

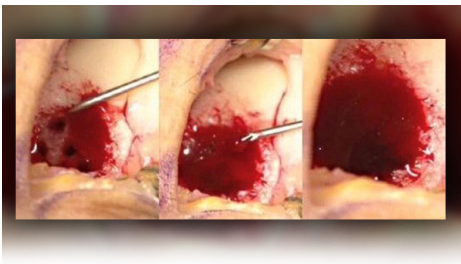
Orthopedics • This Week

WEEK IN REVIEW

4 Unpacking Those Physician Rating Sites >> Do physician ratings websites actually measure anything useful? Or do they create more problems than solutions? Two recent studies provide clear insights into the flaws and power of physician rating websites. Can orthopedic surgeons use these ratings to build their practice?

8 Washington Update: January 2016 >> Medical Device cybersecurity concerns and continued payment reforms are dominating the agenda in Washington at the start of 2016. Both CMS and FDA are making recommendations which will affect orthopedic surgeons, clinics and patients. Here are highlights and lowlights.

12 Smith & Nephew's Bet on Cartilage Repair >> Surprise! Smith & Nephew's new cartilage regeneration product, BST-CarGel has a handful of clinical trials and regulatory approvals around the globe. Piramal Life Sciences—India's massive life science company—quietly funded it. Then last week SNN bought it. BST-CarGel is a chitosan-based material. It's different. Here's the scoop.



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BREAKING NEWS

- 19 With Six Months of Biomet, Zimmer Sales Pop 28% for 2015
- 20 ConMed Beats Wall Street's Sales Estimates for 2015
- 21 VertiFlex Raises \$27 Million for Superion Spacer
- 22 LDR Invests In, Allies With PolyShape
- 23 DePuy Ends Year With a Bang, Synthes With a Whimper
- 26 Fewer-Than-Expected People Taking Obamacare Subsidy

16 American Joint Replacement Registry: 618 Hospitals, 4,500 Surgeons, Robust Data >> The American Joint Registry has made extraordinary progress in the last three years and now encompasses 618 hospitals, 4,500 surgeons and all 50 states. Supported by every major large joint surgeon society, the AJRR is a vital and necessary part of every surgeons and manufacturers tool kit.



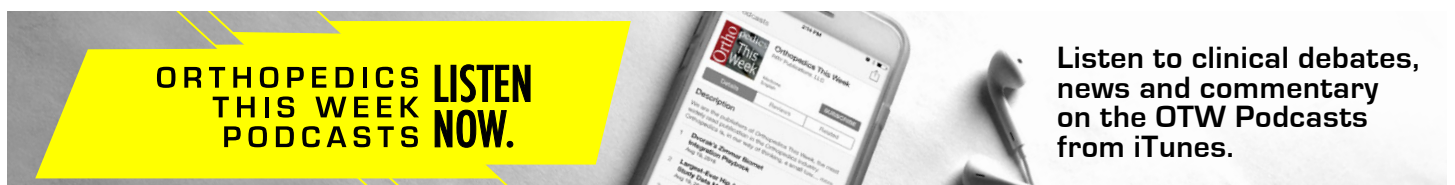
For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: To the extent that institutional investors are paying attention to the fundamentals of orthopedics (rising demand and a greater number of insured patients in the U.S.) funds are flowing toward orthopedic implant suppliers. Unfortunately, those investors are few and far between. Orthopedic equities, simply based on business fundamentals—sales, profits, demand—have never been more attractive than they are right now.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Stryker	22.94%	5.20%	Rousing numbers to end 2015 and for 2016, as expected, SYK started the year with an acquisition—\$2.8 billion for Sage Products.
2	1	Zimmer Biomet	31.22	(3.13)	Yes, top line wasn't quite what analyst's expected, but it doesn't matter—2016 is going to be a very strong year. In all respects.
3	7	Exactech	10.26	10.43	Big jump for this small, integrated orthopedics company. Small float, no doubt, contributes to EXAC's volatility. But so, too, is its uniqueness.
4	3	Integra LifeSciences	13.74	(10.12)	Sold off along with the overall equity market this past month but consensus on Wall Street is that IART will post a decent EPS gain for 2015.
5	4	Smith & Nephew	19.66	(6.47)	Issues press release announcing that CEO has cancer, highly treatable, and that he will continue as CEO. SNN won't miss a step.
6	9	Medtronic	27.92	(2.08)	MDT's management reaffirmed sales guidance but raised the lower end of its earnings outlook. All good.
7	10	Johnson & Johnson	26.73	0.64	Strong DePuy results to end 2015. All the tailwinds—rising demand, more insured—are in place for 2016 so expect more good news.
8	8	Globus Medical	30.19	(11.65)	Globus settles 4 patent lawsuits with DePuy Synthes. Terms weren't disclosed. Sales for 2015 expected to be up 15%.
9	5	NuVasive	13.35	(15.85)	Both of the leading independent spine companies sold off in January. Which is kind of nuts. Both NUVA and GMED are delivering strong sales and earnings growth.
10	6	ConMed	11.10	(16.73)	ConMed's 2015 sales report was good and SurgiQuest is exciting, but Wall Street didn't see it that way. With a tough overall market, it was easy to sell.



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	\$0.42	\$43	41.53%
2	Aurora Spine	ASG	\$0.18	\$3	33.75%
3	Exactech	EXAC	\$20.01	\$282	10.43%
4	Stryker	SYK	\$99.15	\$37,233	5.20%
5	MicroPort Scientific	853	\$0.47	\$671	4.13%
6	Johnson & Johnson	JNJ	\$104.44	\$288,980	0.64%
7	Orthofix	OFIX	\$39.47	\$746	-0.28%
8	Medtronic	MDT	\$75.92	\$106,755	-2.08%
9	Zimmer Biomet	ZBH	\$99.26	\$20,227	-3.13%
10	Smith & Nephew	SNN	\$33.56	\$15,044	-6.47%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	K2M Group Hldgs	KTWO	\$14.21	\$586	-29.13%
2	LDR Holding Corp	LDRH	\$18.37	\$534	-26.49%
3	RTI Biologics Inc	RTIX	\$3.21	\$185	-19.75%
4	ConMed	CNMD	\$36.94	\$1,023	-16.73%
5	Wright Med Grp N.V	WMGI	\$19.95	\$2,048	-16.53%
6	NuVasive	NUVA	\$46.12	\$2,264	-15.85%
7	SeaSpine Hldgs Corp	SPNE	\$14.46	\$161	-14.99%
8	MiMedx Group	MDXG	\$8.32	\$907	-12.70%
9	CryoLife	CRY	\$9.83	\$280	-12.62%
10	Globus Medical	GMED	\$24.95	\$2,376	-11.65%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	RTI Biologics Inc	RTIX	\$3.21	\$185	16.24
2	Johnson & Johnson	JNJ	\$104.44	\$288,980	17.91
3	Exactech	EXAC	\$20.01	\$282	17.98
4	Globus Medical	GMED	\$24.95	\$2,376	19.25
5	Stryker	SYK	\$99.15	\$37,233	21.01

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	CryoLife	CRY	\$9.83	\$280	64.50
2	NuVasive	NUVA	\$46.12	\$2,264	52.94
3	MiMedx Group	MDXG	\$8.32	\$907	46.22
4	Smith & Nephew	SNN	\$33.56	\$15,044	30.03
5	Integra LifeSciences	IART	\$61.45	\$2,273	27.01

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	RTI Biologics Inc	RTIX	\$3.21	\$185	1.08
2	Globus Medical	GMED	\$24.95	\$2,376	1.50
3	Exactech	EXAC	\$20.01	\$282	2.02
4	CryoLife	CRY	\$9.83	\$280	2.15
5	Stryker	SYK	\$99.15	\$37,233	2.25

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Smith & Nephew	SNN	\$33.56	\$15,044	4.62
2	NuVasive	NUVA	\$46.12	\$2,264	4.03
3	Medtronic	MDT	\$75.92	\$106,755	3.79
4	Johnson & Johnson	JNJ	\$104.44	\$288,980	3.48
5	MiMedx Group	MDXG	\$8.32	\$907	3.08

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	\$0.42	\$43	0.21
2	RTI Biologics Inc	RTIX	\$3.21	\$185	0.71
3	Xtant Medical Hldgs	XTNT	\$2.30	\$27	0.77
4	Exactech	EXAC	\$20.01	\$282	1.13
5	SeaSpine Hldgs Corp	SPNE	\$14.46	\$161	1.16

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$1.18	\$210	33.33
2	MiMedx Group	MDXG	\$8.32	\$907	7.67
3	Wright Med Grp N.V	WMGI	\$19.95	\$2,048	5.94
4	Medtronic	MDT	\$75.92	\$106,755	5.27
5	Globus Medical	GMED	\$24.95	\$2,376	5.01

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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Unpacking Those Physician Rating Sites

BY ROBIN YOUNG

What are those physician rating sites actually measuring and can they help orthopedists to build their practices?

A 2014 American Board of Internal Medicine (ABIM) study concluded:

1. Physician rating websites (PRWs) are extremely popular with patients
2. But ratings have a strong upward bias
3. And they don't correlate with actual quality of care

Another study, this one from American Society for Surgery of the Hand (ASSH), found:

1. More than 65% of physician don't like the website ratings
2. 62% found inaccuracies in their profiles
3. 90% of physicians have not made any adjustments based on ratings

Bottom line, the popularity of physician website ratings is exploding. Patients use them for surgeon information before, during and after treatment.

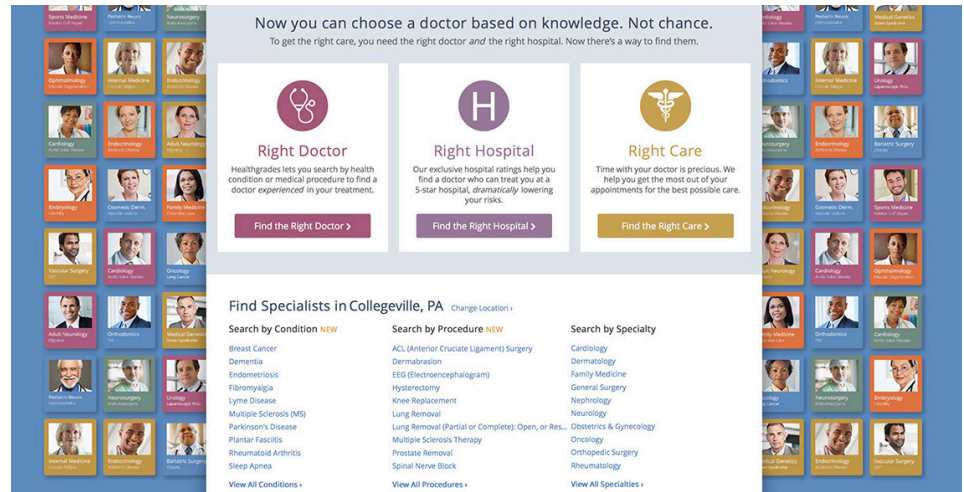
But surgeons don't know how to take advantage of these sites.

Since the ratings have an upward bias, is this generally good for surgeons? Since the information is highly flawed, is this bad for surgeons?

Let's look at the details.

The ABIM Study

Researchers from the American Board of Internal Medicine (ABIM) sampled



Courtesy of HealthGrades.com

1,299 physicians who'd completed a Practice Improvement Module and asked them a series of question regarding physician ratings websites.

