Service.



15 Della Valle v Callaghan: Dual Mobility Obviates the Need for Constrained Liners in Revision THA >> Dual mobility is the new kid on the block for total hip arthroplasty but it's not for everyone. John Callaghan reminds us that the constrained liners can work well, especially in older patients while Craig Della Valle argues that constrained liners have metal rings that can break. What's the right answer? This week's debate may have found it. Read on.

BREAKING NEWS

- 19 Bioventus Acquires BioStructures

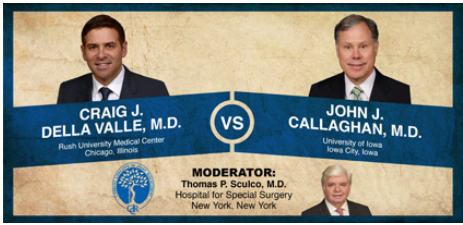
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For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Last Friday's strong job's report (nonfarm payrolls increased by 211,000) pushed the overall stock market higher but it also fueled fears of a dollar rally. Why? A strong jobs report supports higher Fed interest rates and equity markets are prepping for a Fed rate hike on December 16. In past cycles, the U.S. dollar rallies ahead of Fed rate hikes. For global ortho companies it raises currency concerns. But, more broadly, more employment means more insurance coverage means more demand for orthopedic products and services.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Zimmer Biomet	31.22%	(6.72%)	Zimmer beat Q3 estimates which signal that the integration of Biomet is going well. But a stronger dollar raises headwinds for Q4.
1	1	Stryker	22.94	(3.24)	Both SYK and ZBH should benefit from these strong employment numbers and a rising U.S. economy.
3	6	Medtronic	27.92	2.60	Medtronic's deal with Covidien to become an Ireland based company freed up \$9.3 billion in cash. Is that a strategy for ZBH and SYK?
4	4	Integra LifeSciences	13.74	2.63	For 2015, most analysts expect sales will decline about 5%. But for 2016, the same analysts are predicting a 10% sales increase.
5	5	Globus Medical	30.19	3.29	GMED building a VERY interesting portfolio of spine, trauma and biologic products on top of a proven management organization.
6	3	Orthofix	2.35	(1.09)	Institutional investors are increasing their interest in OFIX—in the hopes that this operational turnaround gathers momentum.
7	8	Johnson & Johnson	28.44	0.99	Pays out more than half its earnings as dividends. Bought back \$6.2 billion of its own stock. Has increased dividend every year for 50 years.
8	10	CONMED	11.10	3.40	The glow over the SurgiQuest purchase continues to attract investors—6th best performing orthopedics stock.
9	9	Exactech	10.26	(0.17)	EXAC is the 2nd least expensive orthopedic equity on the Power Rankings. But its earnings performance versus analyst estimates has been inconsistent.
10	7	NuVasive	13.25	0.75	NUVA's valuation, which is comparatively high, should become more attractive as Q4 and Q1 2016 are reported.



Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	\$9.00	\$981	19.21%
2	Wright Med Grp N.V	WMGI	\$23.10	\$2,371	14.24%
3	SeaSpine Hldgs Corp	SPNE	\$16.05	\$178	6.43%
4	K2M Group Hldgs	KTWO	\$21.15	\$872	6.23%
5	RTI Biologics Inc	RTIX	\$4.09	\$236	4.07%
6	CONMED	CNMD	\$42.63	\$1,181	3.40%
7	Globus Medical	GMED	\$26.72	\$2,544	3.29%
8	Integra LifeSciences	IART	\$64.86	\$2,399	2.63%
9	Medtronic	MDT	\$78.14	\$110,460	2.60%
10	Johnson & Johnson	JNJ	\$102.95	\$284,857	0.99%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Alphatec Holdings	ATEC	\$0.23	\$23	-34.30%
2	MicroPort Scientific	853	\$0.38	\$541	-12.49%
3	Zimmer Biomet	ZBH	\$100.55	\$20,490	-6.72%
4	Aurora Spine	ASG	\$0.17	\$3	-5.83%
5	LDR Holding Corp	LDRH	\$25.23	\$733	-5.29%
6	TiGenix	TIG.BR	\$1.03	\$182	-4.81%
7	Xtant Medical Hldgs	XTNT	\$2.83	\$34	-4.07%
8	Stryker	SYK	\$94.34	\$35,427	-3.24%
9	Orthofix	OFIX	\$39.88	\$753	-1.09%
10	Smith & Nephew	SNN	\$33.87	\$15,175	-0.70%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Exactech	EXAC	\$17.97	\$253	16.15
2	Johnson & Johnson	JNJ	\$102.95	\$284,857	17.94
3	Zimmer Biomet	ZBH	\$100.55	\$20,490	19.90
4	Stryker	SYK	\$94.34	\$35,427	20.48
5	Globus Medical	GMED	\$26.72	\$2,544	20.61

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	CryoLife	CRY	\$10.68	\$304	70.08
2	NuVasive	NUVA	\$51.30	\$2,519	58.89
3	MiMedx Group	MDXG	\$9.00	\$981	50.00
4	Smith & Nephew	SNN	\$33.87	\$15,175	30.29
5	Integra LifeSciences	IART	\$64.86	\$2,399	28.51

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	RTI Biologics Inc	RTIX	\$4.09	\$236	1.38
2	Globus Medical	GMED	\$26.72	\$2,544	1.61
3	Exactech	EXAC	\$17.97	\$253	1.81
4	Zimmer Biomet	ZBH	\$100.55	\$20,490	1.97
5	Smith & Nephew	SNN	\$33.87	\$15,175	1.97

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
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2	NuVasive	NUVA	\$51.30	\$2,519	3.85
3	MiMedx Group	MDXG	\$9.00	\$981	3.33
4	Johnson & Johnson	JNJ	\$102.95	\$284,857	3.30
5	Integra LifeSciences	IART	\$64.86	\$2,399	2.52

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	\$0.23	\$23	0.11
2	RTI Biologics Inc	RTIX	\$4.09	\$236	0.90
3	Xtant Medical Hldgs	XTNT	\$2.83	\$34	0.95
4	Exactech	EXAC	\$17.97	\$253	1.02
5	SeaSpine Hldgs Corp	SPNE	\$16.05	\$178	1.28

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$1.03	\$182	29.03
2	MiMedx Group	MDXG	\$9.00	\$981	8.30
3	Wright Med Grp N.V	WMGI	\$23.10	\$2,371	6.87
4	Medtronic	MDT	\$78.14	\$110,460	5.45
5	Globus Medical	GMED	\$26.72	\$2,544	5.36

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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Is the Marketplace Unraveling Obamacare?

BY WALTER EISNER

The Affordable Care Act (a.k.a. Obamacare/ACA) has been under attack through constitutional challenges, legislative defunding efforts and politicians running for national offices in 2012 and 2014 urging repeal of the law.

None of the challenges have shaken the foundation of the legislation designed to provide as many uninsured Americans as possible with affordable and subsidized health insurance.

The political threats were largely symbolic because President Obama vowed to veto any legislation that repealed the Act. Congress would need a two-thirds majority to override the veto and Congress has shown that it can't agree on almost anything with a simple majority. In addition, the President handily won reelection in 2012 by running on passage of the Act.

The constitutional threat at the Supreme Court was swatted away by two conservative justices, Chief Justice Roberts and Justice Kennedy. So the Act lived on.

UnitedHealth's Bombshell

But now, there's a serious threat from the very business community that stood to gain the most by government forcing people to buy their product, the insurance industry. The industry was an early supporter of the Act as it stood to gain what economists call, "economic rent."

On Tuesday, December 1, 2015, the head of the largest insurer in the U.S. dropped a bombshell and told investors that their company was losing money on the government-run health insur-

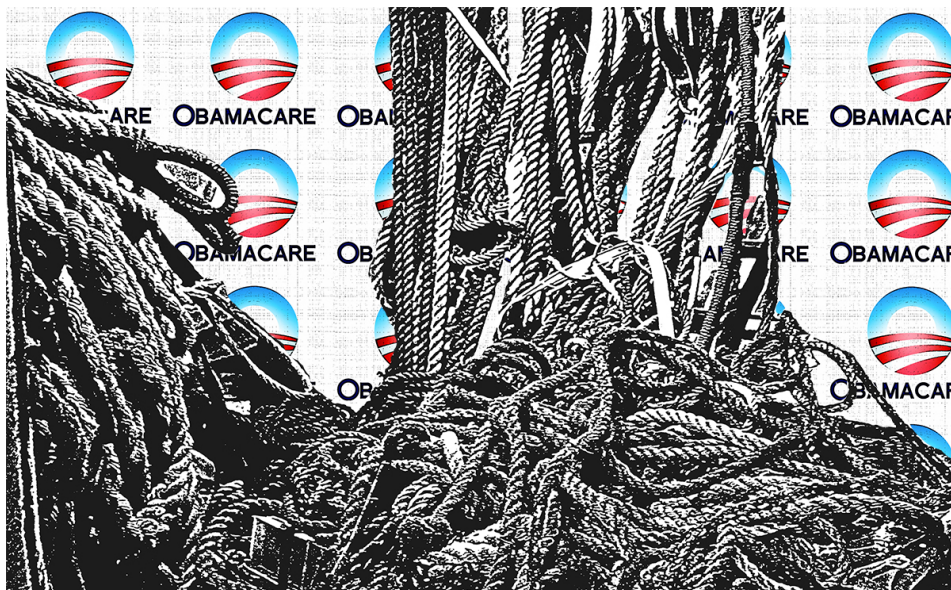


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ance exchanges and should have stayed out of participating in any of the plans.

