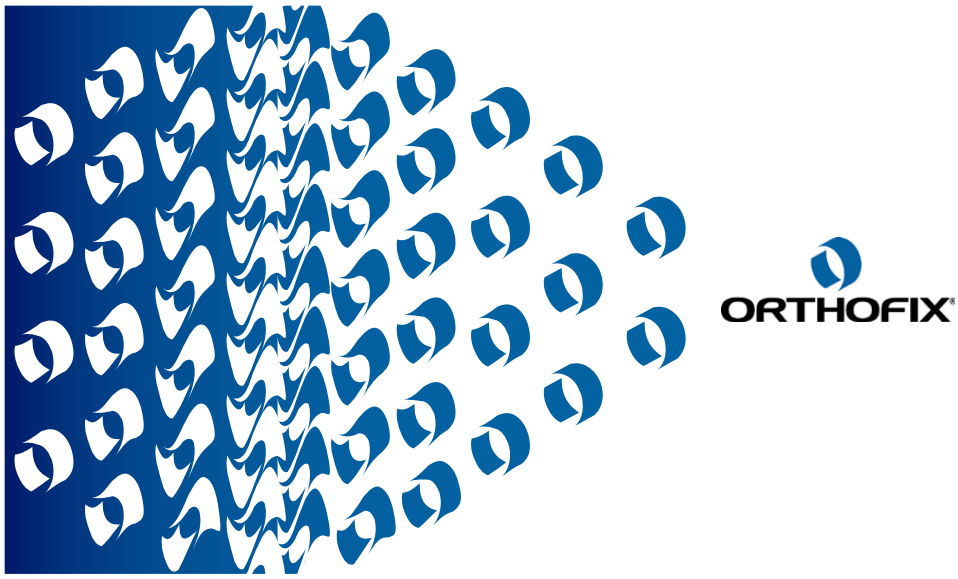
VOLUME 11, ISSUE 12 | APRIL 14, 2015

Orthopedics This Week

WEEK IN REVIEW



BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: More than 31,000 people attended AAOS this year, up almost 10% from last year's 28,000. We thought it looked more crowded and the numbers bear that out. More papers were presented this year (915 vs 825 in 2014). And physicians from 126 countries—excluding Canada and the U.S.—attended. If those aren't the signs of a healthy orthopedic community, we don't know what is.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Integra LifeSciences	12.57%	4.31%	The spin-off of SeaSpine, greater operational focus and, still, the lowest valuation in ortho equals #1 in the PR.
2	2	Exactech	10.44	16.23	Investors gravitating to smaller market cap ortho companies. EXAC offers value plus a particularly attractive shoulder franchise.
3	8	Orthofix	7.46	12.85	This is the Brad Mason we were expecting. He has OFIX on track and ready to move. Up big time this week.
4	5	Stryker	11.52	3.63	Are investors looking past Stryker? SYK has become so cheap, it is now the 2nd least expensive equity in ortho.
5	6	Medtronic	28.84	2.47	Under Doug King, Medtronic Spine gets expanded indications for key products like Vertex and grows (!) BMP sales.
6	7	Zimmer	29.12	1.05	It's been a slow motion courtship and rehearsal dinner with Biomet. Marriage is imminent. Will there be a honeymoon?
7	10	Johnson & Johnson	28.44	3.80	Signs exclusive deal with Radlink for real-time image guidance for hip replacement cases—2nd visualization purchase in two months.
8	3	MicroPort Scientific	16.53	20.99	Literally overnight, MicroPort got expensive. Up 21% in one month. Strategically, still one of the most intriguing ortho companies.
9	4	ConMed	10.51	(2.34)	Investors looking for signs that the clean-up will also raise profit margins and sales growth rates.
10	9	Alphatec	0.33	(4.67)	The key to Alphatec is earnings and cash flow. That's exactly where management is heading, but investors still on the sidelines.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MicroPort Scientific	853	$0.56	$793	20.99%
2	Exactech	EXAC	$25.78	$359	16.23%
3	K2M Group Holdings	KTWO	$23.12	$915	15.89%
4	Orthofix	OFIX	$37.32	$700	12.85%
5	MiMedx Group	MDXG	$10.89	$1,156	11.58%
6	Globus Medical	GMED	$25.28	$2,394	7.48%
7	RTI Biologics Inc.	RTIX	$5.60	$320	6.06%
8	Bacterin Intl Holdings	BONE	$3.92	$26	5.95%
9	Smith & Nephew	SNN	$34.98	$15,665	4.61%
10	Integra LifeSciences	IART	$61.71	$2,023	4.31%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Aurora Spine	ASG	$0.97	$19	-11.61%
2	Alphatec Holdings	ATEC	$1.43	$143	-4.67%
3	ConMed	CNMD	$49.28	$1,359	-2.34%
4	TiGenix	TIG.BR	$0.74	$119	-1.82%
5	Wright Medical	WMGI	$26.30	$1,351	-0.60%
6	NuVasive	NUVA	$44.76	$2,155	-0.58%
7	LDR Holding Corp.	LDRH	$37.99	$1,009	0.00%
8	CryoLife	CRY	$10.36	$292	0.29%
9	Zimmer Holdings	ZMH	$117.45	$19,967	1.05%
10	Medtronic	MDT	$77.93	$111,055	2.47%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$102.06	$283,784	17.09
2	Globus Medical	GMED	$25.28	$2,394	19.36
3	Medtronic	MDT	$77.93	$111,055	19.49
4	Zimmer Holdings	ZMH	$117.45	$19,967	20.12
5	Stryker	SYK	$93.74	$35,525	21.60