They found NO statistically significant correlation between the online ratings given by patients about their physicians and the clinical quality of care delivered by those same practices.

Their study results were published in the *Journal of the American Medical Association (JAMA)* and are available at: <http://archinte.jamanetwork.com/article.aspx?articleid=1936577>

The study came at a particularly good time. Physician rating websites are exploding in two ways. First, as a tool for patients to use to evaluate a prospective surgeon. And second, as way for surgeons to market their practices directly to patients.

According to the ABIM study authors: "One-third of consumers in the United States who consulted physician website ratings reported selecting and/or avoid-

ing physicians because of these ratings." A February 19, 2014 *JAMA* study bears this out. Said those investigators: "Fifty-nine percent of respondents reported physician rating sites to be "somewhat important" (40%; 95% CI, 36%-44%) or "very important" (19%; 95% CI, 16%-23%) when choosing a physician."

The lead ABIM study author was quoted in the *JAMA* article as saying: "Our study is important because it is one of only a handful of studies to examine the ability of physician website ratings to reflect the quality of care patients are likely to receive. The results of our study should make consumers think twice about relying only on these website ratings as a source of quality information. This study also highlights the need for more valid and reliable physician quality information to be made publicly available."

Details From the ABIM study

The study's authors found that website ratings existed for 61.0% of physicians, with 5.6 patient ratings per physician

and a mean normalized rating of 81.6% (which we interpret as a B+ rating).

BUT...the investigators found that the association between physician website ratings and clinical quality measures (QMs) was not only small, it was also statistically insignificant. Less than a 0.3 percentage point change was associated with a 20 percentage point rating change.

Looking at patient experience QMs, associations were also small but statistically significant. Just under 1.7% point changes in QM was associated with a 20% change in the rating.

Here's the table that the researchers used to illustrate the findings of their study. (See table on page 6.)

The ASSH Study

American Society for Surgery of the Hand (ASSH) Ethics and Profession-

alism Committee took a fresh look at physician rating websites and considered their resulting ethical and professional implication on physician behavior.

The authors of the study were Julie Balch Samora, M.D., PhD. Scott D. Lifchez, M.D., and Philip E. Blazar, M.D.

The investigators sent a 14-item questionnaire to 2,664 active ASSH members who practice in both private and academic settings in the U.S.

ASSH Results

Three hundred and twelve of the surveyed members responded to the survey, a 12% response rate. More than 65% of the respondents had a slightly or highly unfavorable impression of these websites. Only 34% of respondents had ever updated or created a profile for PRWs.

Importantly, 62% had observed inaccuracies in their profile. Almost 90% of respondents had not made any changes in their practice owing to comments or reviews. One-third of respondents had solicited favorable reviews from patients, and 3% of respondents have paid to improve their ratings.

Here is what the ASSH researchers concluded:

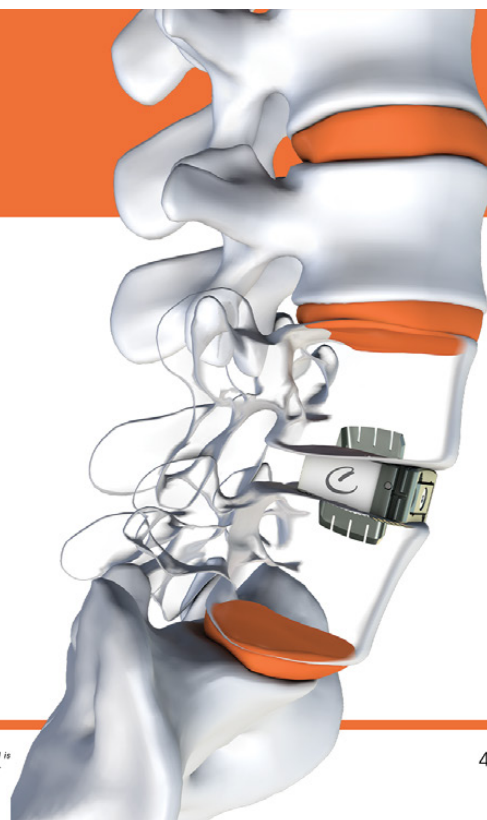
“There are several ethical implications that physician rating websites pose to practicing physicians. We contend that it is morally unsound to pay for good reviews. The recourse for physicians when an inaccurate and potentially libelous review has been written is unclear. Some physicians have required patients to sign a waiver preventing them from posting negative comments online. We propose the development of a task force to assess the profession-



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Physician Website Ratings From Health Websites Identified by Google Searches				
Health Website	No (%)		Mean (SD)	
	Physicians Rated ^a	First Website in Search Result	Ratings No.	Normalized Website Ratings ^b
Healthgrades	613 (47.2)	531 (86.6)	7.0 (6.1)	80.9 (19.9)
UCompareHealthCare	466 (35.9)	68 (14.6)	3.6 (3.9)	83.0 (21.9)
Vitals	363 (27.9)	139 (38.3)	6.3 (7.4)	83.5 (18.7)
AVVO	207 (15.9)	38 (18.4)	NA	76.1(7.0)
Wellness	101 (7.8)	13 (12.9)	3.9 (5.6)	84.9 (14.6)
RateMDs	22 (1.7)	0	4.0 (3.1)	77.3 (20.2)
Vimo	18 (1.4)	1 (5.6)	NA	74.9 (23.6)
ZocDoc	8 (0.6)	2 (25.0)	13.4 (12.4)	94.5 (4.6)
First Website Only	792 (61.0)	792 (100)	6.3 (6.2)	81.8 (19.7)
All 8 sites	792 (61.0)	792 (100)	5.6 (6.1)	81.6 (19.1)

^a Percentage based on a denominator of 1,200 physicians included in the Google Search

^b Normalized rating equals a physician's average rating from a website divided by the website maximum rating
Source: Google Search

al, ethical, and legal implications of PRWs, including working with companies to improve accuracy of information, oversight, and feedback opportunities.”

More Ethical Issues

According to the Hay Group, two-thirds of physician pay incentives are based on patient satisfaction scores. The Centers for Medicaid and Medicare Services (CMS) is increasingly basing their hospital payments on quality metrics, with patient satisfaction surveys being a significant component.

Doing what's best for the patient is not always popular. Physicians know this and, as a survey by *Emergency Physicians Monthly* reported recently, 59% of emergency room physicians said that patient surveys increased the number of tests they ordered.

Another survey, this one by the South Carolina Medical Association, asked its

members whether they'd ever ordered a test they felt was inappropriate because of patient satisfaction survey pressures, and 55% of 131 respondents said yes. Nearly half said they'd improperly prescribed antibiotics and narcotic pain medication in direct response to patient satisfaction surveys.

Senators Dianne Feinstein, D-California, and Charles Grassley, R-Iowa, wrote a 2014 letter to Marilyn Tavenner, a CMS administrator saying: “There is growing anecdotal evidence that these (patient satisfaction) surveys may be having the unintended effect of encouraging practitioners to prescribe opioid pain relievers (OPRs) unnecessarily and improperly, which can ultimately harm patients and further contribute to the United States' prescription OPR epidemic.”

And then there is the huge 50,000 patient *JAMA* study which found that patients who were more satisfied with their doctors had higher health care

costs, were hospitalized more frequently, and had higher death rates compared to less satisfied patients.

Bottom line: Doctors who have mixed patient reviews probably provide better care because they will say no to patients.

Train Has Left the Station

The physician rating train left the station a long time ago.

Payers, most notably CMS (see PhysicianCompare, a U.S. government directory of health care providers who accept Medicare beneficiaries), for profit physician rating websites and social media sites like Facebook or Twitter are putting physician ratings—as deeply flawed as they are—on the Internet for all to see and many to use.

No way this doesn't continue to grow.

As the new studies are implying, it is time for a coordinated set of ratings which combine the subjective elements (staff friendliness, parking convenience, wait times) with basic information (where the physician practices, went to school, certifications for certain specialties, any disciplinary actions by a state licensing board) and objective information (long-term outcome data, recovery information, surgical infection rates and so forth).

Standardization. A Good Housekeeping Seal of Approval. For both the physician and patient's benefit.

And finally, but most importantly, orthopedic physicians need an independent party to step in, seek out and correct inaccurate and flawed website information on their behalf.

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Washington Update: January 2016

BY ROBIN YOUNG

CMS (Centers for Medicare and Medicaid Services)

MedPAC Meeting Notes – MedPAC (Medicare Payment Advisory Commission) met on January 14 and 15 to vote on final recommendations for its upcoming March report to Congress.

Unfortunately orthopedic services, non-stroke neurology conditions and the “least frail” patients would likely be targeted for payment decreases.

Among other recommendations is a modest payment increase (1.65%) for hospitals in 2017 and no raise at all for providers in a number of other settings. MedPAC’s analysts are projecting an aggregate Medicare margin of negative 9%, which is down from their 2014 negative 5.8% forecast.

MedPAC’s recommended 1.65% payment increase for hospitals was roughly half the 3.20% increase that the American Hospital Association had requested.

The MedPAC commission also proposed a 10% cut in payments to safety-net hospitals participating in the 340B discount drug program. MedPAC also voted to eliminate a 2017 pricing update for ambulatory surgical centers (ASC). Home health agencies, skilled nursing facility, inpatient rehabilitation facilities and long term care hospitals were also dealt a “no payment increases” recommendation for 2017.

On the positive side, MedPAC did recommend payment increases for patients requiring ventilator care, severe wound care or for critical chronic conditions.



Wikimedia Commons and Kevin McCoy

MedPAC’s thinking here is that they would like a more unified PPS (Prospective Payment System) to span across the care continuum and “correct some shortcomings” and “systematic biases” in the current policies.

MedPAC’s PPS report will be finalized in April and presented to Congress in June. The report is a recommendation and Congress is not obligated to follow it.

ACA Enrollment – The number of people enrolled in health coverage through the insurance exchanges established under the Affordable Care Act (ACA) is now 11.3 million, which is higher than HHS (Health and Human Services) forecasted for the third open-enrollment period with days to go before the deadline. HHS reported that the vast majority of ACA enrollees (75%) are from 38 states that use the HealthCare.gov enrollment platform and the rest are in states using their own marketplaces.

Open enrollment ends January 31. Those who want coverage beginning February 1 must have signed up by January 15.

CMS acting Administrator Andy Slavitt noted in a conference call with reporters that people younger than 35 make up 35% of the total number of consumers who enrolled or were automatically re-enrolled in a plan and more than 41% of all new customers. Kevin Counihan, CEO of health insurance marketplaces for the CMS, said the increased penalty for not having health insurance this year has been strong motivator.

People who go without coverage in 2016 will have to pay 2.5% of their annual household income or \$695 per adult and \$347.50 per child without insurance, whichever is greater.

ACA enrollment notes from around the country:

- The momentum of open enrollment continues to wind down, with growth of less than 75,000 consumers in week 10, from January 3 to January 9, 2016. (*Healthcare Finance*, 1/13/16)
- The Administration's "special enrollment" categories have allowed people to wait until they become ill or need medical services to sign up, driving up costs broadly, insurers told federal health officials. "Individuals enrolled through special enrollment periods are utilizing up to 55 percent more services than their open enrollment counterparts" who sign up in the regular period, the Blue Cross and Blue Shield Association, told the Administration. (*The New York Times*, 1/9/16)
- Health insurers in the Affordable Care Act exchanges will see changes from CMS this year to strengthen the market, including eliminating

special enrollment periods and an early look at plans' risk-adjustment data, the top CMS official said on Monday. (*Modern Healthcare*, 1/12/16)

- "We believe it is incredibly important, in the business we're in, that we insure all Americans," Aetna Chief Executive Mark Bertolini said. "We believe we have an obligation to stick it out and work with it until we know that it won't work. And I believe it is too early to give up on this process." (*Business Insurance*, 1/13/16)

ACO Expansion: On January 11, CMS announced 121 new ACO participants. ACOs now represent 49 states and the District of Columbia.