Stephen Hemsley, the CEO of UnitedHealth Group, said offering policies through the health exchanges was "a bad decision. In retrospect, we should have stayed out longer. It will take more than a season or two for this market to develop."



Stephen Hemsley, CEO UnitedHealth Group / Forbes

In mid-November the company announced that it might drop out of the exchanges altogether for 2017. Next year, he says the company will make decisions on a market-by-market basis about whether to keep selling exchange policies.

"A Money Loser" For Insurers

Lee Schafer, a business writer at the Minneapolis-based *Star Tribune*, said the company has earned a reputation for good management. "If it can't sell insurance through an exchange and make money, the whole program created by the ACA to get more people private health insurance must be in trouble."

Schafer wrote that it's too soon to conclude that the ACA exchange market is on its way to a collapse. "What UnitedHealth did do was be a lot more direct than others in the industry about how

it thinks this government-run market should really work.”

It’s pretty easy to understand why the company is having second thoughts. UnitedHealth is not making money with the customers it’s gotten through the exchanges.

In 2015, noted Schafer, the company is on 23 individual public exchanges, insuring about 540,000 people as of last reported count. “While that’s a big chunk of customers—and risk—for just about any insurer, it’s not for a company the size of Minnetonka-based UnitedHealth, which has about 46 million people in all of its plans.”

As the company explained on a conference call for shareholders late in the week before Thanksgiving, it had thought in the fall of 2014 that its initiative with ACA-related exchanges would be roughly a break-even business in 2015.

Instead, it turned out to be a money loser, and the company expects the same result next year.

UnitedHealth was one of the companies that started slowly with the exchanges, sitting out the first year entirely. But before getting too wound up about Hemsley’s bombshell, the company said the same things about Medicare Advantage, before figuring out the economics and becoming the biggest participant in that program.

Overall Healthcare Spending Rising

Hemsley’s comments came right before the Centers for Medicare and Medicaid Services announced on December 2, 2015 that healthcare spending grew by 5.3% in 2014, the fastest rate in seven years. The jump, according to the agency, was primarily due to increased insurance coverage through Medicaid and the ACA, as well as a 12.2% spike

in spending on prescription drugs. Another industry heavily engaged in “economic rent.”

So if overall healthcare spending is up, why hasn’t UnitedHealth figured out how to make money on policies it offers on the exchanges?

Unanticipated Risk

So far the company has found that people who signed up for its insurance plans through an exchange are using a lot more healthcare services than anticipated. What’s worse is that healthy people have been dropping their coverage and sicker people buying in outside of the normal open enrollment period, meaning they signed up when they could after a life event like a marriage or the birth of a child.

As the 2016 open enrollment period on the exchanges got underway, UnitedHealth

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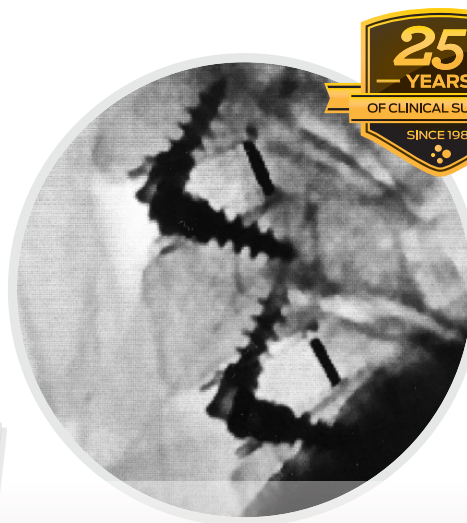
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still had policies listed on them. But it cut its marketing as well as cut commissions paid to brokers, creating an incentive for the brokers trying to help people find insurance to go somewhere else.

Small Risk and Risk Mitigator

There are a couple of points to keep in mind before declaring the demise of Obamacare. The individual market was about 7% of health insurers' revenue in 2014. By far most Americans get their insurance coverage through their jobs or through government plans such as Medicare. So it's a very small portion of an insurer's revenue stream.

The other is that the authors of the ACA anticipated the difficulty some insurance companies would have as a new form of the individual market got established. Congress tried to protect them with something called the "Risk Corridor Program." The program is intended to reimburse

insurance companies that ended up insuring too many costly customers, with money collected from insurers that had a good experience with costs.

But those numbers didn't balance as the government reported in October that insurers had \$2.87 billion in risk corridor claims for 2014. Insurers with a better-than-expected experience, however, only owed \$362 million in risk corridor contributions. That means that risk corridor payments for 2014 will cover less than 13% of claims.

That shortfall is cited by critics of the Act as one reason that two-dozen or so non-profit cooperatives created by the Act look like they are in danger of surviving.

Insurance Industry

Avik Roy, an ACA critic who serves as GOP presidential candidate Marco Rubio's health care advisor, suspects

UnitedHealth may just be the first domino to fall. Other commercial insurers, such as Aetna, Anthem, and Cigna, have raised premiums by double digits and still say they can't make the numbers work in their favor. Hence, they have withdrawn from counties where their losses were particularly acute.

For example, state filings of the non-profit Blue Cross Blue Shield (BCBS) show that the company barely broke even in the first half of 2015. In Texas last year, BCBS collected \$2.1 billion in premiums and paid out \$2.5 billion in claims.

The big private insurers like Aetna and UnitedHealth are in much better shape to withstand losses. Yet it's no surprise that generally prices through the exchanges increased this year, along with deductibles.

But not everyone was crying that the sky was falling. Some big insurers followed



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up UnitedHealth's announcement with calming statements of their own, saying that unlike UnitedHealth they weren't thinking about quitting the market.

Anthem, an operator of Blue Cross plans, added that its executives were "continuing our dialogue with policy-makers and regulators regarding how we can improve the stability of the individual market."

Anthem has a big stake in talking up "stability" and keeping government regulators happy. The company is seeking government approval to acquire Cigna for \$48 billion.

Sign-Up Projections Falling Short

Another factor cited by ACA critics is that things will get worse if there are far fewer patients enrolling in the exchanges than projected, but those signing up

are too old or sick for anything resembling a balanced risk pool.

The government has reported that it only expects 1.3 million new members to buy coverage next year, compared to the 8 million projected when the law as passed. This means that overall enrollment by 2016 will be somewhere between 9.4 million and 11.4 million. That's only half of the 21 million initially predicted.

This, argues critics, forces companies to jack up rates so much that only those eligible for full subsidies (the relatively poor) or the sick find it worth their while to buy coverage. The relatively young and healthy are opting to pay the penalty and "go naked." This, in turn, is forcing insurers to raise prices even more, which is causing more healthy people to drop out, unleashing the dreaded adverse selection spiral.

The *Tribune's* Schafer said we already knew that through the ACA we decided to deliver an important benefit to people but also that it should be run through private insurance firms. "What UnitedHealth has told us is that it's also up to us to make sure those private firms have a fair shot at making money at it."

Wait and See

Hemsley told investors that the company tried to grow conservatively and did not believe markets would form this slowly. He said the company will narrow decisions on whether to stay in the exchanges. "We will not knowingly lose money on this product line in 2017."

However, noting UnitedHealth's experience with Medicare Advantage, he added that any decisions on the exchange business may not be permanent. ♦

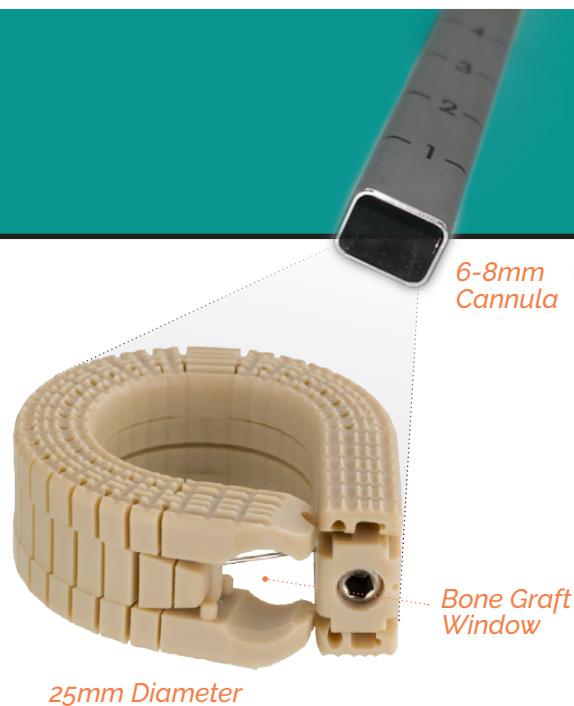
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Trauma Training Must Change for Global Care // Rothman's Bensalem Hospital: Best for VBP // Neel Anand, M.D. Wins SMISS Award

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

We Must Change Training for Global Trauma Not many would attempt to change the government. A few brave orthopedic traumatologists are doing just that, however.

Andrew Pollak, M.D. is chief of Orthopaedics for the University of Maryland Medical System and a past president of the Orthopaedic Trauma Association (OTA). He told *OTW*, "Around the world, trauma kills more people than HIV, malaria, and tuberculosis combined! Even more astoundingly, the number of people who sustain permanent disability as a result of traumatic events is between ten and fifty times greater than the number of people who lose their lives. To address this scourge, we must effectuate a change in how we fund international medical programs. In essence, we are asking that the U.S. government make room for orthopaedic surgical treatment."

"Our proposed initiative—The Orthopaedic Trauma Care Specialist (OTCS) program—is a two-year residency that would focus primarily on the management of orthopaedic trauma, and would address the specific needs of the country in question."