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MiMedx Group	MDXG	$10.89	$1,156	217.70
2	NuVasive	NUVA	$44.76	$2,155	107.34
3	RTI Biologics Inc.	RTIX	$5.60	$320	106.09
4	Orthofix	OFIX	$37.32	$700	93.74
5	CryoLife	CRY	$10.36	$292	47.97

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$25.28	$2,394	1.48
2	ConMed	CNMD	$49.28	$1,359	1.50
3	CryoLife	CRY	$10.36	$292	1.60
4	Medtronic	MDT	$77.93	$111,055	2.39
5	Integra LifeSciences	IART	$61.71	$2,023	2.40

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MiMedx Group	MDXG	$10.89	$1,156	14.51
2	NuVasive	NUVA	$44.76	$2,155	9.39
3	RTI Biologics Inc.	RTIX	$5.60	$320	7.07
4	Orthofix	OFIX	$37.32	$700	5.09
5	Smith & Nephew	SNN	$34.98	$15,665	4.60

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.43	$143	0.69
2	Bacterin Intl Holdings	BONE	$3.92	$26	0.74
3	RTI Biologics Inc.	RTIX	$5.60	$320	1.22
4	Exactech	EXAC	$25.78	$359	1.45
5	Orthofix	OFIX	$37.32	$700	1.71

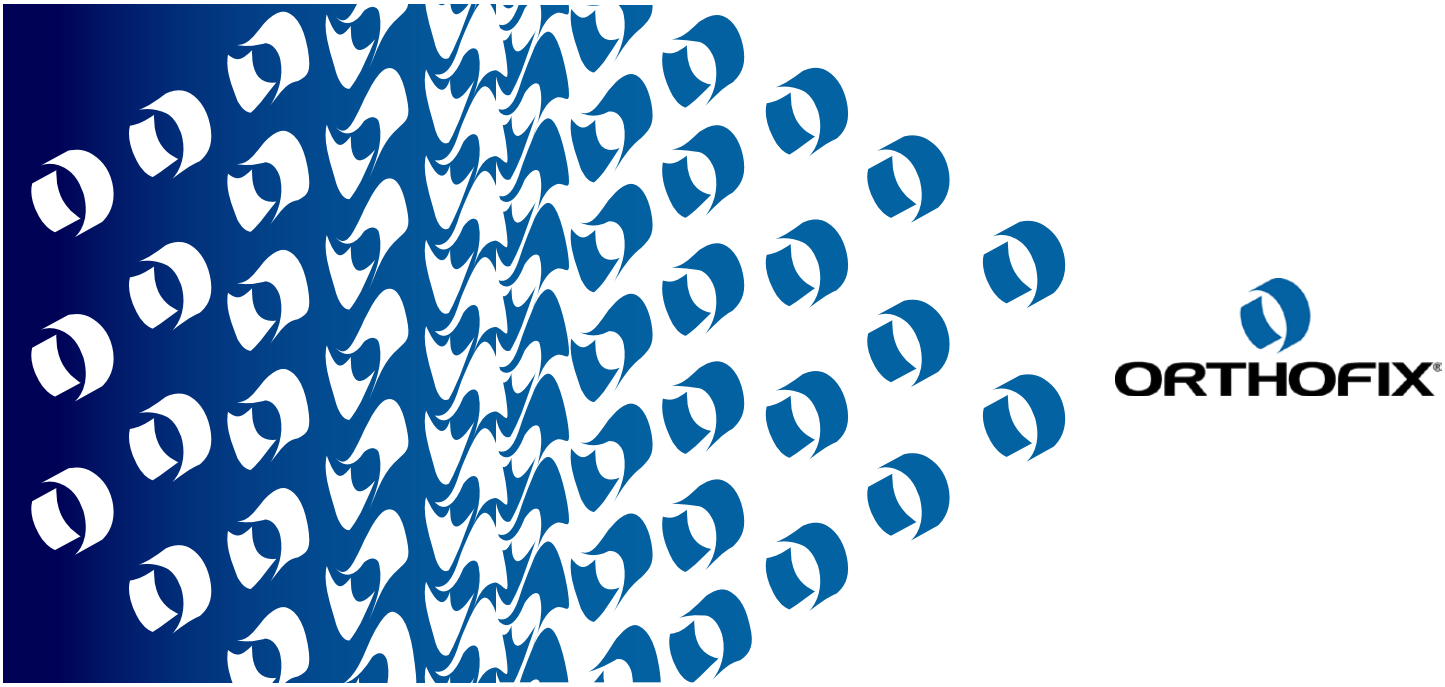
HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.74	$119	14.21
2	MiMedx Group	MDXG	$10.89	$1,156	9.78
3	LDR Holding Corp.	LDRH	$37.99	$1,009	7.54
4	Medtronic	MDT	$77.93	$111,055	6.34
5	K2M Group Holdings	KTWO	$23.12	$915	5.81