Said HHS Secretary Sylvia Burwell; "Americans will get better care and we will spend our health care dollars more wisely because these hospitals and pro-


viders have made a commitment to change how they do business and work with patients. We are moving Medicare and the entire health care system toward paying providers based on the quality, rather than the quantity of care they give patients."

In 2014, said CMS, ACOs delivered net program savings of \$411 million for 333 Medicare Shared Savings Program (SSP) ACOs and 20 Pioneer ACOs. ACOs that reported in both 2013 and 2014 improved on 27 of the 33 quality measures, including patients' ratings of clinicians' communication, beneficiaries' rating of their doctors, screening for tobacco use and cessation, screening for high blood pressure, and Electronic Health Record use.


CMS also reported:

- Nearly 8.9 million beneficiaries served in either Shared Savings Pro-

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gram (SSP), the Next Generation ACO Model, Pioneer ACO Model, and the Comprehensive ESRD Care Model

- A total of 477 ACOs across SSP, Pioneer ACO Model, Next Generation ACO Model, and Comprehensive ESRD Care Model
- 64 ACOs are in a risk-bearing track including SSP, Pioneer ACO Model, Next Generation ACO Model, and Comprehensive ESRD Care Model
- CMS's goal is to move 30% of traditional Medicare fee-for-service payments into alternative payment models that pay providers based on the quality rather than the quantity of care they provide patients by 2016—and 50% by 2017.

FDA

On January 22, the FDA issued guidelines for device manufacturers regard-

ing steps they need to take in order to identify cybersecurity risks and remediation efforts.

How vulnerable are devices to cybersecurity threats?

Any device that relies on software, communicates over any network and has interoperability is vulnerable.

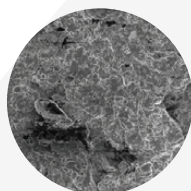
Specifically, the FDA is asking manufacturers to self-assess cyber vulnerability—which is difficult. In its guidance document, FDA's staff said that conventional medical device risk management approaches like "reasonable worst-case estimate" can work but they'd prefer companies to use a cybersecurity vulnerability assessment tool or similar scoring system. The Agency's staff offered by way of example the "Common Vulnerability Scoring System," Version 3.0. That system assigns

numerical ratings which correspond to high, medium or low risks for several factors including:

- Attack Vector (physical, local, adjacent, network)
- Attack Complexity (high, low)
- Privileges Required (none, low, high)
- User Interaction (none, required)
- Scope (changed, unchanged)
- Confidentiality Impact (high, low, none)
- Integrity Impact (none, low, high)
- Availability Impact (high, low, none)
- Exploit Code Maturity (high, functional, proof-of-concept, unproven)
- Remediation Level (unavailable, work-around, temporary fix, official fix, not defined)
- Report Confidence (confirmed, reasonable, unknown, not defined)



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This increased focus on cybersecurity has been in the works for a while. Providers, regulators and consumers have all raised the alarm that hackers could somehow affect any kind of connected medical device (think robots, pumps, pacemakers, records, etc.). Hacked devices could be made less safe, effective and data secure.

If implemented, the FDA guidance would begin to incorporate these cyber security measures as part of routine post-market surveillance of medical device products and to report back to the FDA.

Last July, for example, the FDA issued a warning to providers about Hospira's Symbiq Infusion System and advised

them to stop using the product because of cybersecurity vulnerabilities.

"Only when we work collaboratively and openly in a trusted environment will we be able to best protect patient safety and stay ahead of cyber security threats," said Dr. Suzanne Schwartz, acting director of emergency preparedness/operations and medical countermeasures in the FDA's Center for Devices and Radiological Health.

As part of the new guidance, the FDA said that routine updates or patches would not require device makers to notify the Agency. But where a vulnerability could lead to serious adverse health outcomes or death, manufacturers would be required to notify the

FDA, which has the sole authority to approve medical devices.

Device makers would also not be required to report problems if the manufacturers notify product users and address the problem within 30 days of learning about the vulnerability, or if the manufacturers shares information with other companies to prevent cyber threats.

Medtronic, which supports the Agency's engagement with industry on this topic, said through a spokesperson that the company was reviewing the Agency's guidance, which is open for public comment for 90 days, and would continue to work closely with regulators on this issue. ♦

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 1. Erulker JS, Grauer JN, Patel TC, Panjabi MM. Flexibility analysis of posterolateral fusions in a New Zealand white rabbit model. *Spine (Phila Pa 1976)*. 2001 May 15;26(10):1125-30.

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Smith & Nephew's Bet on Cartilage Repair

BY ROBIN YOUNG

Piramal Life Sciences, India's billion dollar (revenues) life sciences behemoth, had quietly invested in a novel cartilage repair technology—including funding numerous clinical studies and moving it through the regulatory processes around the world. Then, as it was ready to break into the U.S. market—Piramal sold the technology to Smith & Nephew.

The deal, whose terms were not disclosed, was announced by both Piramal and Smith & Nephew on January 12, 2016.

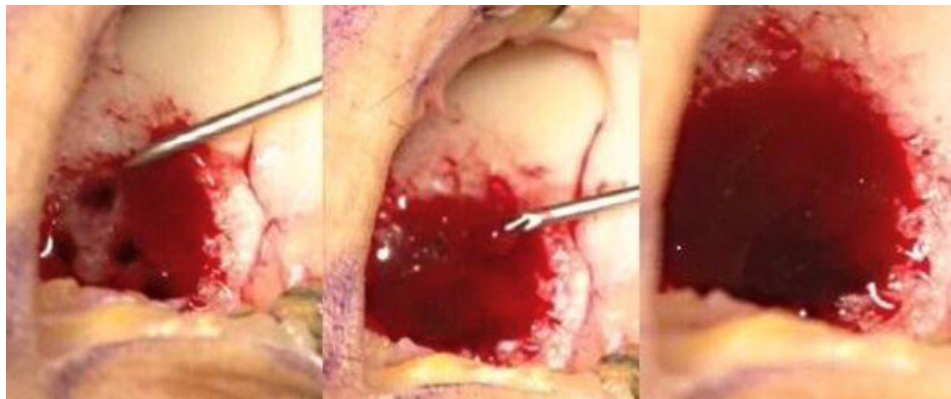
The technology, called BST-CarGel is a chitosan implant which has been shown to be an effective hyaline cartilage regeneration technology in a couple multicenter, randomized control clinical studies.

What Is BST-CarGel?

BST-CarGel is a first-line cartilage repair implant/fill which is designed to be used by the surgeon as part of a microfracture and other bone marrow stimulation procedures for treating most sizes of focal cartilage tears.

The implant, which is approved by regulatory authorities for clinical use in a number of countries around the world, including Australia, Canada and most of Europe, is a biopolymer, chitosan-based material which is mixed by the physician with a patient's own blood and then implanted into the joint.

It can be delivered arthroscopically and, importantly, can be used to treat damaged cartilage in any synovial joint—whether knee, hip, ankle or shoulder.



Courtesy of Smith & Nephew

Once implanted by the physician in the diseased joint, BST-CarGel acts as a scaffold, adhering to the cartilage surface to stabilize the blood clot creating conditions and, according to researchers who've tested it, will support cartilage regeneration and healing.

BST-CarGel's Clinical Trials

There have been several clinical studies conducted by researchers which tests chitosan-beta glycerolphosphate-based implants (BST-CarGel) as an adjunct to microfracture. The most recent one was published in the journal *Cartilage* in 2015.

A list of all BST-CarGel's studies is at the end of this article.

The study, which was sponsored by Piramal Life Sciences, enrolled 80 patients, aged 18 to 55 years, with grade III or IV focal lesions on the femoral condyles. Patients were randomized to receive BST-CarGel treatment with microfracture or microfracture alone and all patients followed the standardized 12-week rehabilitation.

Co-primary endpoints were repair tissue quantity and quality as evaluated using 3-dimensional MRI quantification of the degree of lesion filling (%) and T2 relaxation times. Secondary endpoints were clinical benefit measured with WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) questionnaires and safety.

The seven participating centers were:

- Dalhousie University, Halifax, Nova Scotia, Canada
- University of British Columbia, Vancouver, British Columbia, Canada
- CEU San Pablo University School of Medicine, Madrid, Spain
- University of Calgary Sports Medicine Centre, Calgary, Alberta, Canada
- Department of Orthopedics, CHA-Pavillon Infant-Jesus, Quebec, Canada
- Hospital Charles LeMoyné, Greenfield Park, Quebec, Canada
- University of South Florida, Tampa, Florida, USA

As reported in the journal *Cartilage*, the researchers found, using a blinded MRI analysis, that patients treated with

BST-CarGel had a significantly greater treatment effect for lesion filling ($P = 0.017$) over five years when compared to patients who'd been treated with microfracture alone.

The researchers also reported that they saw a significantly greater treatment effect for BST-CarGel for repair tissue T2 relaxation times ($P = 0.026$), which were closer to native cartilage as compared and contrasted to patients treated with microfracture alone.

Finally, patients treated with BST-CarGel and microfracture showed highly significant improvement at five years from pretreatment baseline for each WOMAC subscale ($P < 0.0001$), and there were no differences between the treatment groups. Safety was comparable for both groups.

After reviewing the study data, the researchers concluded that BST-CarGel

was an effective mid-term cartilage repair treatment. At five years, patients treated with BST-CarGel had sustained and significantly superior repair tissue quantity and quality over microfracture alone. Clinical benefits following BST-CarGel and microfracture treatment were highly significant over baseline levels.

Chitosan

BST-CarGel is a chitosan-based product—which is quite different from other types of microfracture cartilage/bone fills.

Chitosan is a naturally occurring biologic whose active ingredients, chitin/chitosan, are found in the shells of crustaceans, such as lobsters, crabs, and shrimp. It is one of the most abundant biodegradable materials in the world.

Initially, chitosan was used in agriculture as an organic seed treatment and

plant growth enhancer. Turns out chitosan increases photosynthesis, promotes and enhances plant growth, stimulates nutrient uptake, increases germination and sprouting, and boosts plant vigor. Using chitosan in agriculture reduced environmental stress due to drought and soil deficiencies, strengthened seed vitality, improved stand quality, increased yields, and reduced fruit decay of vegetables, fruits and citrus crops.

Chitosan applications for plants and crops are regulated by the EPA, and the USDA's National Organic Program.

Now chitosan is building a market in trauma and orthopedics.

The first medical applications were to rapidly clot blood and the FDA approved it for bandages and other hemostatic agents. The U.S. Marine Corps tested chitosan and found that

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it quickly stopped bleeding resulting in 100% survival of otherwise lethal arterial wounds.

Chitosan hemostatics work better than gauze dressings and increase patient survival. Both the U.S. and UK used chitosan bandages on the battlefields of Iraq and Afghanistan.

Chitosan is hypoallergenic and naturally antibacterial. It also reduces pain by blocking nerve endings.