"Our experience in responding to global disasters has been that in many developing countries there are outstanding medical schools that are graduating doctors who are ready to begin residency training. But there are no residency programs. As a result, these doctors often go to other countries such as France or elsewhere in Europe to gain



Medical Surgery in Haiti / Source: Wikimedia Commons, U.S. Navy and Chief Mass Communication Specialist Robert J. Fluegel

superb experience, and then decide not to return to their home countries."

"For the most part, traditional orthopaedic residency training prepares people to do things that are completely irrelevant in the developing world. Shoulder arthroscopy, for example, is a first world procedure. Many hospitals and accident wards in the developing world are overwhelmed with trauma patients—as opposed those who need a hip replacement for arthritis. Our silos of American medicine are not a good fit for these low and middle income countries, and we need to develop a program that would allow people to be trained in a shorter period of time—and trained for conditions that effect *their* communities."

"One such issue in many countries is road traffic accidents. Part of the problem is that traffic signals appear far less quickly than roadways appear. People are being injured and taken to centers that have no capacity to care for them. A femur fracture is splinted and elevated without adequate reduction or surgical stabilization often leading to prolonged or permanent disability. One might say that this is a real crime given that operative care can be taught simply and lead to almost zero long term disability."

"We have submitted our proposals to the U.S. Agency for International Development and the Centers for Disease Control and Prevention. The problem is that they are not used to the model; they are accustomed to mod-

els that address HIV, etc., not surgical care. If we obtain funding, the next step will be to define our partners. We have already identified our partners in Haiti, and we will define other partners and build relationships in other countries (perhaps Botswana or Nigeria)."

"Trauma is a major threat to the economies of the developing world. And the OTCS would be a launching pad that could create other graduate medical education programs such as emergency maternal and obstetric care. There are many opportunities here to advance care and make a major impact on the lives of millions of people worldwide."

Rothman Orthopaedic Specialty Hospital Wins Major Award Rothman Orthopaedic Specialty Hospital (ROSH) in Bensalem, Pennsylvania, has been "crowned" best hospital for Value Based Purchasing (VBP) by the Centers for Medicare & Medicaid Services (CMS). Commenting on this honor is Alexander R. Vaccaro, M.D., Ph.D., MBA, president and Richard H. Rothman Professor and Chairman of the Department of Orthopaedic Surgery at the Rothman Institute.

Asked how ROSH provides such high quality healthcare, Dr. Vaccaro told *OTW*, "High quality healthcare is the ability to apply evidence based practice to the health services we provide in order to achieve favored outcomes. This innovation begins with the surgeons at the Rothman Institute and is replicated at the Rothman Orthopaedic Specialty Hospital by the devoted providers. ROSH structures this approach on a framework that focuses on efficiency, high quality, and cost containment."

"Efficiency is measured through interactive care and tracked with the patient navigation process. At each interval, a dedicated nurse navigator guides the

patient through their entire episode of care which starts 30 days prior to surgery and continues 90 day post operatively. Efficiency is also measured through the structure of the facility. The model for ROSH includes a team of professionals that stay well-informed in the discipline of orthopaedic care. By working together they create a system of care that functions in unison rather than individually."

"Quality is measured through the strategic use of big data and information technology. Collaborating with entities like Harvard Business School, ROSH use business analytics to evaluate trends and discover opportunities for improvement and cost management. FORCE Therapeutics is a system that allows us to track patient progress through rehabilitation and OBERD [outcomes based electronic research database] collects the necessary data to analyze detailed information about patient outcomes over an extended period of time. Frequent review of patient satisfaction scores provides the necessary feedback in evaluating our processes. Focusing solely on orthopaedics affords us the ability to synthesize data quickly and respond to all deviations."

"Cost containment in the facility is managed through several different methods. For one, ROSH empowers the staff to recognize inefficiencies and waste. This allows for a cooperative team approach where everyone works towards a unified goal. As a part of a local consortium ROSH meets with like facilities to discuss contracting, best practices, and price investigation. Big data and technology are also utilized in cost containment. ROSH was an integral part in developing a targeted software application used for case cost accounting."

"This framework provides a solid foundation for continued success in ortho-

paedic care. By constantly evaluating these areas ROSH maintain the highest quality of healthcare services."

As for how ROSH's value-based purchasing efforts stand out from the crowd, Dr. Vaccaro noted, "ROSH is the only orthopaedic-specific specialty hospital in the region. By being specialty specific we are better positioned to improve quality, patient satisfaction and efficiency than most other hospitals. The robust orthopaedic clinical research performed by the Rothman Institute surgeons allows us to continually develop evidence based best practices and establish the standards and protocols to monitor and improve outcomes, satisfaction and efficiency through our data systems."

"ROSH will continue to monitor and improve established practices and processes. Through structured performance improvement plans a robust quality program will continue to guide future health care services. Understanding that a targeted focus on high quality does not translate to higher cost, ROSH will coordinate a deliberate approach to maintaining the existing model. We continue to build our data base which will allow us to further develop predictive modeling to improve quality, patient satisfaction and cost. This will also provide for enhanced care coordination for every patient who is operated on at ROSH."

Neel Anand, M.D. Awarded Best Paper at SMISS Neel Anand, M.D., M.Ch.Orth., director of Spine Trauma at the Cedars-Sinai Spine Center, has been honored with the Global Forum Best Paper Award by the Society for Minimally Invasive Spine Surgery (SMISS). Dr. Anand tells *OTW*, "While circumferential minimally invasive surgical correction (CMIS) for adult spinal deformity (ASD) is getting popular, pre-

dictors for outcomes have not been well studied. My team and I noticed that some patients were not getting optimum functional results so we set out to study them. Using our extensive database, we posed the questions, 'Is there a major difference between ten of the best patients and ten of the worst?' and 'If so, what is the difference?' Because the Oswestry Disability Index (ODI) is a marker of postoperative disability, we selected the best and worst ODIs and looked at factors such as BMI [body mass index], diabetes, etc. All of them showed no difference. You're not operating on someone who is in a very bad state, so there is some selection bias."

"The ten best patients had significantly lower preoperative ODI and Visual Analog Scale [VAS], fewer complications and lower incidence of postoperative pseudoarthrosis. A full 80% of

the patients in the worst outcome group were operated on before 2011. Patient factors (age, sex, depression, diabetes, BMI, smoking) and baseline deformity (COBB angle, AVT, Coronal Balance, SVA, PI-LL mismatch) were not statistically significant."

"We found that the complication rate was significantly higher in those with the worst ODI (as expected). Six out of ten worst patients experienced major complications, of which four had pseudoarthrosis (nonunion). Nine of the ten patients with worst outcomes underwent surgery before 2011, which is likely an indication of our learning curve for this procedure. We used to do a lateral transpsoas fusion at L4-L5, then an AxiaLIF followed by the insertion of posterior pedicle percutaneous screws. We were not getting optimal sagittal balance when using

the AxiaLIF for L5-S1, and we started recognizing that we were getting late nonunions with AxiaLIF. That is why in 2011 we stopped using it and began using ALIF."

"In addition, instead of going through the psoas muscle, we began to go in anterior to the psoas. There were a small number of patients (1-3%) who experience lumbar plexus issues with the transpsoas approach, so we changed the approach to go ante-psoas thereby avoiding going through the substance of the psoas muscle but rather started going anterior to the psoas with an oblique trajectory."

"I would like to give credit to two medical students who gave their all to this project: Ryan and Jason Cohen, twin brothers who dedicated their time, effort and passion towards this study." ♦

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Floating Vessel of Hope Seeking Volunteer Surgeons // NYU Langone’s Launching Pad for Researchers! // Rush’s Fracture Liaison Service Ramping Up

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

Floating Island of Hope It’s a floating OR (five of them, actually) that roams the world helping the globe’s neediest citizens. This state-of-the-art floating island of hope is named *Africa Mercy* and is owned and operated under the auspices of Mercy Ships, a 37-year-old entity that offers the chance of a new life to those who have no other help. In total, Mercy Ships has visited 587 ports and their volunteer surgeons have performed more than 81,000 life-changing or life-saving operations.

Mercy Ships is committed to serving countries in the lower third of the UN Human Development Index. Mercy Ships goes where it is invited to serve in a country, and where the government must agree to full participation.

The *Africa Mercy* is currently docked in Toamasina, Madagascar. That is where OTW found Frank Haydon, M.D., an orthopedic surgeon and longtime volunteer with Mercy Ships. He said, “My wife is a nurse, and serves as the orthopedic team leader on the ship. In nursing school she had a roommate who toured a Mercy Ship and got her interested in participating. We have been volunteering with this fantastic organization for seven years. I am the lead orthopedic surgeon and we have two new surgeons coming soon. We primarily treat angular deformities of the lower leg (tibia vara and tibia valgus). In Madagascar we are seeing quite a lot of rickets because the kids are surviving on white rice three times a day and are thus deficient in calcium and



Courtesy of mercyships.org

vitamin D. We also treat clubfeet and just this year we have started an off-ship Ponseti program for those under the age of three.”

“I am doing an average of four surgeries per day, most of which are bilateral procedures. The patients range in age from 4-17, with an average age of 5. We would love to have more surgeons who are willing to come for two weeks at a time. We have a CT scanner, X-ray capability, a lab, and a Nikon Coolscope for remote diagnosis.”

“The transformation that you get to participate in is life-changing for all involved. These are people who have no access to healthcare and who live on a few dollars a day. Their deformity has separated them from the rest of society for perhaps their whole lives...and we get to change that!”

“Each year there is a child that stands out for me. There was a boy who walked for two days to reach the ship, despite having a horrible foot infection. He was close to death when he arrived; we amputated his foot and within 24 hours he began to recover. We provide miracles for those who can’t do it for themselves.”