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

Orthofixed and Transformed?

BY WALTER EISNER



RRY Publications LLC, logo courtesy of Orthofix International N.V.

Orthofix International N.V. has finally lifted the financial veil that fell over the company when its new CEO, Brad Mason, informed his board in 2013 that financial reports dating back to 2011 couldn't be relied upon.

On March 31, 2015, the company filed their long awaited restated financial statements for fiscal years 2011, 2012 and 2013 and the fiscal quarter ended March 31, 2014. The company also filed 10-Qs for the quarters that ended on June 30, 2014 and September 30, 2014.

Orthofix has endured more perils than Pauline.

Dissident pirate shareholders tried to take over the board after the company acquired Blackstone Medical in 2006. Then, by association, they were dragged into a 2006 Blackstone kickback scandal in Arkansas. That was followed by rogue sales employees in the Northeast who paid providers to use the company's bone-stim devices, resulting in a major fine and corporate integrity agreement with the U.S. Department of Justice.

CEO Musical Chairs

This all happened while there was a game of musical chairs in the CEO's office following Charles Federico's retirement in 2006after a long tenure. In 2013, the board of directors asked Brad Mason to become the third CEO since Federico after bidding farewell to Bob Vaters. Alan Milinazzo, who succeeded Federico, was on the job five years. Vaters less than two years.

Mason knew the company well after having spent seven years at Orthofix managing first BREG, then Spine and finally all of Orthofix Americas. Then he retired, but the challenge to renew the company brought him back.

Mason Reorganizes

Mason moved quickly to reorganize the company into different operating units and brought in a new set of financial experts.

One person who worked with Mason wrote this assessment: "Brad has always had an uncanny ability to place right team members in the right place, sup-

Brad Mason/Orthofix Orthofix International N.V.

port them and then let them do their jobs. He hires people whose jobs will grow into their abilities rather than people whose jobs will outgrow them."

But the perils weren't over.

Accounting Weaknesses Discovered

Mason's new team determined that the company's previous financial controls didn't meet generally accepted accounting principles and investors could not rely on financial numbers reported all the way back to 2011. After one attempt at restating numbers, a second restatement had to be initiated.

The restated financials are still a couple of quarters short, but Mason told us during an April 3 interview that the company hopes to be current with financial reports to the Securities and Exchange Commission (SEC) by the end of April.

Mason said that the restatement had nothing to do with the issues of the past that led to their corporate integrity agreement and was instead solely related to technical accounting errors and weaknesses in their accounting controls.

Mason told us that about four months after becoming CEO, the company was closing the second quarter and found some things that "didn't look quite right." This led to Mason to ask the board's audit committee to do an independent investigation. They did and the company started the first restatement in 2013.

The company finished that first restatement at end of the first quarter of 2014. But as they were closing the books for the second quarter of 2014 they saw some technical errors, which were significant enough to trigger the second restatement.

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Mason said he believes the root causes of the second restatement issues were weaknesses in the company's internal control over financial reporting systems, which the company has been working to remediate. He said that if you look at the organization today, it has a new CFO and a substantially new finance support staff, including an outside consulting group that does internal audits. "The team that was there a few years ago has been replaced with a

highly experienced and talented team that has fresh eyes on everything."