One last scientific point: as a hemostatic agent chitosan works by interacting between the cell membrane of erythrocytes (negative charge) and the protonated chitosan (positive charge) and thereby attracts platelets to speed up thrombus formation.

When chitosan breaks down in the body it becomes a glucosamine.

All of these capabilities open up many potential medical uses for chitosan. Aside from orthopedics, several companies have introduced chitosan products for burn treatment. Burns, like other wounds, are difficult to heal because they are associated with membrane destabilization, energy depletion, and hypoxia, all of which can cause tissue necrosis if not treated properly or quickly enough. Chitosan-gelation bandages using nano-fibrin have been shown to be more durable in clinical studies of burn treatments than ointments, while still allowing gas exchange at the cell surface.

How Smith & Nephew Will Roll Out BST-CarGel

Clearly, Smith & Nephew has an exciting and differentiated cartilage repair product on their hands.

The company will be marketing BST-CarGel as an adjunct to microfracture surgery where it acts as a scaffold and stabilizes the blood clot in the cartilage lesion. In clinical studies, BST-CarGel showed that it can impede blood clot retraction while still allowing normal clotting to occur. Finally it stays where it's put by adhering to the cartilage lesion surface.

In animal studies, researchers found that BST-CarGel increased inflammatory and bone marrow derived stromal cell recruitment, increased vascularization of the provisional repair tissue and increased intra-membraneous bone formation and subchondral bone remodeling.

"BST-CarGel augments our existing joint repair portfolio with a new option that is differentiated with strong clinical evidence and targets an area of

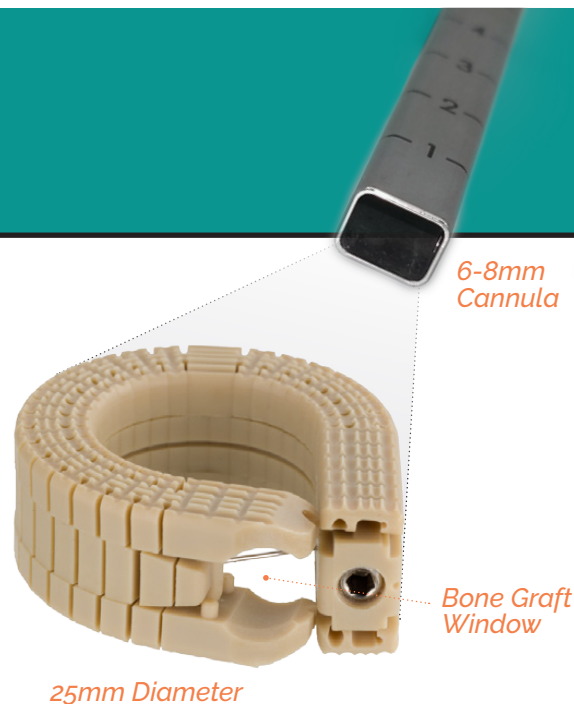
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significant patient need and surgeon demand,” said Scott Schaffner, vice president, Sports Medicine for Smith & Nephew. “We are committed to seeking and investing in next-generation technologies to widen access across our global customer base.”

Recent clinical studies of BST CarGel.

2015

Shive MS, Stanish WD, McCormack R, Forriol F, Mohtadi N, Pelet S, Desnoyers J, Méthot S, Vehik K, Restrepo A. “BST-CarGel® Treatment Maintains Cartilage Repair Superiority over Microfracture at 5 Years in a Multicenter Randomized Controlled Trial”. *Cartilage*, 6(2): 62-72.

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2014

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2013

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2011

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American Joint Replacement Registry: 618 Hospitals, 4,500 Surgeons, Robust Data

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

To get the right diagnosis, you must ask the right questions. On a macro scale, that means asking a wide range of well-thought out questions and getting them into an enormous database that is regularly mined by physicians and hospitals for the benefit of patients.

The American Joint Replacement Registry (AJRR) is the tool that fits the bill.

Joint replacement registries, in general, collect information on a combination of hip replacements, knee replacements (both total and unicompartmental), shoulder replacements, ankle replacements and elbow replacements.

Since the first registry was established in 1975 in Sweden, there have been 31 national registries established around the world.

The early registries, almost all from Scandinavian countries, only tracked surgeon and implant performance and the main outcome collected was implant failure. Recently, however, registries are adding patient-reported outcome measures. The AJRR is adding additional dimensions to the range and quantity of data collected.

Here is a list of all the major international arthroplasty registries courtesy of the International Society of Arthroplasty Registers (ISAR).

The American Joint Replacement Registry

Daniel J. Berry, M.D. is head of the AJRR Board of Directors as well as past chair of Orthopaedic Surgery at Mayo Clinic in Minnesota. He recently agreed to



For more information, please visit www.ajrr.net

Dr. Berry said, “The AJRR started out with modest data collection—Level I

demographic data such as what implant was used and what type of procedure was performed. If you analyze that over time (and you also have information on which procedures were revised) then you can get a lot of information on patient/implant/healthcare system factors that affect the need for revisions.”

Country	Name: Type	Year Started	Website
Sweden	SKAR: National	1975	http://www.myknee.se/en
Sweden	SHAR: National	1979	http://www.shpr.se/en
Finland	National	1980	
Norway	NAR: National	1994	http://nrlweb.ihelse.net/eng/
Denmark	DHR: National	1997	http://www.dhr.dk/
Australia	AOANJRR: National	1999	https://aoanjrr.sahmri.com/
New Zealand	NZJR: National	1999	http://www.nzoa.org.nz/nz-joint-registry
United States	KPTJRR: Private	2001	http://www.kpimplantregistries.org/
United Kingdom	NJR: National	2003	http://www.njrcentre.org.uk/njrcentre/default.aspx
Canada	CJRR: National	2003	https://www.cihi.ca/en/types-of-care/specialized-services/joint-replacements/canadian-joint-replacement-registry
Holland	LROI: National	2007	http://www.lroi.nl/en/home
United States	CJRR: Regional		http://www.ajrr.net/
United States	AJRR: National	2012	http://www.ajrr.net/

Source: Courtesy of the International Society of Arthroplasty Registers

“We are now moving on to Level II data, which will give users additional details on patient characteristics and complications. This includes, for example, details on the medical status of the patient and specifics on the level of surgical complexity. The depth and scope of this information gives users the power to do risk adjustment and thus benchmark themselves against national data in a way that most surgeons would trust. Most hospitals and surgeons want to get their own data back in a useful form that will help them make the appropriate interventions. So the Level II data allows us to ask, ‘How do patient comorbidities and certain aspects of patient care effect outcomes of surgery?’”

“Recently, we have moved to a Level III patient-reported outcome (PRO) platform, an extra dimension of detailed information regarding how patients are affected by disease processes or by interventions. PRO data is information that has not been modified by caregivers or hospitals in any way. We are asking questions such as, ‘How were you (the patient) before and after surgery with regard to pain, functioning, and overall health?’”

“In designing this system we attempted to be consistent with outcome measures used nationally and internationally for hip and knee arthroplasty. The patient survey includes joint-specific outcomes measures on things such as hip disability, osteoarthritis outcomes, etc. Most national groups want to have more general information about how procedures affect patient satisfaction and functioning. The most commonly used quality of life measurement tools are the Patient Reported Outcomes Measurement Information Systems (PROMIS)-Global and the Veterans Rand 12 Item Health Survey (VR-12). As for disease-specific measures, the Hip dysfunction and

Osteoarthritis Outcome Score/Knee injury and Osteoarthritis Outcome Score (HOOS/KOOS) are frequently relied upon.”

All of which does not come for free. “We are fortunate,” says Dr. Berry, “to have funding from a variety of sources, including the orthopedic societies. The orthopedic manufacturing industry has also participated at a high level because they understand that outcomes reporting will only increase in importance...and that it must be done in a careful and unimpeachable manner. In addition, part of the AJRR business model is the collection of modest subscription fees from hospital-users. This cost can be spread over the 600+ hospitals that are now members of our network.”

“Hospitals are thrilled about the AJRR because they have been looking for a cost-effective platform that allows them to collect information on hips and knees. The software system is designed to be seamless and to allow the electronic transfer of data with only a modest amount of work on the part of the hospital. Hospitals know that this PRO data could go a long way toward demonstrating their value in this new era of quality measurement.”

“There is a growing recognition in the orthopedic community that being part of a registry has two benefits: one is that such participation gives you the

Excerpt from 2015 AJRR Annual Report

Here are some data excerpts from the most recent AJRR Annual Report:

- More female than male: 56.8% of hips, 61.6% of knees
- Mean age: 67.7 years for hip, 66.1 for knee

Nearly half of all patients in the registry are not likely represented in Medicare data sets.

Rheumatoid arthritis has nearly vanished as a diagnosis prior to joint replacement (less than one half of 1% of procedures).

Femoral neck fracture accounts for >1 in 10 hip arthroplasties.

Surface replacement arthroplasty is <0.5% of hip procedures.

Knee arthroplasties were performed almost exclusively for osteoarthritis, and often used highly cross-linked or enhanced polyethylene. Posterior-stabilized components were used in over half of all knee arthroplasties, and cruciate retaining designs were used in nearly a third. Unicompartmental replacements accounted for around 1 out of 20 primary procedures.

Revisions are 10% of all hip arthroplasties performed annually, whereas for knees, it was lower at 8.1% of all knee arthroplasties per year.

big picture benefit of knowing that all of the work you do is in the database that will eventually benefit *all* joint

replacement patients. The other benefit is specific to the practice or hospital. You have comparative data on quality improvement initiatives that allows you to benchmark yourself against national data. On a personal level, surgeons can use this data to participate in the Physician Quality Reporting System from the Centers for Medicare and Medicaid Services (CMS), which should help them avoid penalties. And eventually, we hope participation in the registry will have other valuable benefits. For example, physicians might make use of the registry for recredentialing because AJRR will be a data platform.”

“Most countries that have adopted a registry system have one major national registry; our goal is to be *that* registry for North America. It’s fair to say that no other U.S. registry has anywhere near the breadth and scope of data that the AJRR has been able to collect. We were recently endorsed by the American Association of Hip and Knee Surgeons

(AAHKS) as being the organization’s official registry. This is so important, in part because AAHKS has over 2,700 members that come from the U.S., as well as members from 38 other countries.”

“AJRR has made unbelievable progress in the last two-three years. At this point we have 618 hospitals and nearly 4,500 surgeons, with all 50 states represented. CMS has told the orthopedic community that as of summer 2016 we will have access to claims data, meaning that we will be able to track longitudinal information on how all CMS patients in the registry are doing—even if they have subsequent surgery at a hospital that is not submitting data to us.”

“This year we will continue to recruit hospitals and to refine how our data are submitted and returned to hospitals. This entails converting everything to make it compatible with ICD-9 and ICD-10 codes. We are obtaining detailed information about all implants

used in U.S. in a library form that allows us to track the characteristics of each implant. We will be able to say, for example, ‘Does this fall into the category of cemented/uncemented?’ The data will give us power to analyze outcomes at a granular level.”