The goal of Mercy Ships is to have is to have two orthopedic surgeons working together during each field service.

If you wish to find out more information about how to volunteer please visit <https://volunteer.mercyships.org/>. To make a donation to Mercy Ships, please visit <https://www.mercyships.org/ways-to-give/>

NYU Langone Upping Ante on Research In what is a trailblazing twist, surgeons from NYU Langone

Medical Center are changing the face of research at their institution. Thomas Errico, M.D. is chief of the Division of Spine Surgery at NYU Langone Medical Center. He told OTW, “Ten years ago I considered having a more formal research lab which would include varying levels of researchers. The idea was to provide more evidence of the effectiveness of spine surgery, but also to have an environment that is essentially a launching pad for academic careers. After two years of searching I secured real estate across the street from the Hospital for Joint Diseases and we took the opportunity to set up a research lab on the first floor of a Brownstone. Our existing research team, directed by Alex Lee, R.N, began with the SPORT Trial (Spine Patient Outcomes Research Trial); Frank Schwab, M.D. and Virginie Lafage, Ph.D. came on board and started an extremely prolific collaboration.

Ground breaking progress was made in many areas, including sagittal balance and pelvic parameters. We train four spine fellows a year, most of whom are busy doing surgeries, trying to find a job and raise families. We realized we needed more help than just spine fellows to do meaningful research so we expanded our team. It is now a place where a college premed student can come because he or she wants to do a year of research to amplify their medical school application. Or one of our researchers might be someone who graduated from medical school, but did not get the residency of their choice. And we sometimes take orthopedic residents in the middle of residency. Many of our early researchers are now well into medical school, residencies and fellowships. Our mantra is, ‘The Brownstone is a launching ground—not a landing spot.’ Take what you learn here and ‘fly with it!’”

“It is a boost rather than a magic pill; if someone was lousy in college that can’t be erased. If a medical student is not a great applicant to begin with then working in our lab can’t help him or her get into an orthopedic residency.”

“In order to keep this initiative underway, we are seeking better funding. Twenty years ago I founded a nonprofit spine scoliosis research entity called Spine and Scoliosis Research; over the years we have collected money that can now be used for this laboratory. We also fund the research via gainsharing obtained by cost savings for the hospital. Other grants have been obtained but we are constantly seeking more.”

Shay Bess, M.D. is chief of the Adult Spinal Deformity Service for the Division of Spine Surgery and Director of Spine Research in the Department of

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Orthopaedic Surgery at NYU Langone Medical Center and Hospital for Joint Diseases. He told OTW, “The research Brownstone is an ideal setting for collaborative research because it creates an environment that thrives on finding synergies, and brings together a critical mass of people who are interested in getting things done.”

“We are working on a number of projects, including our efforts with the International Spine Study Group, which is an incredibly productive multi-center research group that has the same approach to research that exists within the Brownstone at NYU; namely productivity through collaborative efforts and combined intelligence. Additionally, we have access to large national databases that allows us to examine larger questions and provides the impetus to hone in on the granular aspects of the questions with more detailed data-

bases. We are also combining efforts with the Orthopaedic Trauma and Adult Reconstruction services at NYU to investigate what determines patient satisfaction during the hospital stay and the interplay between pain control, patient satisfaction and postoperative discharge status. The future thrust of our research will be aimed at refining the methodology by which we assess patient reported quality of life. This will involve implementing more advanced questionnaires into our patient assessment practices. These advanced questionnaires will be more accurate than the standard forms that are traditionally used and, of equal importance, will reduce patient question burden and save patient time. In the end, this vast array of collaborative efforts helps foster the careers of the budding academicians at the NYU Brownstone as they strive to answer the specifics of ‘what’ ‘how’ ‘when’ and ‘why.’”

Rush Ortho: Automated Program Preventing Secondary Fractures At Rush University Medical Center physicians are elevating fracture prevention to a new level. Sanford Baim, M.D. is director of the Bone Metabolic Disease Program in the Rush Section of Endocrinology. Dr. Baim, who established and leads Rush’s Fracture Liaison Service (FLS), and is working with orthopedic surgery at Rush told OTW, “After having implemented this program at another university we found it made a real difference in preventing additional osteoporotic fractures. The chair and executive vice chair of the department of medicine recruited me to develop the program at Rush and thus establish a comprehensive approach to identifying patients at risk for re-fracture.”

“This totally automated program is actually part of the Epic electronic health records system at Rush. It iden-



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tifies patients 50 years and older who have sustained a fracture at the time of admission or who have had a fracture since the age of 50 in their medical record. If a patient meets either of those criteria, a FLS alert is generated by the patient's orthopedic surgeon, hospitalist, neurosurgeon, or medical team to decide whether a fracture liaison consult is required. This includes all patients admitted through the ER, those who come to the ER, but are not admitted and sent to orthopedic surgery in the outpatient setting for follow up, and those who go to the Rush rehabilitation center. Since this is specific to a fragility fracture that is synonymous for an osteoporotic fracture, someone who, for example, comes into the ER due to a car wreck and has a fracture, does not usually require a consult unless the patient's

orthopedic surgeon finds skeletal fragility at the time of surgery or additional medical reasons for a consult are apparent."

"The other great aspect of the Rush Fracture Liaison Service is that it serves as a training program since physicians in general are not aware of fragility fractures being consistent with the clinical diagnosis of osteoporosis irrespective of the bone density scan diagnosis. Patients are seen in consultation with fellow and residents and are assessed to determine if the patient has underlying secondary reasons for osteoporosis inclusive of metabolic bone diseases and mineral disorders. An essential feature of the service is education of the Rush attending staff (orthopedics, neurology, rehabilitation, etc.) about secondary fracture prevention."

"Unfortunately, greater than half of fractures occur in patients not identified as osteoporotic by a bone density scan and as such many physicians say, 'My gosh...we just fixed a hip fracture and we need to do something so that the patient doesn't have another fracture.'"

"At present we have almost completed collecting the first 100 patient consults and are analyzing the data that will soon be presented to our medical staff as part of a quality improvement program at Rush. Following this, we will publish our results and explain how important this is for secondary fracture prevention. Once we are have completed this aspect of our secondary fracture prevention program, we will turn our attention to primary fracture prevention across the entire Rush system." ♦

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Della Valle v Callaghan: Dual Mobility Obviates the Need for Constrained Liners in Revision THA

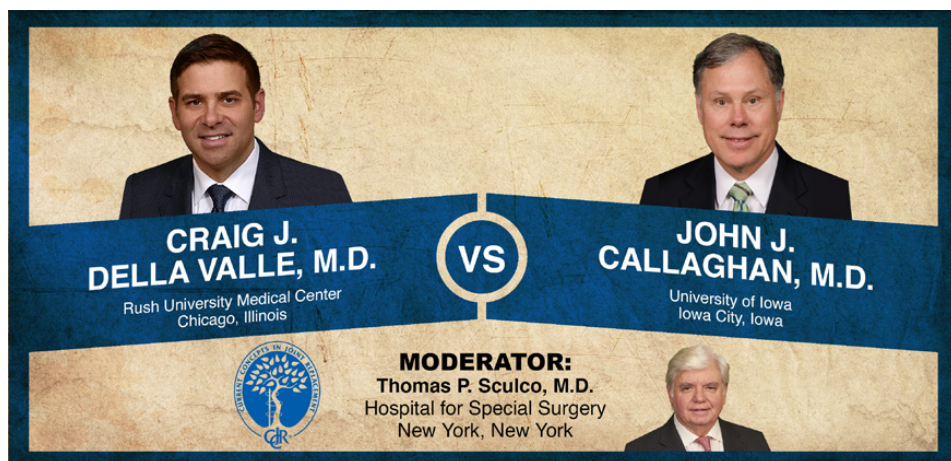
BY OTW STAFF

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 "Dual Mobility Obviates the Need for Constrained Liners in Revision THA." For the proposition is Craig J. Della Valle, M.D. Rush University Medical Center, Chicago, Illinois. John J. Callaghan, M.D. University of Iowa, Iowa City, Iowa, is opposing. Moderating is Thomas P. Sculco, M.D., Hospital for Special Surgery, New York, New York.

Dr. Della Valle: Dislocation, like it or not, is the number one reason for revision of a total hip in the United States and is also probably the most common complication after revision total hip replacement. Constrained liners have been used very heavily in the past to solve or prevent these kinds of events from occurring. That being said, I think a lot of the issues that we've seen have been changed, to a certain extent, by large femoral heads and I think they've really become the mainstay for preventing and treating instability.

This has really been facilitated by cross-linked polyethylene. Several studies have basically shown that there doesn't seem to be a meaningful increase in wear with larger head sizes.

Two randomized control trials—one that I was involved in with Garbuz showed that when you compare a 32mm head or a 28mm head to a 36mm or larger head, there's a decreased risk of dislocation with larger heads. And I think



Current Concepts in Joint Replacement/RRY Photo Creation

that large heads in general have really decreased the use of constrained liners.

Big heads don't always work, however. There is a great article by Mike Ries that basically showed even when large heads were used, if you have situations such as deficient abductors, you need a constrained liner in that situation because a large head just doesn't seem to work.

Constrained liners are obviously a very tantalizing solution and can be very effective. You can either engage into a compatible shell or you can cement into a well-fixed shell, and John Callaghan has done some beautiful work showing a very high rate of success, a 94% success rate at four years, with only one liner failing at the cemented interface... and that's with a constrained liner that was cemented in place.

I think, however, that a lot of those cases predated the routine use of large femoral heads. I think a lot of the problems that John reported on, in contemporary practice would probably be

solved simply with a large head and I don't think they were the same level of complexity that we use constrained liners for today.