Mason: "We're a Much Different Company"

"Our shareholders rely on the numbers we report. We have to get them right. Orthofix is a much different company today than it was when I came in as the CEO two years ago," he added.

For example, over the last 18 months, two-thirds of the board members are new, including Chairman Ron Matricaria, and the Chairman of the Audit Committee, Jim Hinrichs, who most recently was the CFO at CareFusion Corporation. Additionally, said Mason, well over half of the senior management positions have been replaced…"not for wrongdoing, but to drive the execution of the company's long-term strategy." Eleven out of 13 of Mason's senior team members are new in their roles at Orthofix.

Cultural Value

According to Mason, there is a culture at Orthofix today that "will not tolerate even the slightest breach of integrity. Integrity is the number one cultural value and is spoken about every day." In regard to the corporate integrity agreement with the government, Orthofix is in its third year of the five-year agreement and "everything is going very well."

Mason is hopeful the company will publish its 2014 full-year numbers sometime in April and at that time be able to discuss openly all topics and results in addition to a look into what the company sees ahead for itself.

Rebuilding Infrastructure and R&D

"What we have said in the past," continued Mason, "is that the current key strategies for the company are optimizing its sales channels worldwide, rebuilding its infrastructure and investing more in research and development."

For example, in the past 18 months each of the company's business units have been increasing their geographic sales coverage as well as improving sales and field education and training. The company has also developed a company-wide infrastructure process improvement initiative named "Bluecore," which has numerous work streams focused around implementing a new ERP [enterprise resource planning] system as well as process and control improvements in finance, order to cash and supply chain.

Betting on PEMF

Mason believes there has been too little investment over the years by the company in expanding some of its core product technologies, particularly in its PEMF (pulsed electromagnetic field therapy) technology, which is used in the company's bone growth stimulator products. The company is now doing some heavy investing there, as demonstrated by two recently approved IDE's (investigational device exemption) and a third one expected soon. The company also just announced acquiring an option to purchase eNeura, a company that uses PEMF to treat migraine headache.

While this might not intuitively be in Orthofix's "wheel house," Mason says the company has core competencies in the design and manufacturing of PEMF devices as well as third party reimbursement expertise that could be a significant driver of this business.

By the Numbers

How has the company been performing? Financials have now been published through the third quarter of 2014. Orthofix has always been a good cash flow company, said Mason. "Cash flow is a great indicator of the health of a company and the numbers show that Orthofix is financially in good health and the restatements have not adversely affected our performance to any significant degree."

The company also has a very strong balance sheet, no debt and lots of cash in the bank while continuing to create new cash every quarter. Additionally, its gross margins are improving and sales and marketing expenses decreasing. G&A (general and administrative) costs are high and Mason expects that to continue as they make the investments necessary to strengthen their infrastructure, processes and controls. Once that is complete, he expects those costs to drop.

Business Performance

The company now has four business units, up from the two that existed when Mason became CEO. He says each has their challenges and opportunities, but all are executing on their strategies and three of the four have very good momentum.

Mason said he split the business units to give both management and the shareholders better visibility into each unit. "When I arrived, it was very difficult to see what was really happening at the business unit level because of the way it was segmented. Some businesses with high margins were concealing the performance of businesses with lower margins. I want each business to stand on its own and be visible. If we have a business that isn't performing well, I don't want that to be hidden, I want to fix it," said Mason.

An example of this is the Spine Fixation business. The sales have dropped significantly in the last two years as the company intentionally restructured it for long-term profitability and success. According to Mason, he believes he was late in making the necessary changes, but says it is now structured for success going forward on both the top and bottom lines and given time, believes it will be a very good business for Orthofix.

On the other hand, Mason believes the other three business units, BioStim, Biologics and Extremity Fixation, are doing very well and executing the strategies that were developed in 2013.

Successful Transformation?

The story of Orthofix's transformation is now becoming clearer. Mason says he expects that the actions the company has taken over the last two years will continue to transform the company in the years to come and believes that all of its stakeholders will benefit from these efforts.