“Not only are we now the largest registry in the country, we go to great lengths to ensure that our leadership reflects the views of all parties involved. Members of our Board of Directors include surgeons, industry representatives, patient advocates, and hospital administration. And our Public Advisory Board does a terrific job of representing the concerns, interests and questions of our patients. I think that over the course of a decade the AJRR will fundamentally change arthroplasty in North America.” ♦

2015 AJRR Annual Report:

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COMPANY

With Six Months of Biomet, Zimmer Sales Pop 28% for 2015

Zimmer and Biomet's merger was final on June 29, 2015 and for the next six months the #1 question on Wall Street was about integration of the two companies.

The answer to that question came in the form a pro forma (excluding currency effects) sales of \$1.93 billion for the fourth quarter, up 0.5%—which showed that distribution is still finding its sea legs—but earnings that beat Wall Street's consensus—which shows that the Zimmer Biomet team had truly integrated the two company's systems well—as promised.

Adjusted earnings (adjusted for merger related costs and inventory or manufac-

turing charges) for the combined companies reached a very respectable \$428 million in the final quarter, up 39%. Put a different way, those adjusted earnings represent about 22% of sales.

Said President and CEO David Dvorak: "At the close of a transformational year for Zimmer Biomet, we achieved top line growth supported by sequential improvement from our joint reconstructive and S.E.T. businesses in the



Courtesy of Zimmer Biomet and RRY Publications LLC

U.S. In addition, we finished the year with strong earnings results, as we continued to execute on our global integration plans. Importantly, the substantial completion of our commercial integration in 2015, combined with the breadth of our musculoskeletal portfolio, positions our sales teams to accelerate our growth as we progress through 2016."

For 2016, Dvorak and his team are guiding Wall Street's analysts to expect a modest 1.5% — 2.5% sales growth (before considering what the dollar might do).

As we've now seen with Stryker, DePuy, ConMed and Zimmer Biomet, the orthopedic industry had a very good 2015 and the strong final quarter points to an excellent 2016. Demand for orthopedic products is riding a demographic, employment and insurance wave. The larger manufacturers are finding operational leverages through consolidation. And cash flows are high.

Here are the numbers for Zimmer Biomet. (See tables on the left.)

Wall Street's Take

- **BMO Capital Market:** "We continue to have a higher level of confidence in its ability to deliver EPS,

Three Months (\$ in thousands)	4Q2015	4Q2014	Change	Pro Forma, Excluding Currency Effects
Knees	\$712,000	\$496,300	43.5%	2.2%
Hips	470,000	338,100	39.1	(0.6)
S.E.T	404,000	229,100	76.3	1.6%
Dental	116,000	66,800	72.7	(6.7)
Spine & CMF	148,000	55,700	166.1	(2.0)
Other	84,000	36,900	125.7	3.3
TOTAL SALES	\$1,934,000	\$1,222,900	58.1%	0.5%

Full Year (\$ in thousands)	2015	2014	Change
Knees	\$2,277,000	\$1,895,200	20.1%
Hips	1,537,000	1,326,400	15.9
S.E.T	1,215,000	863,200	40.7
Dental	336,000	242,800	38.2
Spine & CMF	404,000	207,200	95.2
Other	229,000	138,500	65.3
TOTAL SALES	\$5,998,000	\$4,673,300	28.3%

Source: Zimmer Biomet public company documents

while the revenue delivery is more of a show-me story. The pieces of the puzzle do seem in place, including the salesforce cross-training (completed); no worries regarding expiration of stay-in-place contracts (those were mostly for Biomet employees, and for the term until the deal closed, back in June 2015); the ability to cross-sell products which neither sales team had before; and new product launches (we expect to hear more about that at AAOS, March 1-5 in Orlando). Multiple times during the earnings call, management was asked questions regarding its confidence, and multiple times it reiterated their belief that “we are confident that we can provide sequential revenue improvement throughout 2016”. This, we believe, is key to the stock working this year, and it will take a quarter-by-quarter tracking of progress for it to prove out.”

- **Wells Fargo:** “Management confident it can deliver accelerating top-line growth through 2016. In Q4, ZBH’s adjusted pro forma growth was 0.5%, slightly lower than Q3 (+0.7%) and at the low end of its guidance (+0.5% – 1.5%). Management characterized Q4 as a quarter of stability with progress made in the commercial channel integration (which is substantially complete). ZBH continues to expect growth to accelerate sequentially through 2016. ZBH provided Q1 revenue growth guidance of +0.5% – 1.0% on a constant currency (cc) basis which implies an acceleration over Q4. For the full year, ZBH expects growth to be 1.5% – 2.5% cc and the company expects to exit 2016 with growth at or above market growth of 3%.” — RRY

ConMed Beats Wall Street’s Sales Estimates for 2015

For the last three months of a very eventful 2015, ConMed Corporation (home of Linvatec, Hall, Concept and Shutt) reported \$191 million in sales—which pulled the full year up to \$719 million—higher than Wall Street’s \$189.7 million estimate for the quarter.



Courtesy of ConMed Corporation

While better than Wall Street expected, ConMed’s sales were still down about 2.0% from the same quarter in 2014—before currency effects. The effects of currency translation on ConMed’s sales outside the U.S. pulled the overall sales growth rates down. Excluding currency, ConMed’s sales were actually UP by a half a percent for the quarter and UP one percent for the full year.

Three Months (\$ in thousands)	4Q2015	4Q2014	Change	Excluding Currency Effects
Orthopedic Surgery	\$104,200	\$101,700	2.4%	5.9%
General Surgery	\$70,900	\$75,400	(6.0%)	(4.5%)
Surgical Visualization	\$15,900	\$17,900	(10.8%)	(8.5%)
TOTAL SALES	\$191,000	\$195,000	(2.0%)	0.5%

Full Year (\$ in thousands)	2015	2014	Change	Excluding Currency Effects
Orthopedic Surgery	\$389,000	\$402,800	(3.4%)	0.7%
General Surgery	\$274,200	\$279,300	(1.8%)	(0.01%)
Surgical Visualization	\$55,900	\$58,000	(3.3%)	(0.01%)
TOTAL SALES	\$719,200	\$740,100	(2.8%)	0.03%

Source: ConMed Corporation public company documents

ConMed, Stryker Corporation and JNJ’s DePuy Synthes Companies have all reported a stronger-than-expected sales report for the final quarter of 2015.

Here are the numbers for ConMed. (See table below.)

With rising profit margins and a number of new initiatives including the SurgiQuest growth platform CEO Curt Hartman and his team raised their sales guidance for 2016. SurgiQuest, Hartman and his team expect, will kick in between \$55 million – \$60 million and bring the full year’s sales range to between \$760 million – \$770 million for 2016.

Wall Street’s Take

Needham & Co.: “To simplify, the 2016 math looks like this: organic cash EPS growth of 7% plus SurgiQuest accretion of 10% offset by 21% of currency headwind results, unfortunately, in a 4% decline in cash EPS. While disappointing, we believe that two consecutive quarters of positive revenue growth show that the turnaround is happening—albeit more slowly than we hoped.” — RRY

VertiFlex Raises \$27 Million for Superior Spacer

VertiFlex, Inc. has raised nearly \$27 million for its FDA-approved (May 2015) Superior Interspinous Spacer (ISS).

According to a Security and Exchange Commission regulatory filing, the funding consists of \$10.5 million in new cash, a \$16.2 million debt conversion and another \$105,000 in warrants. Eight unnamed investors participated in the funding.

The Superior Spacer, according to the company, is for the treatment of patients with lumbar spinal stenosis. The device is designed to achieve indirect spinal decompression for patients suffering from neurogenic intermittent claudication due to moderate lumbar spinal ste-

nosis. It is implanted minimally invasively through a cannula designed to be less traumatic to the patient. It can be implanted under general or local anesthesia.

The company submitted the following "Indications for Use" in its PMA (pre-market approval) application:

Treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, confirmed by X-ray, MRI and/or CT evidence of thickened ligamentum flavum, narrowed

lateral recess, and/or central canal or foraminal narrowing.

Patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain. The Superior ISS may be implanted at one or two adjacent lumbar (L) levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5.



Superior Interspinous Spacer/VertiFlex, Inc. and RRY Publications LLC

The collage features several pages from the magazine. The central focus is the 'OTW GamePlan Sports Bracket for January 16, 17 & 18, 2016', which lists various sports events and includes a 'PICK A WINNER! LEARN POINTS! WIN PRIZES!' section. Other visible content includes 'Reader Statistics for OTW', 'OTW Mailbox List', 'OTW GamePlan.com' logo, and a 'NOTABLE AND QUORABLE' section with a list of names and dates.



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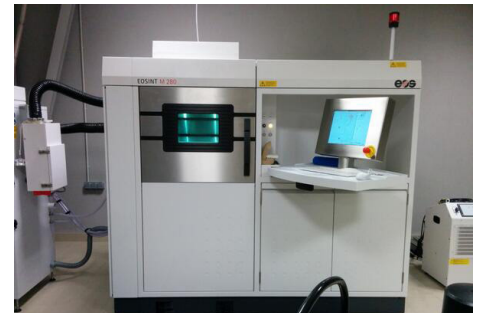
After the FDA approval, the company's co-Medical Director, Nick Shamie, M.D., Professor & Chief, UCLA Orthopaedic Spine Surgery, said, "As an early adopter of interspinous spacers, they have provided tremendous improvement for my patients suffering from lumbar stenosis. As a next-generation technology, Superior offers the potential for even greater clinical benefit, with the least invasive indirect decompression possible, and the ability for patients to avoid traditional open spine surgery."

The company said it intended to follow the IDE (investigational device exemption) subjects for up to five years. — WE

LDR Invests In, Allies With Poly-Shape

LDR Holding Corporation has announced that it has made a minority investment in Poly-Shape, SAS, a French manufacturing company specializing in laser sintering. In addition, LDR has entered into an exclusive partnership with Poly-Shape for the development of spinal implants. The investment was made through LDR's wholly owned subsidiary, LDR Médical, SAS.

LDR President and CEO Christophe Lavigne noted in the January 21, 2016 news release, "As a company with a passion for innovation, LDR is very



Poly-Shape machine/Courtesy of LDR Holding Corporation

pleased with this alliance. Poly-Shape has developed a reputation for its novel manufacturing techniques, and for the production of parts that meet the rigorous quality and functional standards of its clients, which include Formula One race teams and companies developing aerospace applications. Access to this experience and capability supports our

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philosophy of utilizing cutting-edge technology to bring high-quality spinal implants and instruments to our surgeon customers and their patients. The collaboration will help us continue to develop and deliver best-in-class products for Minimal Implant Volume (MIVo) spinal surgery.”

Stéphane Abed, Poly-Shape co-founder and CEO, added, “Poly-Shape is excited to partner with LDR and to leverage our additive manufacturing expertise, proven in aerospace and racing, to produce novel spinal implants that will benefit patients and physicians. I believe LDR is an ideal partner for Poly-Shape in that we share a similar philosophy based on innovation that provides true, measurable benefits.”

Asked how Poly-Shape’s manufacturing techniques will benefit orthopedic patients, Lavigne told *OTW*, “Poly-Shape uses an innovative 3D laser sintering manufacturing process that “builds” parts layer by layer. This technology is now being applied to make medical implants. Orthopedic patients stand to benefit because the technology may result in optimized implants with more intricate features that have been impractical or even impossible with traditional manufacturing methods.”