It's also imperative to understand that different constrained liners work differently. The Tripolar Constrained (Stryker) has, in my mind, the best track record. When you compare that to some of the ring-locking ones, like the DePuy Constrained liner that I reported on when I went for my fellowship, we had a much higher rate with the ring-lock designs. Again, many of these problems in the past probably would be successfully treated with large heads today.

So one of the problems with constrained liners is increased stresses at the bone implant interface. In one case when I was a chief resident we did a structural allograft, very complicated deficient abductors, used a constrained liner like I should have. Then the patient came in at their six-week visit and had torn their fresh cup right out of the acetabulum.

In addition, constrained liners decrease range of motion, for most of the designs. There are unique designs out there that I think may have skirted that problem but they create higher stresses on the polyethylene. They can often require thin polyethylene and some of them aren't cross-linked. They may increase the risk of late loosening, and usually require open reduction if they fail.

I think John and I will certainly agree that whether you use a constrained liner or a dual mobility bearing, constrained liners do not compensate for component malposition. I think you really need to optimize the position of components and all other factors in the reconstruction to wind up with something that's successful.

We really looked at dual mobility as an alternative to constrained liners. There's a lot of European literature that sup-

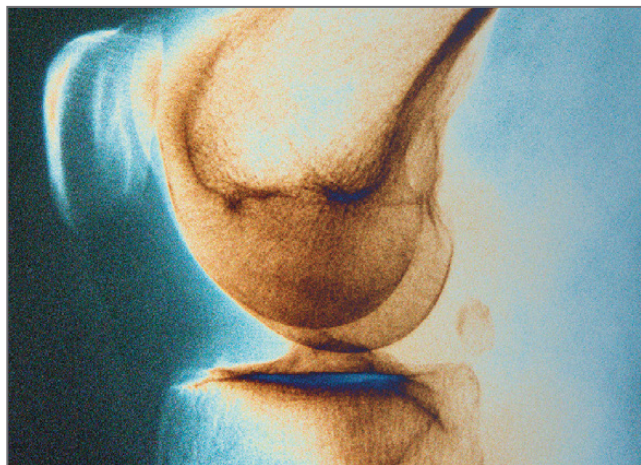
ports their use for both treatment and prevention of instability.

While dual mobility does have its own problems, including intraprosthetic dislocation, wear and concerns about high torque at the bearing surface, it also solves some pretty difficult problems. Patients who are completely abductor deficient and even in the most challenging situations, we found these bearings were successful.

In a clinical series we have 43 constrained liners versus 31 dual mobilities. It is a non-randomized series, but the indications were similar. Basically we looked for abductor deficiency, revisions for instability, or any inadequate stability at the time of revision with a larger head. We found recurrent instability 23% versus 13% with dual mobility and two of those were early cases where we cemented that liner into place and it mechanically failed. We looked

at repeat revision for instability...it was 26% versus 6.5% for dual mobility. The constrained liners did have a longer follow-up. Yet, three of our dual mobilities that we used in the series were for treatment of constrained liners. Based on this, dual mobility has really become our go-to instead of a constrained liner.

I think my take-home points are if you're dealing with patients with complex situations, you absolutely need to optimize all other factors, including component position and soft tissue balance. I think large femoral heads should be your first option to optimize stability. Really I think you should keep in mind that constrained liners, while useful—and I still think they have a role—have several serious disadvantages you need to think about. And at least in our experience, we've had dual mobility emerge as a really good alternative and at least at short-term follow-up are showing a lower risk of failure.



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Dr. Callaghan: I'm going to talk about the use of constrained liners and how dual mobility may not be the way to go. The dual mobility is the new kid on the block and Craig Della Valle is not a young guy any more, but he's about 20 years younger than me. There is no question...I think we all have some interest in this device.

We're always trying to find better solutions for dislocation. There's no question about it. Dislocation rates are from 6% to 20% following revision surgery. Revision for dislocation, even in Craig's group, is still only 85% successful.

I think all of us would use the increase in stability only as needed and I think Craig really articulated this well. You have to also realize that in bearing surface technologies the concave surface should be soft and the convex surface should be hard. This is why polyethylene liners in metal heads have worked

so well. And that's one of the concerns with dual mobility. In addition, you can't use screws in the non-modular shell and you have to use modularity in the screwed shells. We don't know what the effects of that are going to be.

Why have constrained liners gotten a bad rap? There's all types of constrained liners. It's really the tri-polar type of design that's had the best track record. All our experience has been with the constrained insert...the tri-polar type of insert. At 10-year follow-up we reported a 93% success in preventing dislocation in complex cases. And the failures that did occur were in the younger patient, <45 years, and I would agree, the younger patient is where we should think about using the dual mobility cup. You can get osteolysis, but it was very low in our series.

We have cemented constrained liners into well-fixed shells with a lot of success.

We're just doing our 10-year follow-up of these and there's been no change in the success rate, 94% at 4 years. Nowadays, they actually have a way of doing that where you don't have to prepare the liner.

So do we have failures, absolutely, and goes to what Craig said. You've got to make sure you don't cement that liner proud. You can't put it into a malaligned shell. You can't use it in a real tough reconstruction where you've put bone graft.

How about dual mobility at Tom Sculco's institution? They're not working out quite as well—10% revision rate at two years; 13% revised if it was treatment for dislocation. I was just recently in France and it's interesting that the French who developed the prostheses are doing less dual mobilities and we're starting to do more.

So if you're in a sand trap, you first have to get out; constrained liners get you

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out of the sand trap. We still are liberal with the use of constrained liners; we use dual mobilities in patients with spine pathology and in complex cases in young patients. And Dr. Della Valle would sleep a lot better if he would use more of these, I think. I'm afraid he's going too much the other way.

Moderator Sculco: Craig, let's go to you first. John brought up, and it seemed like the 23% incidence of dislocation in your constrained liner series seems very, very high...

Dr. Della Valle: That's because we're using them when you need them and that's what really led us to dual mobility. You take these patients who are abductor deficient, or multi dislocators... that's why we've looked for a change because we've looked at our results and said, 'Hey, most of our failures are these constrained liners.' Interestingly, we've done analyses and looked at our dislocations overall. We found that the constrained liners were actually protective because without the constrained liners they should even have a higher dislocation rate. But none the less, 23% failure rate. You look at that and say, 'I need to look at something different.' So if you use this mechanical construct with constraint in it and the patients who are abductor deficient, I think that over time they're going to fail.

Moderator Sculco: I reported on this and our incidence was similar to John's. Is there anything different in that series? Granted there are serious cases...in my series some of them had polio. Was there anything else that you could point to in terms of that dislocation rate being so high?

Dr. Della Valle: Again, I think there were severe cases where they had deficient abductors and those types of things, and once you get two, three years post-operatively we started to see

the constrained liners break. The ring breaks, dislocates, pulls out, or something like that happens over time.

Moderator Sculco: John, let's go back to you now. You're constrained liner experience has been pretty good. Have you seen mechanical problems like Craig is mentioning? Those rings, the metal rings do break, and that can lead to instability of those tri-polars. In general, you've had pretty good results. Is that still your experience?

Dr. Callaghan: Our experience is still pretty good and I want to give Craig some credit in that they have a very complex practice there at Rush and you have to take that into account. I am more concerned about constraint in the younger patient. All of our failures in that earlier study were in patients under age 45. So I think that patient is the one that I would experiment with dual mobility for sure. I still think older patients are better off going right to a constrained liner.

Dr. Della Valle: I have two quick questions. The series you reported in 2004, a lot of those cases, do you think those are cases now that you would have solved with just a big head? Do you think they were not as complicated?

Dr. Callaghan: Very good point. A lot of those could have been solved with a big head. We have one series just for treatment of dislocation and I should go back and look at those as we look at the 20-year results to see which ones may not have required a constrained liner because abductor deficiencies were not as big a problem back in that time. Abductor deficiency has been a new problem related, I think, a lot to metal-on-metal, at least in my own practice.

Moderator Sculco: I'd like to thank the speakers who've done a wonderful job here. ♦

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Bioventus Acquires BioStructures

Bioventus LLC, a company specializing in orthobiologics, has announced the acquisition of BioStructures LLC, a maker of bioresorbable bone graft products for spinal and orthopedic applications. The agreement covers the entire portfolio of current products in addition to the company's entire research and development pipeline. Employees of BioStructures will be given the opportunity to join Bioventus.

"The acquisition of BioStructures aligns with our strategy to be a leader in orthobiologics, building on the launch of the Bioventus Surgical business with the OsteoAMP acquisition in 2014, and our longer term development of the next generation BMP [bone morphogenetic proteins],"



Courtesy of Bioventus and BioStructures

said Tony Bihl, Bioventus CEO, in the November 30, 2015 news release. "This now gives Bioventus a broad offering of bone grafting solutions backed by clinical and technical data to benefit patients, surgeons, and hospitals."

"This is a great event for BioStructures, Bioventus, our customers and our employees. We believe the combination of our product offerings will result in a truly unique and robust portfolio benefiting patients, surgeons and hospitals not found in the market today," said Russell Cook, BioStructures CEO. "This acquisition will continue to allow the culture of innovation, as well as advance the positive momentum we have built at BioStructures. We are

happy to announce the transaction and look forward to the future with confidence and excitement."

Regarding what impressed the company about BioStructures, Tony Bihl told OTW, "We were impressed with the broad portfolio of synthetic bone graft offerings and of the very robust R&D pipeline of new products, and then with the quality of the team and founders who created some of the best products we see in this market."