Have the Perils of Orthofix ended? Probably not, after all, they are in the spine business. But has Mason pulled the company off the tracks from the rush of the oncoming locomotive? By all appearances the answer is a solid "YES" and we'll see in the next set of financial reports as well as from a successful completion of the integrity agreement how far he and his team have come these past two years. ♦

Bisphosphonates: Discontinue After How Many Years? // Alert: Diabetics Nearly 19x More Likely to Experience Infection After ACL Surgery // PE Debris, Osteolytic Cysts, and Total Ankle Replacement

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

Pixabay

Bisphosphonates: Discontinue After How Many Years? Blanketing patients with bisphosphonates is increasingly being shown to be problematic, say researchers from the Warren Alpert Medical School of Brown University. "Atypical femur fractures are on the rise," says Travis Blood, M.D., a resident in orthopedic surgery at Brown. Along with Drs. Feller, Cohen, Born, and Hayda, Dr. Blood set out to see if there was a time limit that should be assigned to the use of bisphosphonates. He tells *OTW*, "We are seeing a vast increase in these low-energy fractures throughout the American health system. And, despite the lack of clarity as to the exact mechanism of these fractures, patients are routinely told to take bisphosphonates. For our study, we went through the current literature—47 studies—and found that bisphosphonates can help prevent fragility fractures in the spine, distal radius, and femoral neck. The problem is that no one has fully examined the long term side effects of these drugs, until recently."

"While there is no long term data showing exactly how long people should take bisphosphonates, we do know that problems are arising in these patients at the 8-10 year mark. There is no difference between men and women as far as side effects, but there is a higher prevalence of fractures in patients taking long term steroids."

"An atypical femur fracture usually occurs in older adults, and typically begins on the lateral cortex of the femur. This is thought to be due to an accumulation of small stress fractures that do not heal under bisphosphonate therapy. With the constant tensional forces pulling on the lateral side of the femur, these fractures propagate towards the medial cortex—and may actually cause a breakage of the medial cortex."

"We have been fixing complete atypical fractures with an intramedullary nail, but what is to be done about the contralateral side? If the patient has this kind of fracture and is on bisphosphonates then the treating physician must always obtain X-rays of the other side. If the patient is in pain, but the X-ray doesn't show a fracture, then you should get an MRI. Then, if the fracture *is* present on MRI and the person is in pain then we will fix it prophylactically. If a fracture appears on the MRI, but the person is not in pain then a trial of conserve treatment is recommended."

"Even though these are rare fractures the numbers are telling. One study (Shane et al., 2010) found that for those taking bisphosphonates for more than two years the fracture rate was 2 per 100,000 patient-years; as it increased to eight years of bisphosphonate use that number jumped to 78 per 100,000. Another study (Dell et al., 2012) found

that at the eight-year mark the fracture rate increased to 113 per 100,000."

"One option is to stop prescribing these drugs, but with the proven benefit in reduction of fragility fractures it is better that we develop a system to monitor the medication side effects. We could also shorten the timeframe that patients use bisphosphonates. Ideally, researchers would do a study where patients stop the drug and give the body a chance to recover then restart them in an attempt to prevent the long term complications. Perhaps then patients who halted use of these drugs continue taking calcium and vitamin D and get DEXA scans to monitor bone quality. There is still a lot we don't know."

Alert: Diabetics Nearly 19 Times More Likely to Experience Infection After ACL Surgery Any new information on hazardous postop infections can potentially save lives. Now, researchers from the MOON Group (Multicenter Orthopaedics Outcomes Network) have answered a significant question regarding infection: Does diabetes increase the risk of infection after anterior cruciate ligament reconstruction (ACLR)? Kurt Spindler, M.D., an orthopedic surgeon at Cleveland Clinic's Department of Orthopaedic Surgery and Cleveland Clinic Sports Health, tells *OTW*, "It's actually been challenging to identify risk factors in those who undergo ACLR because of the low rates of infection. Diabetes, on the other hand, is increasingly rapidly. My colleagues and I examined data from the MOON cohort from 2002-2005 and identified patients with postoperative infections. We looked at age, body mass index, smoking status, history of diabetes, and graft choice for each patient."

"While we suspected that diabetics are at increased risk as compared to non-diabetics, it was surprising to find that patients with diabetes were 18.8 times more likely to have an infection after undergoing ACLR."

"We also found that use of bone-tendon-bone autograft is associated with lower risk of infection after ACLR, while patient age, BMI [body mass index], and smoking status are not associated with infection risk in these patients."

"Orthopedic surgeons should be extra careful with diabetic patients: meticulous with your surgical technique, timely with the preoperative antibiotics, and thorough when it comes to postoperative wound management. And by all means, counsel patients regarding their increased risk and the importance of controlling their glucose levels."