“This partnership exemplifies LDR’s passion for innovation, and desire to leverage novel technology to improve the implants and instruments that we provide to our surgeon customers for the treatment of their patients. 3D laser sintering technology, specifically, demonstrates how novel methods like additive manufacturing processes can be implemented to support our philosophy of designing, developing and distributing medical devices that enable Minimal Implant Volume (MIVo) spinal surgery.” — *EH*

DePuy Ends Year With a Bang, Synthes With a Whimper

Johnson and Johnson’s DePuy Synthes business ended 2015 on a clear upswing, if we’re looking at large joint reconstruction, but a slog if we’re talking trauma and spine.

For the final quarter of 2015, DePuy Synthes sold nearly \$760 million of hip and knee implants, instruments and other related products—which was about 1% higher than the \$751 million sold at the end of 2014.

But, of course, those numbers are in U.S. dollars. Most of these sales were in other currencies. Adjusting for currency effects and, impressively, hip/knee revenues rose about 6%. Which means that DePuy ended 2015 with a bang.

Spine and trauma...more difficult.

For the last quarter of the year, DePuy Synthes sold about \$1.7 billion of spine and trauma products which was about 1% lower than the same quarter in 2014.

Again, those are U.S. dollars, so adjusting for currency effects, and the growth rates were actually up about 4%.



DePuy Synthes
JOINT RECONSTRUCTION

COMPANIES OF *Johnson & Johnson*

Courtesy of Johnson & Johnson

Three Months	4Q2015	4Q2014	Change	Excluding Currency Effects
Hips and Knees	\$759,000	\$751,000	1.1%	6.0%
Spine, Trauma and Other	\$1,664,000	\$1,690,000	(1.1%)	3.7%
Total DePuy Synthes	\$2,423,000	\$2,441,000	(0.0%)	4.5%

Full Year	2015	2014	Change	Excluding Currency Effects
Hips and Knees	\$2,828,000	\$2,901,000	(2.5%)	3.0%
Spine, Trauma and Other	\$6,434,000	\$6,774,000	(5.0%)	1.1%
Total DePuy Synthes	\$9,262,000	\$9,675,000	(4.3%)	1.7%

Source: Johnson & Johnson/DePuy Synthes company documents

United States Sales Pulled up Rest of the World

U.S. demand for DePuy Synthes orthopedic products was extraordinary. No doubt helped by rising employment (and therefore insurance coverage) and the 11 million newly enrolled Obamacare beneficiaries, DePuy Synthes packed up, shipped and billed for 9.8% more hips, 7.6% more knees, 6.3% more spine and 7.7% more trauma products in the last quarter as compared to the fourth quarter of 2014.

Outside the U.S (OUS) demand, however, was a sharp contrast.

OUS DePuy Synthes booked 9.6% fewer hip sales, 8.5% fewer knee sales, 7.7% fewer trauma sales and 13.4% less spine sales.

Overall, the U.S. booked an impressive 7.4% sales growth while OUS sales fell by 10.6%.

Coming on the heels of Stryker's strong finish to 2015, DePuy Synthes' numbers are signaling that the orthopedic industry is both thriving and growing sales at an increasing rate. Despite the gloom and doom on Wall Street, orthopedics is very healthy and delivering excellent sales growth and operating profit margins.

Wall Street's Take

- **Wells Fargo:** "In our view, management's overall tone was very positive, expressing confidence in the growth outlook of the end-markets and JNJ's ability to outpace the market growth. With nearly \$20B[illion] of net cash, M&A remains a key focus for the company with management emphasized that it will be disciplined and decisive in doing deals. We increased our 2016 EPS estimate

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to \$6.51 from \$6.38 and we forecast 2017 EPS of \$6.90. Raising our valuation range to \$111-\$113 (from \$108-\$110) based on 16x our 2017 EPS forecast."

- **RBC Capital Markets:** "JNJ's 4Q15 MD&D results appeared stable sequentially excluding the benefit from extra shipping days. JNJ's MD&D sales of \$6.43B (RBCe: \$6.36B, cons: \$6.33B) were up ~1.8% y/y cc (vs. +1.3% in 3Q15), excluding acquisitions, divestitures, and the impact from extra selling days. Management continues to see a slightly positive trend in U.S. healthcare utilization and noted that hospital admissions were up ~2% y/y, with US surgical procedures up ~1%+ y/y."
- **BMO Capital Markets:** "This was a particularly good quarter for JNJ, underscoring why a diversified health care product portfolio continues to make sense for it: in Consumer, the full portfolio is benefiting the franchise, with the full return of its Tylenol products; in Medical Devices, Electrophysiology, Vistakon and Orthopaedics were standouts."
- **Needham & Co.:** "JNJ's results seem to indicate that med tech markets were stable to slightly improve on a global basis in 4Q15 with some improvement in U.S. growth offsetting some deterioration in emerging markets growth. We think this is positive for our med tech universe." — RRY

Massive Supplier Directory Now Organized and Available

There's a new kid on the block. RepResponse opened officially with the New Year to focus on a remedy for the lack of communication that often exists between medical product and service providers and their healthcare facility customers.

Dan Liefkort and his partner, both former orthopedic medical device representatives, had seen the computers plastered with post it notes listing names and contact information of major suppliers in the offices of medical facilities. It was clear to them that this was an efficiency breakdown. While the contact information of basic providers who were used daily was immediately available, those that were not used as frequently were often difficult to locate and contact.



Courtesy of RepResponse

They decided what was needed was a directory listing every product and service together with the name and contact information of the provider and make it available to medical institutions. RepResponse's data base online now has over 14,000 hospitals and surgery centers accessible, over 70 medical areas (specialties) available and more than 300 companies and their services listed. The specialties include everything from plastic surgery to radiology to construction services. "Our goal was to create an all encompassing platform for the healthcare facility," said Liefkort, who is the managing partner.

Liefkort also points out that having the ability to compare options allows the healthcare facility to reduce pricing and gain better customer service. He notes that the personnel on the supply and healthcare side are constantly fluctuating and having one place that always keeps contacts up to date could be critical.

The company is currently running two pilot programs at facilities in South Florida. Liefkort said, "From our experience thus far, once facilities know about RepResponse, they are excited to use it." — BY



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Fewer Than Expected People Taking Obamacare Subsidy

The non-partisan Congressional Budget Office (CBO) reported on January 25, 2016, that fewer people than expected are taking advantage of subsidies to purchase health insurance under the Affordable Care Act (ACA). The CBO study, based on updated enrollment figures up through last month, says that 11 million people are likely to purchase subsidized policies under the health care law, down about 4 million from estimates issued early last year.

Last fall, the Department of Health and Human Services predicted that only 10 million customers would sign up and

pay premiums through online insurance markets by the end of 2016.

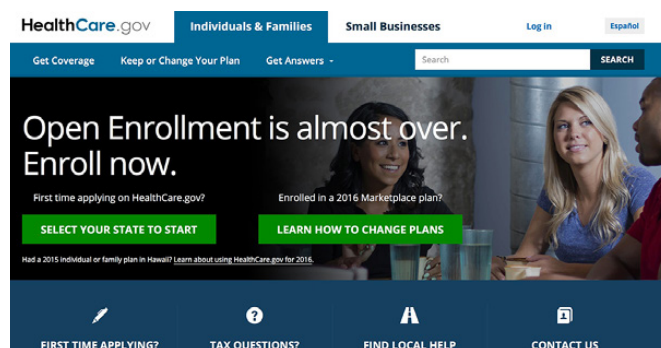
AP reports that the budget office had previously projected a monthly average of 21 million enrolled in 2016, with 15 million of those customers receiving taxpayer-financed subsidies to help pay their premiums. The new estimate is for a monthly enrollment of 13 million, with 11 million of those receiving subsidies.

The Obama Administration's enrollment target, calculated in a different way, is to have 10 million customers signed up and paying premiums at the end of 2016.

The CBO makes estimates on legislation and the budget and

economy for lawmakers on Capitol Hill, including a beginning-of-the-year report detailing the budget and economic picture facing Congress. Last week the agency warned of worsening deficits and somewhat slower economic growth. The budget office promises a fuller estimate of the health care law in a March update.

The last chance for people to sign up for ACA coverage for 2016 was January 31, 2016. — WE



Courtesy of healthcare.gov.

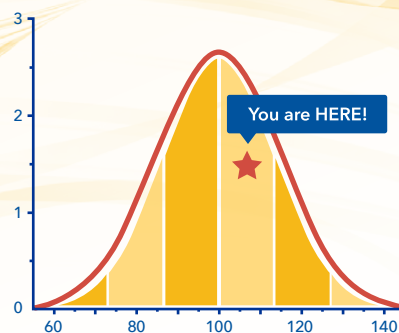
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LARGE JOINTS

Mass Board of Registration Tells Surgeons to Stay Put in OR

According to the *Boston Globe* and *Fierce* writer Zack Budryk, surgeons in Massachusetts may soon have to document when they enter or leave the operating room during a surgery. The Massachusetts Board of Registration in Medicine has approved the rule, but before it can take effect it must have the approval of several state agencies. Another stipulation is that primary surgeons must designate a backup doctor to assume their responsibilities if they leave the operating room.

The underlying questions being raised relate to, are surgeons being stretched too thin? Are they being scheduled for more than one surgery at a time? Are patients learning, after the fact, that their surgeons were scheduled for another procedure at the same time as theirs?



Wikimedia Commons and Damon Sacks

Budryk reported that three patients, including former Red Sox pitcher Bobby Jenks, are suing a former spinal surgeon at Massachusetts General Hospital over their inability to determine, based on medical records, whether he was present during their procedure due to multiple schedules listing him as attending surgeon during overlapping surgeries.

Other Boston hospitals report that they already document the movement in and out of operating rooms of the surgeons

as well as the nurses. Massachusetts Nurses Association spokesman David Schildmeier called the vote a positive development.

Not everyone is in agreement. Partners HealthCare CEO David Torchiana, M.D., told the *Globe* writer, "There are people in this city who are alive today after the Boston Marathon bombings that went to all of our teaching hospitals and we opened up rooms and did a bunch of surgeries simultaneously." — BY

JNJ Leads \$15 Million Funding for Innovative Cartilage Technology

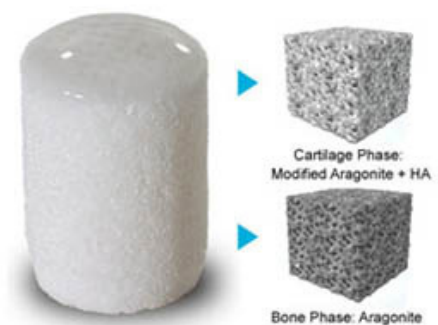
Johnson & Johnson Innovation (JJDC investors) joins a blue chip list of venture investors including Elon, Accelmed, Access Medical Ventures, and Peregrine Ventures to fund an innovative cartilage repair technology called Agili-C and a promising young Israeli company named CartiHeal, Ltd.

Agili-C, the technology that has attracted these top venture investors, is a calcium carbonite and HA (hyaluronic acid) implant that has been shown in several post-marketing studies (phase IV stud-

ies) to provide significant improvement in knee pain level, as well as reduction in related symptoms. Investigators who reviewed MRIs and histological findings of joints with an Agili-C implant found regeneration of hyaline cartilage and its underlying subchondral bone.

The key to Agili-C is a novel (to orthopedics) type of calcium carbonate named Aragonite. Aragonite is, one of the two common, naturally occurring, crystal forms of calcium carbonate, CaCO_3 (the other form being the mineral calcite), which is formed by biological and physical processes, including precipitation from marine and freshwater environments.