"First priorities for us are to secure the ongoing product supply to physicians through the strong distribution channel in place, and welcome the BioStructures employees to Bioventus." — EH

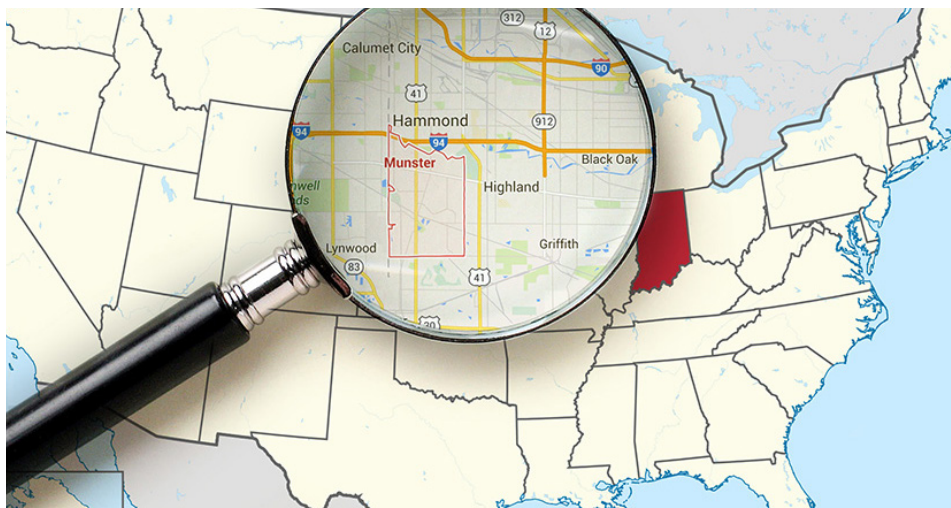
Rush Expanding to Indiana!

With the turn of the calendar, residents of Northwest Indiana will have access to the quality care offered by the orthopedic program ranked 6th in the country by *U.S. News & World Report*...Midwest Orthopaedics at Rush (MOR). The expansion into Northwest Indiana will begin January 4, 2016. MOR physicians will see patients at 9200 Calumet Avenue in Munster.

Dennis Viellieu, MOR CEO, was born and raised in Highland, Indiana. In the November 30, 2015 news release Viellieu noted, "A significant number of our patients live in Northwest Indiana and we wanted to make it more convenient for them and other local residents who

want top-ranked orthopedic services close to home. Our clinic will offer superior care for patients with orthopedic conditions, ranging from the most basic to the most complex."

As indicated in the news release, "The clinic will staff sports medicine physicians and orthopedic surgeons with expertise in the following specialties: spine; foot and ankle; hand, wrist and



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elbow; shoulder; joint replacement; and spine tumors. In addition, patients will have access to MOR's well-respected physical and occupational therapists; a full range of diagnostic services, including CT scans and MRIs; and a center for Durable Medical Equipment (DME) where patients can purchase medical braces and other devices."

Viellieu told *OTW*, "I think the physicians of MOR selected Northwest Indiana as really our first geographic expansion in over 10 years for a number of reasons. It's a less-regulated market in an industry that has gotten more and more intensely regulated. So it's a friendlier provider market and also happens to be less expensive as well, which is probably somewhat related to the regulatory environment. Also, the market is less saturated with providers than the alternative Illinois markets, and so a little easier to develop as a result. In addition, I think the physicians had an appreciation for the patients we were already seeing from the Indiana market at our Illinois locations. And I think we offered something that will be very unique in Indiana—and that is an academic practice. With at least five academic medical centers in the Chicago area and only one program based in Indianapolis in Indiana, I think that provides us with the opportunity to bring something that is very unique to Northwest Indiana."

"To get things going we have initiated a media campaign that includes billboards, advertisements and online search elements and we have already begun offering introductory and educational seminars to both providers and patients in the market."

"In addition, we will look for opportunities to get involved with the communities, employers, schools and other organizations what would benefit from musculoskeletal care and education." — *EH*

LEGAL

Stryker's "Big Easy" Poaching Lawsuit to Proceed in Michigan

A federal judge in Michigan ruled on November 19, 2015 that a former New Orleans sales rep for Stryker Corporation must face the music of breach of contract and breach of fiduciary duty charges.

Christopher Ridgeway, the former rep, tried to make a technical argument that he worked for Stryker Leibinger, not Howmedica Osteonics, a Stryker subsidiary that is suing Ridgeway, and therefore only Leibinger could issue a non-compete agreement.

"Common-Law Rule of Reason"

The judge was having none of that. He said that Michigan does not prohibit non-compete agreements outside of the employer-employee context. "Michigan has a common-law rule of reason that contemplates the enforceability of non-competition agreements that qualify as reasonable."

Ridgeway and Biomet Sued

Stryker fired Ridgeway on September 10, 2013 for allegedly engineering an elaborate scheme to take his Stryker customers to Biomet, Inc. Stryker then sued Ridgeway and Biomet for Breach of Contract and Fiduciary Duty, Misappropriation of Trade Secrets and Tortious Interference. In a 2013 article titled "*Flip-*

pin' Cakes and Poachin' Reps in the Big Easy," we reported that Stryker said Ridgeway used secret code words to engineer the scheme. The "flipped" customers were allegedly referred to as "pancakes."

Stryker claims that Ridgeway used his knowledge of Stryker's confidential and proprietary information to enter the market and sell his genetic testing devices to Stryker's customers and diverted Stryker's funds to promote his personal business.

In early September 2013, Stryker said it learned that Ridgeway was devoting at least 50% of his time to operating two medical supply side businesses, through which he was "exploiting relationships with Stryker's customers to sell other medical devices." Stryker also said it learned that Ridgeway was requiring other Stryker employees to participate in such sales endeavors for his side businesses.

Non-Compete Questions

MassDevice reported that the judge also ruled that Ridgeway's alternative argument, that the subsidiary not party to



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the non-compete should not be able to enforce it, should be aired out at trial.

“The evidence is sufficient to create an issue of fact as to whether Ridgeway was ever employed by Stryker Leibinger,” wrote the judge. “Whether Ridgeway was ever employed by Stryker Leibinger, whether Stryker Leibinger had a reasonable competitive business interest justifying a non-compete agreement, whether the non-compete agreement was assigned to Howmedica Osteonics, and whether Stryker and Howmedica Osteonics were related or associated entities who could reasonably enforce the non-compete agreement all present questions of fact for trial.”

As for Stryker’s claim for breach of fiduciary duty, the judge found “sufficient evidence to create issues of fact as to whether Ridgeway had an agency relationship with Stryker and/or Howmedica Osteonics that would give rise to a fiduciary duty.” — WE

Jury Punishes Wright Medical With \$11 Million Verdict Over Conserv Hip

Another metal-on-metal hip maker has lost a bellwether trial in a federal court.

After a two week trial, a federal jury in Atlanta awarded \$11 million to Robyn Christiansen, a retired ski instructor implanted with an allegedly defective metal-on-metal hip implant made by Wright Medical Technology, Inc.

The jury, according to the *Atlanta Journal-Constitution*, deliberated for three days and reached the verdict on November 25, 2015. The jury awarded Christiansen \$1 million in compensa-

tory damages and a whopping \$10 million in punitive damages. Wright Medical’s senior vice president and chief communication officer, Julie Tracy, said the company disagrees with the verdict, and “are considering all of our post-trial options and expect that we will appeal the decision if it is permitted to stand.”

The metal-on-metal hip implant, the Conserv Plus, was found to be defective and the company was held liable for negligent misrepresentation about the device.

This was the first of more than 300 cases that are part of a multi-district litigation case before U.S. District Judge Bill Duffy in Atlanta. There are also hundreds of other cases against the company in a state court in Los Angeles.

Christiansen’s was implanted with the hip device in April 2006, but the device failed after six years. She was then forced to have the implant removed. During that procedure, her surgeon found fluid buildup, tissue necrosis and metallosis, requiring the removal of soft tissue damaged by metal debris, according to a statement from her legal team.

Christiansen’s case was one of ten selected to go through a mediation and trial program. When mediation failed,

her case was picked to be the first one to go to trial.

Wright Medical sold its hip and knee implant business to China-based Micro-Port Medical in 2013 for \$290 million.

Metal-on-metal hips have been very controversial after foreign registries showed higher than normal failure rates. On May 6, 2011, the FDA ordered manufacturers of metal-on-metal hip devices to conduct postmarket surveillance.

Thousands of lawsuits have been filed around the country by patients who have alleged injury from their metal-on-metal hip implants made by various manufacturers. The multi-district cases, in addition to Wright Medical’s, include:

- Zimmer Holding’s Durom Hip Cup (290 filed cases)
- DePuy Orthopaedics, Inc.’s ASR Hip Implant (8,858 filed cases)
- DePuy Orthopaedics, Inc.’s Pinnacle Hip Implant (5,153 filed cases)
- Biomet, Inc.’s M2a Magnum Hip Implant (978 filed cases)

DePuy has reached a multi-billion dollar settlement with patients implanted with the ASR implant. — WE



THE VERDICT

Photo creation by RRY Publications, LLC

Arthrex Suing ArthroCare/Smith & Nephew Again Over Patents

Arthrex, Inc. is suing ArthroCare Corp. and its parent, Smith & Nephew plc, for the second time over certain patent infringement claims.

The first time Arthrex sued over these patents was this past June. That suit alleged 47 counts of infringement related to 12 Arthrex patents. The new suit brings the total to 49 counts relating to the following 13 patents: 9,179,907, 8,821,541, 8,801,755, 8,623,052, 8,343,186, 7,329,272, 7,322,986, 7,195,634, 6,875,216, 6,629,977, 6,511,499, 6,214,031, and 5,993,451.