Poly Debris in Osteolytic Cysts in TAR? While the role of polyethylene (PE) debris in total hip surgery has been thoroughly studied, its role in total ankle replacement (TAR) is unclear. Murray J. Penner, M.D. of St. Paul's Hospital at the University of British Columbia, tells *OTW,* "This is definitely the most important issue facing the advancement of TAR as a viable treatment solution for ankle arthritis. To this end, I undertook a retrospective review of 22 of my revision and re-operation TAR cases, specifically examining the histopathology retrieved from osteolytic lesions. We found evidence of PE in 10 cases and no PE in 12 cases; reports were unavailable for 4 cases."

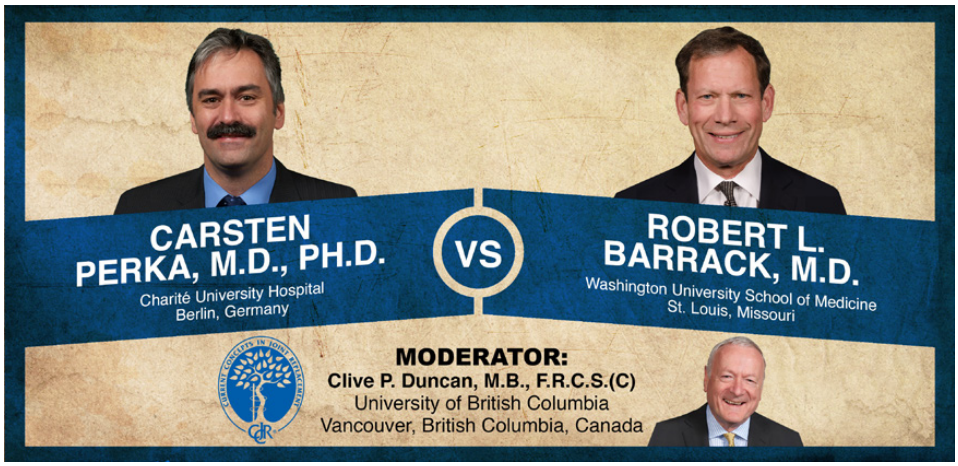
"The early onset of osteolysis in TAR, often within the first year, together with the minimal presence of PE debris found in retrieval specimens and the typical lack of visible bearing wear strongly suggest that the cause of osteolysis in TAR is complex and due to factors other than just PE wear debris. The factors may include bone injury, stress shielding, fluid pressure, and micro-motion. There may be an initial injury to bone from the preparation and implantation on the talus and we know that injury to talar bone is often associated with cystic change, as seen in talar osteochondral cystic lesions. Additionally, studies have demonstrated that the micromotion of TAR components at the time of implantation is typically significantly greater than what is acceptable for bony ingrowth. This is relevant since the hip and knee literature suggests that micromotion, along with fluid pressure at the bone-implant interface, may contribute to osteolysis. Finally, due to complex backside geometry of many TAR component designs, it is difficult to get broad surface contact across the entire bone-implant interface. This means there may be large areas that are not in good contact with bone, and these areas will therefore experience stress shielding. This may contribute to bone resorption since the bone is not being loaded. A specific patient's response to these potential initial and ongoing injuries to the bone-implant interface, mixed with stress shielding and fluid pressure may explain why osteolytic cysts occur in close to 20% of cases within the first year after surgery."

"We are now initiating a multicenter protocol to study the histology retrieved from an osteolytic cyst or revision total ankle. We absolutely need to solve this problem, but small numbers aren't going to cut it. Even a busy ankle replacement surgeon may do only 30 cases per year and substantially fewer revision cases. Preliminary data from our study should be hopefully within two years." ♦

Perka Debates Barrack Over Ceramic on Ceramic Hip

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

"Ceramic-ceramic is a good option for the young, active patient. It is wear resistant, has improved lubrication, and allows thin inserts for large heads," argues Carsten Perka. "Ceramic has long been on a steady decline," says Robert Barrack. "There are malposition issues (leading to impingement and potential for failure), liner breakage and mal-seating and squeaking. Why pay more for something that is not improved?



Current Concepts in Joint Replacement/RRY Photo Creation

This week's Orthopaedic Crossfire® debate was part of the 31st Annual CCJR — Winter meeting, which took place in Orlando this past December and is "Ceramic on Ceramic Hip Arthroplasty: A New Standard." For the proposition is Carsten Perka, M.D., Ph.D. of Charité University Hospital in Berlin, Germany. Robert L. Barrack, M.D. of Washington University School of Medicine in St. Louis is in opposition. Moderating is Clive P. Duncan, M.B., F.R.C.S.(C) of the University of British Columbia.