As the clinical evidence from Agili-C is showing, when implanted in a joint (and physicians have implanted Agili-C in about 200 patients to date) this material appears to be both osteoconduc-



Courtesy of CartiHeal

tive and osteotransductive at the bone phase and chondrogenic at the cartilage phase. When CartiHeal's scientists look at why this is occurring, they point to Aragonite's macro and micro porosity and interconnected porosity as well as its unique chemical composition.

CartiHeal, Ltd., which was founded in 2009 by CEO Nir Altschuler after he developed a way to transform coral into a cartilage regenerative scaffold, is a privately held medical device company based in Israel. The \$15 million investment will be used to, among other purposes, fund European expansion and manufacturing of Agili-C and to advance clinical trials in other therapeutic areas.

Agili-C is, says the company, the world's first off-the-shelf, cell-free cartilage and bone regeneration implant.

Lead investor, JJDC, is a venture capital subsidiary of Johnson & Johnson, Inc. that funds promising new market opportunities in health care and technology. "This round of funding is a testament to our investor's commitment and satisfaction with CartiHeal's progress," says Uri Geiger, managing partner of Accelmed and a CartiHeal board member.

So far, Agili-C has been used to treat patients with painful, arthritically damaged knees. Recently a few physicians have been testing Agili-C in other diseased joints. In the future the company hopes to segue into treating the ankles and big toes and other cases of moderate osteoarthritis.

When treating patients with Agili-C, physicians implant the material using a mini-arthrotomy approach. Once the physician determines the size of the cartilage defect they then drill a hole in

the affected area and insert Agili-C in a press fit manner slightly below the articular surface. Because of drilling, blood from the subchondral bone wicks into the Agili-C's interconnected pores and lays the foundation for both bone and cartilage repair if not also regeneration.

The Agili-C implant is CE Mark certified as a "Bi-phasic, porous, resorbable, tissue regeneration scaffold, for the treatment of articular cartilage and/or osteochondral defects."

"Because the Agili-C implant is suitable for a wide range of pathologies, from traumatic injury to moderate osteoarthritis, the device meets a vast, unmet need," says Altschuler. "This investment positions CartiHeal as a significant player for treating early-onset osteoarthritis that hasn't responded to

conservative treatment but for which joint replacement isn't yet necessary."

The Agili-C implant was named by *Israel 21c* newsletter as "one of the top 10 most extraordinary medical devices that promises to revolutionize global healthcare." In June 2009 it was also designated one of the Top 10 medical devices by *Medtech Insight*, which called Agili-C technology the "holy grail" of orthopedic advances.

For the past three years the device has been successfully implanted in 200 patients in leading orthopedic facilities in Italy, Slovenia, Poland, Belgium, Austria, Romania, Serbia, Switzerland and the Netherlands. CartiHeal is now initiating discussions with the FDA in the U.S. with the aim to begin clinical studies in 2017. — AGL

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SPORTS MEDICINE

New Study: Elevated Concussion Risk in High School Hockey

The old adage “the bigger they are, the harder they fall” should be modified to “the bigger they are, the harder they hit” when referring to younger adolescent males playing collision sports.

Children grow at different rates. By the time boys are 15 years old, they typically weigh between 90 lbs and 175 lbs and stand between 5 ft. and 6 ft. tall (see growth chart from the Centers for Disease Control at the end of this article).

When 15 year old children play collision sports like ice hockey or tackle football, those differences translate into a wide disparity of injury rates—particularly regarding concussions, an injury that can have a life time effect.

According to a newly released study in the *Journal of Pediatrics*, when it comes to suffering from concussion, adolescents competing against more physically mature males run a risk of taking nearly 40% longer to recover—54.5 days as opposed to 33.4 days.

Concussion is the most common injury among young male players. The *Journal of Pediatrics* and *USA Hockey Today* magazine rates concussion as representing more than 15% of injuries among 9 to 16 year-olds and 25% of injuries among high school players.

The study, which was led by Dr Peter Kriz and co-authored by Cynthia Stein, M.D., Janet Kent, M.D., Danielle Ruggieri, BA, Emilie Dolan, BS, Michael O'Brien, M.D., and William P. Mewhan,



Wikimedia Commons and Sgt. 1st Class Jeffrey Smith

III, M.D., enrolled 101 boys between the ages of 9 years to 18 years who had been diagnosed with concussions from playing ice hockey.

The boys were followed at three regional medical centers—Rhode Island Hospital/Hasbro Children’s Hospital, Boston Children’s Hospital, and South Shore Hospital in Weymouth, Massachusetts.

Between September 1, 2012 and March 31, 2015, the children’s symptoms were measured according to the Pubertal Development Scale (PDS). The PDS is a self-assessing rating that for males tracks five areas of growth: height, body hair, facial hair, skin changes, and voice changes. Post-injury studies were done on the young athletes including computerized neurocognitive testing (ImPACT), other neurologic examinations, and a standardized Post-Concussive Symptom Scale.

Typical symptoms of concussion include temporary loss of consciousness upon impact, headache, confusion, dizziness, slurred speech, nausea, vomiting, and fatigue. The study concluded that boys

who fall in the early pubertal stage for the PDS were most at risk for prolonged concussion.

Lead investigator Kriz, who is now assistant team physician at Brown University (fellowship at Rhode Island Hospital/Hasbro Hospital), medical advisor to a number of Providence-area schools and the Providence Bruins professional hockey team, argues that the study results are too conclusive to ignore.

The disparity in children’s maturity rates is creating an un-sustainable risk of concussion injury for smaller players. Should there be a size limit for hockey or football players? Should school districts create new teams of more like-sized players?

Based on this study, Kriz recommends that school districts make rules and participation standards to prevent less mature boys from playing against larger players. Having them compete in leagues grouped by relative age, and discouraging more skilled players from ‘playing up,’ might be one answer.

Unfortunately, such suggestions, as Kriz tells *OTW*, are not practical. “Ice time, transportation, and rink costs are expensive. Adding a junior varsity or freshman team for the sake of injury reduction and player development would likely be cost-prohibitive,” since most public schools typically lack funds for more developmentally appropriate teams.

Since 1994, The American Academy of Pediatrics (AAP) has defined collision sports such as ice hockey, football, boxing, and rodeo, as sports where athletes purposefully hit or collide with other players or inanimate objects such as the ground, equipment, or walls. Contact sports such as soccer and basketball run

the risk as well, but with usually less force and intention.

Speaking with Richard Salit of *The Providence Journal*, Kriz says “there’s been a lot of focus on football and concussion. But it’s important to remember there are other collision sports.” Boy’s ice hockey has a concussive incidence second only to junior and high school football.

The unique aspects of ice hockey such as the head-to-toe equipment worn may offer a false sense of security. Although they do provide protection, they still cannot prevent injury. And the fact most schools don’t, or cannot, offer a variety of teams makes it more imperative that younger players are protect-

Packers Left Tackle Rejects Ankle Surgery

Fans of the Green Bay Packers football team, which includes most of the population of Wisconsin, were cheered to learn that Packers left tackle



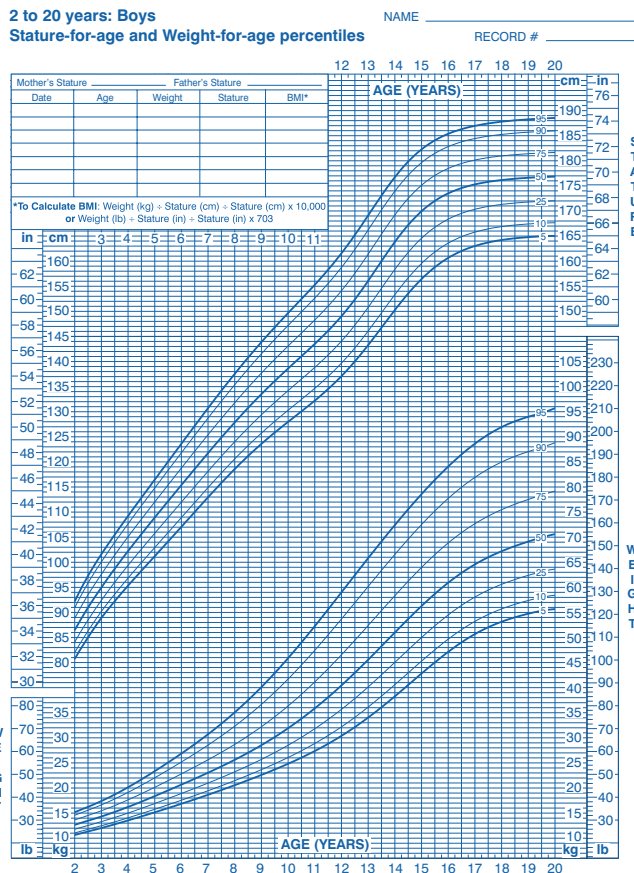
David Bakhtiari/Courtesy of Mike Morbeck and Flickr

David Bakhtiari, who injured five ligaments in his ankle, is not anticipating surgery. According to sportswriter and Packer’s blogger, Tom Silverstein, Bakhtiari missed three games and was not 100% recovered when he played with the Packers against Arizona.

Bakhtiari had sprained five ligaments and torn three of those in the early December game against Oakland. Silverstein reported that the Packers medical staff was not going to let Bakhtiari play until they determined that the normal things he needed to do to play left tackle would be of no more danger to him than if the ligaments were healthy.

Bakhtiari told Silverstein, “It really started responding and I was able to start using it. I felt more like myself. It just was to the point where we felt like it was going to stay with what we were going to do with it. It healed up enough to where it would be safe enough.”

He played well into the 26-20 overtime loss to Arizona. Bakhtiari expects the ankle to heal on its own, according to Silverstein. He plans to take a few weeks off and then begin his normal off-season routine. — BY



NOTE: Forty-four adolescent female ice hockey players were also included in the study, with quite different results in that the heavier girls experienced longer recovery periods from concussion than their peers. However, more trials and participation is needed before results can be collected and analyzed and considered conclusive. — AGL

PEOPLE

In Memoriam: William Howard, M.D.

William H.B. Howard, M.D., the longtime medical director and co-founder of MedStar Union Memorial's Sports Medicine Clinic, passed away on January 10, 2016 at the age of 81.

An incredibly respected Renaissance man who once brought a dog to the OR in a shopping cart, Bill Howard possessed a deep sense of self and of the important things in life.

Survivors include his wife of 62 years, and four daughters: Anne Dechter of Washington, D.C.; Patti Fenwick of Reisterstown; Kate Perri of Wilna; Tarry McGuirk of Bel Air; a sister, Frances Flatau, also of Wilna; and 14 grandchildren.

A funeral was held on January 15, 2016 at Olney Farm, 1001 Old Joppa Road.

Dr. Howard entered the world at Union Memorial Hospital, and several years later began his education in a one-room schoolhouse. He then attended Duke University, and followed that up with a bachelor's degree from the Johns Hopkins University. He was a 1963 graduate of the University of Maryland School of Medicine.

He did his residency in general surgery and orthopedics at Harrisburg Hospital in Pennsylvania and returned to Baltimore, where he ran the emergency room at what is now MedStar Union Memorial Hospital (UMH).

Sensing a profound need for dedicated treatment for athletes, Dr. Howard worked with Drs. Joe Martire, a radiologist, and Roger Michael, then chief of



William H.B. Howard, M.D., Towson Orthopaedic Associates

orthopedics, to open a sports medicine clinic. It began in 1979.