In the new suit filed on November 20, 2015, Arthrex is seeking an injunction and damages on their manufacturing and sale of various lines of implants, including SpeedScrew, SpeedLock, SpeedLock Hip, LabraLock P, MultiFix, BioRaptor Knotless, Footprint PK, TwinFix and Ultra suture anchors, which are sold by Smith & Nephew to compete with Arthrex's PushLock and SwiveLock implants.

Litigation History

Arthrex and Smith & Nephew/ArthroCare have a long history of litigation.

All in all, Law360 reports there have been six cases between Arthrex and Smith & Nephew. Smith & Nephew acquired ArthroCare for \$1.5 billion in 2014.

Back in 2000, Arthrex filed an injunction against ArthroCare to keep ArthroCare from terminating an exclusive distribution agreement. Arthrex was the exclusive distributor for ArthroCare in a large part of the globe. Arthrex also accused ArthroCare of trying to poach its sales reps.

In March 2015, a federal circuit court affirmed a lower court ruling that Arthrex must pay Smith & Nephew \$95 million for infringing a patent for surgical suture methods.

John Schmieding, Arthrex's general counsel, said, "We have full confidence in the strength of our patent position and will not sit back and allow this systematic, serial infringement of our patents, which ultimately harms the growth and advancement of orthopedic medicine and the patients that benefit from those innovations."

Arthrex is headquartered in Naples, Florida, and has developed more than 9,000 products for arthroscopic and minimally invasive orthopedic surgical procedures. — WE

BIOLOGICS

New Information on How Rare Bone Disease Begins

Fibrodysplasia ossificans progressive (FOP), the rare genetic disease where bone is grown within soft tissue, is also known as Stone Man Syndrome. Now, researchers from Japan are delving into the connection between this disease and inflammation.



Wikimedia Commons and Joh-co

According to the November 30, 2015 news release, an immune response or trauma triggers the disease. The team from Japan used induced pluripotent stem (iPS) cells to study the disease because they could "take cells from the patient that are unaffected by FOP and



Courtesy of Arthrex and Smith & Nephew

then reprogram the cells into soft tissue cells for study.”

Researchers at the Center for iPS Cell Research and Application (CiRA), Kyoto University, reprogrammed FOP patient cells and then sought candidate molecules that could explain how the disease initiates. The researchers focused on bone morphogenetic proteins (BMP).

“There are two popular theories,” explains Makoto Ikeya, an associate professor at CiRA involved in the study, in the news release. “In one, BMP signaling is always active. In the other, BMP signaling is abnormally strong when activated.”

This team, which also involved CiRA Professor Junya Toguchida, looked at molecules related with inflammation, finding Activin-A as a candidate drug target. “Using iPS cell technology, the

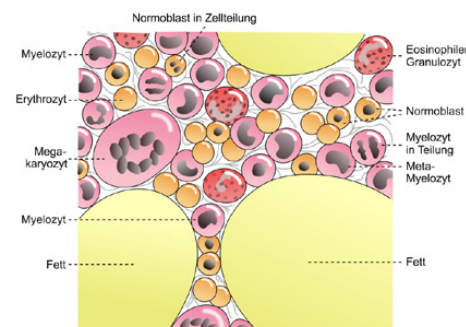
scientists found that only cells harboring the FOP gene mutation would respond to Activin-A by significantly increasing their BMP signaling. Further, transplanting these cells into mice and stimulating them with Activin-A led to abnormal bone.”

Professor Toguchida told OTW, “FOP has been a topic of study in our lab for nearly a decade. We had long believed that current theories were incomplete and prevented any useful treatment. This is a very uncommon disease that even many orthopaedic surgeons are unaware of. We hope that our mouse model will be useful for studying an assortment of orthopaedic diseases of ectopic bone.”

“It was surprising to find the clear connection between inflammation and abnormal bone growth. This finding suggests alternative strategies for drug discovery.” — EH

Bone Marrow-Produced Fat Cells Linked to Chronic Illness?

A team of scientists from the University of Colorado Anschutz Medical Campus has found that fat cells produced by stem cells from human bone marrow may be linked to chronic illnesses.



Human Bone Marrow / Wikimedia Commons, Mysid Inkscape and Gray's Anatomy

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“The study’s senior author, Dwight Klemm, Ph.D., professor of medicine at the University of Colorado School of Medicine, said in the November 24, 2015 news release, “But our paper, along with one recently published by our colleagues in Sweden, shows for the first time fat cells produced by stem cells that originate in the bone marrow inside human fat tissue.”

“Our study suggests that it may be the type of fat-storing cell produced in our bodies that determines risk for disease, rather than the amount of fat,” said Klemm, an expert on obesity and pulmonary hypertension. “This discovery highlights the possibility of new strategies to prevent and reverse fat-related chronic diseases by controlling the production of different types of fat-storing cells.”

Researchers worked with people who had received a bone marrow transplant from another donor. A small sample of their fat tissue was removed, and the DNA from those fat cells was evaluated to determine if it came from the person who donated the bone marrow or the recipient.

“We detected the presence of donor DNA, which indicated that some of the fat cells had grown from cells that originated in the transplanted bone marrow,” said Kathleen Gavin, Ph.D., postdoctoral fellow and lead author on the study.

As indicated in the news release, Dr. Klemm believes it is possible to prevent or reverse fat-related chronic disease by controlling the type of fat-storing cells produced in the body.

Dr. Klemm added, “Even more exciting is the possibility of combining bone marrow or stem cell transplant technology with genetic engineering to tailor-make fat-storing cells with specific desirable functions. By preventing the production of harmful fat cells it may

be possible to prevent or reverse fat-related chronic disease, even without weight loss.”

Dr. Klemm told *OTW*, “Fat cells produced from bone marrow stem cells appear to produce several inflammatory compounds that may link them to chronic diseases like cardiovascular disease and diabetes. Over ten years ago we discovered that certain drugs that stimulate the production of new fat cells also increased the release of circulating stem cells from the bone marrow. We surmised that these circulating stem cells might be the source of some new fat cells. This was significant because it was tacitly believed for over a hundred years that all new fat cells were produced from stem cells that live in fat tissue. We essentially discovered a new source for fat cells.”

“We were surprised by the basic discovery that some new fat cells are produced from stem cells that arise from the bone marrow rather than live in fat tissue. Also, we were surprised to find that these cells have proinflammatory characteristics, which may link them to fat-related chronic disease. Importantly, our latest work confirms that these potentially harmful fat cells are produced in humans.” — *EH*

LARGE JOINTS

Doctors Underutilizing Methotrexate for RA

In a study that involved data from 1274 million patients, researchers from the University of Nebraska Medical Center (UNMC) found that physicians are underutilizing methotrexate in the treatment of rheumatoid arthritis (RA). Led by James O’Dell, M.D., Bruce

Professor of Internal Medicine and chief of the UNMC divisions of rheumatology and immunology, the team found that some physicians are also making the mistake of not keeping patients on the drug long enough before switching them to more expensive biologic drug options.

Using the claims data, researchers followed the treatment of 35,640 RA patients between 2009 and 2014. They found that 43.8% continued with oral methotrexate, 49.2% added or switched to a biologic treatment.

“If oral methotrexate is not producing the desired results,” Dr. O’Dell said in the November 17, 2015 news release, “then the next step should be to try patients on subcutaneous methotrexate at a higher dose.”

“What we found in patients who made a treatment change was that 87% added a biologic instead of trying subcutaneous methotrexate,” he said. “Patients



Wikimedia Commons, National Cancer Institute and James Heilmann, M.D.

switched to biologics too quickly—41% switched in three months or less.”

The study found that 72% of patients who switched from oral to subcutaneous methotrexate stayed on this treatment for five years. The other 28% eventually needed a biologic, at a median of 289 days on subcutaneous methotrexate.

Dr. O'Dell told *OTW*, “The work was originally done to look at the use of subcutaneous (SC) methotrexate (MTX)—we then expanded it because it was clear that MTX in general was badly underutilized. We were most surprised to learn the magnitude of underuse of MTX in terms of dosing, duration and route of administration.”

“Methotrexate is the best drug we have to treat rheumatoid arthritis. Unfortunately, clinicians in the U.S. are not using it early enough, are not using in

at optimal doses and are rarely prescribing subcutaneous methotrexate (which is the most effective way to administer it). This results in under treatment of RA and overuse of biologics.” — *EH*

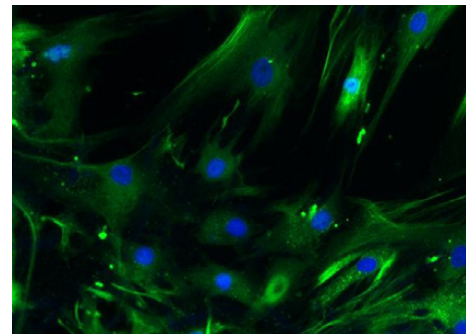
EXTREMITIES

New Drug Could Heal Bones Better and Faster

Researchers from the University of Southampton in the UK are using a protein to help develop a new type of drug that may help bones heal faster and better. The research is published in the journal *Stem Cells*.

As indicated in the November 19, 2015 news release, the researchers demonstrated that “the drug—a protein that activates a molecular pathway called

the ‘Wnt’ pathway—causes stem cells found within bones to divide and to turn into more bone cells. The Wnt pathway is involved in controlling the growth of stem cells, which are ‘master cells’ that help restore tissues after injury. One example of this is in amphibians like salamanders. If these animals lose a leg, they can just regrow a new one.”