Dr. Perka: "The issue is that patients are more active and they are living longer. The registries show that the revision rate is up to 35% in younger patients at 13 to 15 years. This is because of aseptic loosening. The major reasons for revision hip arthroplasty are wear and osteolysis; this has stimulated interest in alternative bearings. The new polys are good, and appear to be a significant improvement…but they are not perfect. We have smaller, but more reactive particles; we are on our third generation in 10 years; there are free radicals, lipid absorption, and material degradation on the second generation after 5-7 years. And there are different failure modes, such as rim failure, scratching, abrasion, creep, surface damage, and impingement."

"In a 2014 poster presented at AAOS [American Academy of Orthopaedic Surgons] the researcher (Rowell) revealed that 12 out of 13 implants showed oxidation. Yes, volumetric wear is low, but this is only true for the 28-32mm heads. If you look at 36mm heads you see that in many cases the mean volumetric wear is above the limit where osteolysis occurs. We need other solutions."

"The criteria for an excellent bearing are low wear, optimal material properties of the surface, excellent clinical results, and robustness. Papers by Kurtz (2011) and Parvizi (2012) show that ceramic-ceramic has the lowest wear rate of all bearings. In addition, you must have optimal material properties. Ceramic-ceramic has excellent chemical stability, superior lubrication, excellent biocompatibility, it is scratch resistant, and it's a well proven technology (more than 10 million implantations). And what is increasingly important is that bigger heads don't increase the wear rate."

"Regarding long term survival, a study by Petsatodis had an 84.4% survival rate at 20.8 years. As far as very young patients (<20), Fishbone's 2012 study found no loosening, no osteolysis, no squeaking, and no fractures. In Byun's 2012 study in patients younger than 30, he found the same result after six years. A 2011 study by Mesko compared ceramic-ceramic to ceramic-poly and found that after 10 years the survivorship of the former bearing was better than the latter (96.8% compared to 92.1%)."

"Of course, there are some downsides, including noises and fractures. The causes of squeaking are not fully understood, but seem to involve component mal-positioning, stem design, cup design, edge loading, impingement, loss of lubrication, body mass index, leg shortening, and geography (New York!). To combat the problem you must have the right surgeon, the right implant, the right patient, and live in the right city."

"The rate of ceramic fracture is low. For Delta ceramics it's below 0.001%

for the head and 0.021% for the insert. As for my own data, we've had many more broken stems over the years than ceramic heads (one broken head and 21 broken stems)."

"So ceramic-ceramic is an attractive option for the young, active patient. It is wear resistant, has improved lubrication, and allows thin inserts for large heads."

Dr. Barrack: "There has been renewed enthusiasm for ceramic in the last 20 years, due to improved manufacturing, taper tolerances, higher strength, and lower wear. In the first decade of the 21st century there was a dramatic rise in alternative bearings, but this peaked about seven years ago and has been on a steady decline ever since."

"So in spite of these major improvements in material and design, thought leaders in the field expressed concerns about the new generation of ceramics. The concerns expressed a decade ago were: the incorporation of modularity, fracture and the consequences of fracture, inability to apply to a used taper, femoral head separation, and limited surgical options. But the two deal breakers—in my mind—were squeaking, and impingement."

"A proposed solution was Delta ceramic, which is a hybrid material. The purported advantages were higher strength (that would lead to fewer fractures), lower wear, more options for heads (but not liners), the ability to revise to a ceramic head (which was solved with the titanium sleeves), and better results as far as squeaking. The problem is that while it's true that it has higher strength and more options for heads, there is not lower wear and squeaking remains an issue."

"These modest material improvements don't begin to overcome the obstacles to adopting this technology. The healthcare environment will not pay more without proof of added value. Total hip design must account for variability in surgeon performance, and the current medical/legal environment is very unforgiving to unproven options. Also, most of the old issues have not been addressed."

"According to Michael Porter, the architect of value based purchasing, you must have outcome divided by

cost in order to add value. So you must either improve the outcome or lower the cost. The FDA trial (2010) found that the outcome with a Delta ceramic was the same, and the complication rate was higher because there were still fractures. A 2011 study from our center found that crosslinked liners have been done for nearly 15 years… and wear and osteolysis were virtually nonexistent at 10 years (even in young patients)."

"Metal-poly performs best in the registries, while ceramic does almost as well…but it's not better. And why pay more for something that is not improved? The most persistent problems are malposition leading to impingement and potential for failure, liner breakage and mal-seating, and squeaking. These hard on hard bearings do not tolerate component malposition; it rapidly accelerates the wear rate and the wear rates go up exponentially with increased anteversion or inclination. And even at major centers we're not very good at avoiding outliers."