Stuart B. Bell, M.D., vice president, Medical Affairs and CMO of MedStar Union Memorial Hospital, said of Dr. Howard in an email:

"Most of you knew and worked with Bill Howard, who suddenly passed away, reportedly near his beloved pick up truck, two days ago. This was a shocker, and a surprise, since he was such vital and energetic person, who always appeared and acted many years younger than his chronological age."

"We all have vivid memories of him. He brought me mint juleps with mint from his farm in 1980, as post op pain relief for the hernia he had just fixed for me. That was the time when you stayed overnight in the hospital for such surgery, and could drink a little bourbon in house also."

"He was a teacher, friend, clinician, athlete, intellectual, innovator, husband, father, grandfather, and drinking companion, amongst other things."

"He was certainly the face of UMH for at least 40 years, an iconic figure, though

he was someone who would scoff at the idea of his iconography."

"He founded the critical program in UMH development, our Sports Medicine program, based on an idea he had (and he had many) derived from his work running our ED, where he would see athletes from Memorial stadium, down the street, for sports injuries. Our sports medicine programs, those of MedStar, and to some extent, our successful orthopaedic programs, are a direct result of his founding efforts."

"He was also a deeply caring physician, in the best, and most complete definition of that role and word. He lived it his entire life, and though a surgeon, he knew much about everything, and we all benefited from his knowledge and personality."

"He taught many of our clinicians, students, nurses, doctors, and also the public at large in his media persona. He reached many in his time here."

"Anyone who knew him, learned something from him, and usually a lot from him. And he was just fun to be around. Thank you Bill, for all you gave to us over your multifaceted and thoroughly, completely lived life."

Anne Dechter is one of Bill Howard's four daughters. Asked about a really fun memory of her dad, she noted, "Daddy absolutely lived for the good story. There's a good one about the time Daddy sneaked a patient's dog into the OR at Union Memorial (in a shopping cart, of course) and successfully removed a large tumor that the owner had been told was inoperable."

As for how he serves as a role model for her, Dechter said, "Daddy was always, always learning. He never stopped. He just drank up information—from

books, the newspaper, the radio, academic papers, other people. And he was passionate about his work. He worked so hard, but I don't think he'd ever consider it 'work.' He did what he loved to do every day. I've tried hard to be like him in those ways—to be a perpetual student, a hard worker—and if I've been at all successful, it's because I had him as a model.”

“I think Daddy would want to be remembered as a hard-working, salt-of-the-earth doctor who did everything in his power to help his patients and friends—whether that was patching up a busted knee so you could play in the next game, talking up a young player to a talent scout, or offering a place to stay to someone in a tough spot. He had zero regard for the rules, especially bureaucratic B.S. that he thought interfered with patient care. I think he'd also like to be remembered for knowing at least a little something about everything—and because he was so incredibly well-read with an excellent memory, he tended to know *a lot* about everything. His bookshelf is filled with a motley assortment of books—on sports, war, science, language, fiction, music, history, etc.”

When Tarry McGuirk talks about her dad, the love and respect shine through. She says, “First and foremost, I want to thank all the family and friends that have reached out to me via email, text,

phone calls, voice messages, and Facebook. I truly feel the positive energy and support you are sending and I have never felt so blessed. Thank you.”

“Next, and WAY harder, I need to thank my dad. I have read so many tributes to him, all so accurate and yet all different. He was a complicated, brilliant, brutally honest, straight forward, horrendously funny man and, yet just a simple down home guy. He was the prominent, well-known, amazing physician who only aspired to be a redneck (and I say that with only love and respect).”

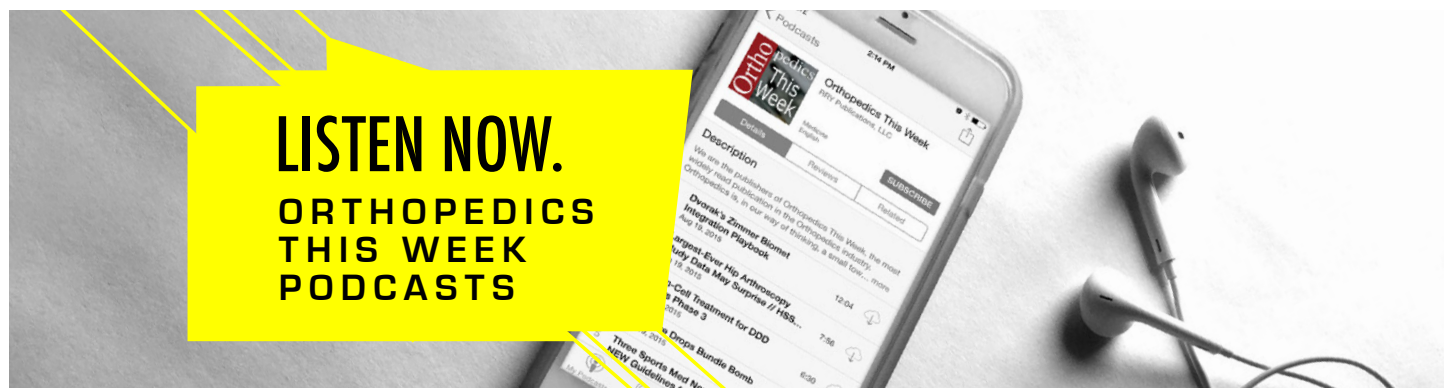
“He was multifaceted, indescribable with simple words, he was larger than life. He was called and known by many different nicknames during his reign here on earth. Doc Howard, Ole Buz-zard, Hack Howard (in reference to his prowess in the operating room) Dog-breath (need I explain?), Roadrunner, (he gave himself this one obviously. His running form and speed was NOTHING like a roadrunner!) Bill, William (often said with exasperated tones by his mother and wife when he was especially ornery). There are others, often said on the rugby field that, I as a lady (no laughing, Daddy) cannot repeat. But my personal favorite name he was called was Daddy.”

“I look back at all his gifts with overwhelming love but am choosing one

that I feel was one of the greatest gifts he gave me and to those who met him. He gave himself, the REAL Bill Howard to all.”

“Everybody says my dad was a hard-working man. I believed that growing up. As I looked beyond the long hours, the immeasurable energy, the dedication to his many patients, I realized it was way more than that. He was the prime example of someone living his passion. He never considered what he did as work. He lived it, he was meant for it, he loved it and boy did it show! He was one of the few remaining doctors who cared, who listened and understood people. He connected. He never bought into the hype and finery of being a famous physician.” Daddy ignored, well more like bucked, the big medicine politics and the monetary rules of the typical sterile hospitals and made Union Memorial a warm and welcoming haven. He exemplified the old style doctor who told you like it was. ‘Quit being a wuss, and walk it off.’ I'd say he was right 99% of the time.”

“I thank you, Daddy, for inspiring me to recognize what is really important. Not the fluff and the finery that cover most people's true selves. Be genuine, be true to who you are, and do what you love. I will forever miss you but carry you always in me.” — EH



5 Rush Surgeons Among Chicago's "Top Docs"

Midwest Orthopaedics at Rush is celebrating these days... five of its physicians were named among the Chicago area's "Top Doctors" in the January 2016 issue of *Chicago Magazine*. They include: Drs. Howard An, Steven Gitelis, Joshua Jacobs and Anthony Romeo (orthopedic surgery) and Mark Cohen for hand surgery.

Howard An, M.D. is a spine, back and neck surgeon at Midwest Orthopaedics at Rush. He is also the Morton International Endowed Chair Professor of Orthopedic Surgery, Director, Division of Spine Surgery and Spine Fellowship Program, Rush University Medical Center.

OTW asked each of these esteemed surgeons about their current research.

Dr. An told OTW, "There are millions of patients with low back pain due to intervertebral disc degeneration, and future treatment will be biological repair or regeneration of degenerated disc tissue. Cell therapy for intervertebral disc degeneration is being investigated as a biologic treatment, and we are actively doing research in this area into 2016."

Mark Cohen, M.D. is the Co-Director of the Midwest Orthopaedics at Rush

Hand, Wrist and Elbow Institute. He has won several research, teaching and achievement awards and is a member of 16 national and international medical societies and associations.

Dr. Cohen told OTW, "We are researching the long term follow-up of a radial head implant that I helped design. We now have some 10 year results that are quite favorable."

Steven Gitelis, M.D. specializes in orthopedic oncology and joint reconstruction and replacement at Midwest Orthopaedics at Rush. Dr. Gitelis currently serves as the Director of the Rush Center for Limb Preservation.

Dr. Gitelis noted, "We plan to look at chemotherapy resistance in osteosarcoma at a molecular biological level to try to better understand this daunting problem. This potentially can help many children with this cancer."

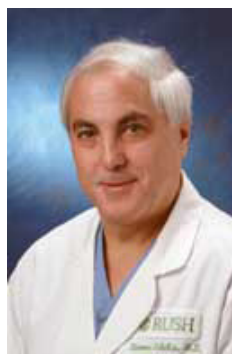
Joshua Jacobs, M.D. is a joint replacement orthopedic surgeon at Midwest Orthopaedics at Rush. In 2013, he served as President of the American Academy of Orthopaedic Surgeons (AAOS).

Dr. Jacobs commented to OTW, "Adverse Local Tissue Reactions (ALTR) due to tribocorrosion at modular junctions of total hip replacement (THR) components has emerged as an increas-

ingly common reason for failure. In collaboration with experts in the fields of materials science, electrochemistry, biomechanics, tribology and histopathology, orthopaedic surgeons in our group will continue research aimed at gaining an understanding of the mechanism(s) of ALTR to mitigate, and ultimately prevent, this failure mode. Improved clinical detection algorithms as well as improvements in the tribocorrosion resistance of THR components are the most promising areas of research likely to have a significant impact on this phenomenon."

Anthony Romeo, M.D. is an orthopedic surgeon with more than 20 years of experience working in academic medicine. Dr. Romeo has been selected to be President of the American Shoulder and Elbow Surgeons from 2017-2018. He also serves as co-team physician for the Chicago White Sox and the Chicago Bulls.

Dr. Romeo noted, "There are two areas that I find exciting. The first is the use of sophisticated imaging program to pre-operative plan shoulder replacements and develop patient specific instrumentation to improve the accuracy and precision of the procedure. In addition, we will be evaluating the impact of stem cells on the ability to improve the results of rotator cuff repairs, including the healing rate of the tendon to bone, and overall clinical outcome." — EH



(L to R): Mark Cohen, M.D., Joshua Jacobs, M.D., Anthony Romeo, M.D., Steven Gitelis, M.D. and Howard An, M.D. / Midwest Orthopaedics at Rush



Orthopedics This Week | RRY Publications LLC

Robin R. Young, CFA

Editor and Publisher

robin@ryortho.com

WRITERS

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

Senior Writer

elizabeth@ryortho.com

Walter Eisner

Senior Writer

walter@ryortho.com

Biloin W. Young

Senior Writer

bgwy@msn.com

ADVERTISING

Tom Bishow

Vice President of Sales

tom@ryortho.com

PRODUCTION

Suzanne Kirchner

Production Manager

suzanne@ryortho.com

Jayne Johnson

Email, Web & Subscription Coordinator

jayne@ryortho.com

Dana Bader

Graphic Designer

dana@ryortho.com

116 Ivywood Lane • Wayne, PA 19087

TOLL FREE: 1-888-749-2153

www.ryortho.com