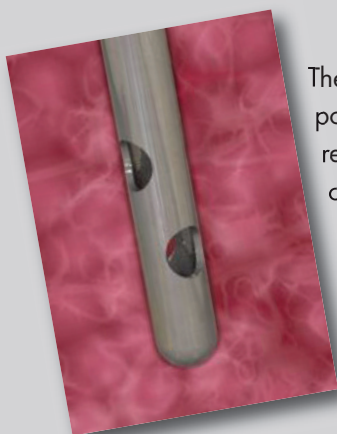
Courtesy of the University of Southampton

Nick Evans, Ph.D., associate professor in bioengineering at the University of Southampton and lead author of the

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study, says: “Bone fractures are a big problem in society, especially in older people. It is getting worse as more people get older and their risk of fracture increases. Most fractures heal completely by themselves, but a surprising number, around 10%, take over six months to heal, or never heal at all. In the worst cases this can lead to several surgical operations, or even amputation.”

“Through our research, we are trying to find ways to chemically stimulate Wnt signaling using drugs. To achieve this, we selectively deliver proteins and other molecules that change Wnt signaling specifically to stem cells, particularly in the bone. This may help us find cures for many diseases, including bone disease, and speed up bone healing after fracture.”

Interestingly, if the Wnt pathway was on too long, the regenerative effect was lost or, even reversed. “This is why it is particularly important to develop technologies for timed and targeted delivery, which is what we have done in this research,” Dr. Evans added.

Dr. Evans told *OTW*, “We wanted to know first whether stem cell populations found in the bone are responsive to Wnt, and second whether we could prime these cells to turn into bone. We also considered that Wnt signaling is pleiotropic in bone biology, and that it may have contrasting effects depending on the cell type.”

“There are several drugs in clinical trials for osteoporosis at the moment based on stimulating Wnt signaling. There are many more in preclinical development. It looks like they are going to work very well in osteoporosis, but the data on fracture healing is not very clear. Our data indicates that this may be because Wnt stimulation can be both stimula-

tory and inhibitory to the conversion of stem cells to bone cells, depending on how mature those cells are. We think that any drug that is developed for bone fracture healing based on Wnt signaling will have to take this into account, and will need to be active only at particular phases of fracture healing.” — *EH*

Rush Ortho Gives Time, Expertise to Chicago Homeless

A very special event occurred last night at the Franciscan House of Mary and Joseph in Chicago. A generous group of 40 volunteers from Rush University Medical School and Midwest Orthopaedics at Rush (MOR) foot and ankle section treated an estimated 170 clients of the shelter last night. Volunteers were led by Drs. Johnny Lin and Simon Lee, MOR foot and ankle surgeons, as they distributed new shoes, socks and treated the feet of the shelter residents.

Dr. Lin told *OTW*, “The most interesting aspect of the event is how something so simple as providing basic foot care and a new pair of shoes and socks can provide excitement and joy to those who need these things the most. The most heartwarming thing is how genuinely thankful each person was for listening to them and giving them attention. It really seemed to have made their day.”

“As a single individual—or even as a single organization—there is no way that we can provide everything that a homeless person needs. But, by performing a simple act of service we can at least take one step in the right direction. Ultimately, we never know what may be the turning point for any of these individual’s lives. Hopefully, the work that the homeless shelter does on a day-to-day basis, supplemented by programs like ours, will increase the success rate for people without homes.” — *EH*



Courtesy of Midwest Orthopaedics at Rush

SPORTS MEDICINE

Soccer Mitigates Effect of Prostate Cancer Treatment

A team of University of Copenhagen scientists has found that for men undergoing treatment for prostate cancer, an hour of soccer several times a week counteracts many of the negative effects of the treatment. This work was part of the Ph.D. thesis defense by Jacob Uth, a physiotherapist at the University Hospitals Centre for Health Research (UCSF) at Copenhagen University in Denmark.

“Our so-called FC Prostate study showed that just 12 weeks of football training increased leg bone mass and elevated the blood-borne bone formation markers osteocalcin and P1NP by 35 and



Courtesy of University of Copenhagen

50%, respectively. After 32 weeks of training we observed a systematic 1-2% increase in bone mineral density at the hip and upper part of the thigh bone in the football players compared to the control group, equivalent to bones 2-4 years younger,” said Peter Krstrup in the November 23, 2015 news release. Krstrup is Jacob Uth’s supervisor and Professor of Team Sport and Health in the Department of Nutrition, Exercise and Sports at Copenhagen University.

“The changes in bone mass in the legs of the football group show a significant correlation with the number of times

they accelerate and brake. This gives an indication that the effect is linked to the specific activity that we see in football, where there is interval running with a lot of accelerating and braking which place great stress on the bone tissue, and that is what makes them stronger,” says Uth.

Professor Krstrup told OTW, “Several years of research into the musculoskeletal effects of football led to this work. Our findings regarding positive bone effects of recreational football for prostate cancer patients are very consistent with our previous findings for untrained young men (Krstrup et al. 2010), untrained young women (Helge et al. 2010), middle-aged women with hypertension (Mohr et al. 2015) and elderly healthy men (Helge et al. 2014).”

“In these studies we have seen minimal effects for swimming (Mohr et al. 2015), continuous running and interval running (Krstrup et al. 2010 and Helge et al.

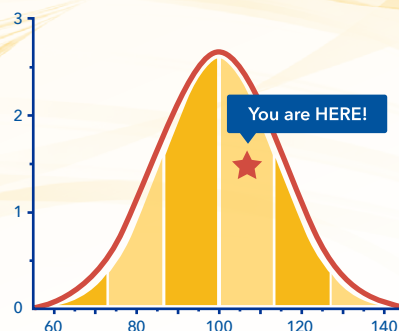
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2010). We would expect little effects of cycling too, as this is not weight-bearing.”

“We are currently investigating the fitness and health effects of Team Handball, Basketball and Volleyball, and we hypothesize that these team sports have some of the same movements (sprints, accelerations, decelerations, turns, jumps, changes of direction, tackles, dribbles, shots) with a high musculoskeletal impact, with positive effects on muscle mass and bone density.”

“Our current research using football as a model is looking into the fitness and health effects of football session for school children (including effects on heart and bone health), the cardiovascular and metabolic effects of football for middle-aged women with type 2 diabetes and the effects of football for patients with other types of cancer than prostate cancer.”

“The most surprising thing about this study is that the men really enjoy playing, and still are three years later, and that the FC Prostate study [results] have led to a nationwide implementation, where local football clubs around all the big hospitals in Denmark are now offering football training for men with prostate cancer.” — EH

SPINE

FDA Ortho Panel to Consider Medtronic’s DIAM Spinal Stabilization System in February

The FDA’s Orthopaedic and Rehabilitation Devices Committee is going to meet on February 19, 2016 to consider Medtronic plc’s premarket application for its DIAM Spinal Stabilization System.

DIAM Indications

According to the FDA, the system is indicated for “skeletally mature patients that have low back pain (with or without radicular pain) with current episode lasting less than 1 year in duration secondary to moderate lumbar degenerative disc disease (DDD) at a single level from L2-L5. DDD is confirmed radiographically with one or more of the following factors: (1) patients must have greater than 2 millimeters of decreased disc height compared to the adjacent level; (2) scarring/thickening of the ligamentum flavum, annulus fibrosis, or facet joint capsule; or (3) herniated nucleus pulposus. The DIAM device is implanted via a minimally invasive posterior approach.”

One Study Result

An October 2009 study cited by PubMed (<http://www.ncbi.nlm.nih.gov/pubmed/19912707>), looked at 68 patients with a degenerative disease of the lumbosacral spine. They suffered from axial pain with signs of nerve root involvement due to disc hernia, foraminal stenosis or disc herniation recurrence. They were followed up for one to three years and evaluated.

None of the patients in the study required revision surgery or had a recurrence of disc herniation. The authors also suggest that the implant protects the whole operated spinal segment, i.e., both intervertebral joints and discs, from being overloaded.

At three-year follow-up the patients reported improvement in their functional state, as measured with an ODI (Oswestry Disability Index), by 64 % on the average. Their axial and nerve root pain was reduced by 71 % on the average. All patients showed improved clinical conditions and the outcomes

were evaluated as excellent in 41 %, good in 51 % and fair in 7.5 % of the patients. The results of implantation were not significantly related to age, gender, operative indications, operated lumbosacral level, method of nerve root decompression or duration of pre-operative problems.

A November 30, 2015 *ClinicalTrials.gov* posting said the clinical trial has been closed. The clinical trial was first received in February 21, 2008, and was last updated on April 24, 2012.

The FDA is not required to call a meeting of its orthopedic committee to make a final decision on approving the device. The fact that the agency wants to meet with its expert panel indicates the staff has some clinical questions it wants the experts to consider.

Time and Place

The February meeting will be held from 8 a.m. to 6 p.m. at the Hilton Washington, DC/North, Salons A, B, C, and D, 620 Perry Pkwy, Gaithersburg, Maryland.

The agency intends to make background material available to the public no later than two business days before the meeting. The material will be available at <http://www.fda.gov/Advisory-Committees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm>. Scroll down to the appropriate advisory committee meeting link. — WE

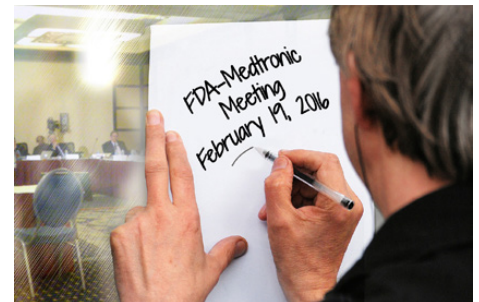


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