"Breakage continues to be a problem, especially with liners. You have to get complete rim exposure and concentric placement and impaction of the liner. This makes ceramics difficult to use—and they are the least compatible with minimally invasive surgery. As we use smaller incisions it is hard to get the liners concentrically seated and impacted without chipping or breaking the liner. Even more concerning is mal-seating. Three consecutive studies show mal-seating in anywhere from 7.2%-17% of cases. This leads to metal debris and other potential problems."

"As for squeaking, a major study by Andrew Shimmin in Australia had 208 consecutive Delta ceramic total hip arthroplasties. Only 69% of these were silent. So in conclusion, the new generation of ceramics is better, but metal-crosslinked polyethylene has improved even more."

Moderator Duncan: "Carsten?"

Dr. Perka: "Ceramic-on-ceramic is a good idea, even if not for every patient. For younger, more active patients it is a good solution. Positioning of the implants and inserts needs more attention than with other designs, yes. But it's possible to prevent impingement with navigation and other things. We can expect better results in the long run."

Moderator Duncan: "Any place for ceramic-on-ceramic in your practice, Robert?"

Dr. Barrack: "I've not used ceramic, except on the femoral head side. The underlying assumption is that there is a second or third decade problem with metal-crosslinked or ceramic-crosslinked, but this is entirely theoretical. Our center was one of the first to start using crosslinked polyethylene (in 1999) and we've yet to see a case of lysis or revision based on wear—even in patients under 50."

Moderator Duncan: "So possibly one indication would be a patient who comes in with a fractured ceramic liner. Is it ceramic for life in that patient or can you revise it to a different bearing surface?"

Dr. Barrack: "When you have a hard-on-hard bearing with debris, using a metal head has a track record of a high incidence of third body wear and destroying a metal head."

Moderator Duncan: "And on the acetabular side, would the same apply to the polyethylene?"

Dr. Barrack: "That would be a serious consideration. If you can put these in and avoid impingement, well…It almost makes it a specialty center procedure because the big data sets show that the average surgeon misses the safe zone so frequently that you can't afford to put a hard-on-hard bearing in outside the safe zone."

Moderator Duncan: "Carsten, let's discuss when the femoral head breaks. Have the adaptors for the trunnion become so good that you don't have to change the stem?"

Dr. Perka: "It depends on the age and activity level of the patient. If there is rim damage of the taper then I would revise the stem. But if there is only a scratch then I would revise it with a titanium sleeve and a ceramic head."

Moderator Duncan: "Thank you, gentlemen." ◆

Please visit www.CCJR.com to register for the 2015 CCJR Spring Meeting, May 17 - 20 in Las Vegas, Nevada.

COMPANY

Biomet's Last Financial Report – Ready for Zimmer

Biomet, Inc. likely reported its last quarterly financials to investors as a stand-alone company on April 9, 2015.

Reported revenue was down 2.6% to $809 million for the quarter that ended on February 28, 2015. But that wasn't the important part of the story, says Wells Fargo analyst Larry Biegelsen.

Revenue Down - Margins and Cash Up

Biegelsen said the key takeaway from the quarter's results was Biomet's significant margin and cash flow improvement over the same period one year ago and that gives him more confidence that Zimmer Holdings Inc.'s earnings estimate is "attainable and could mean potential upside."

All product groups, except Spine and Bone healing showed reported revenue declines. Knees were down 2.8%, hips down 1.7% and Sports, Extremities and Trauma was down 3.4%. A strong U.S. dollar impacted revenue by 4%. Spine climbed 1.2% with the Lanx acquisition now fully included in reports.

Biomet 3Q 2015	Sales $ in million	% Change
Total Reported Sales	**$822.5**	**down 2.6**
Knees	254.2	down 2.8
Hips	162.9	down 1.7
Sports, Extremities, Trauma	169.0	down 3.4
Spine & Bone Healing	115.9	1.2
Dental	64.4	down 5.7
Biologics and Other	56.1	down 6.7

Source: Biomet, Inc.

Wikimedia.org and RRY Publications LLC

Binder's $45 Million Payday

With European and Japanese approvals for the merger with Zimmer now granted, the new ZimmerBiomet combination is expected to be approved by U.S. regulators any day now. It will reportedly be a nice payday for Biomet CEO Jeff Binder. Binder, according to a November 21, 2014 AP report, will make $45 million. Nearly all the pay is in stock awards that he would have had to wait years to receive if the company wasn't sold.

Recon Market Steady

Analysts are always reading the tea leaves of Biomet's reports because they are the first big ortho company to report sales.

Joanne Wuensch of BMO Capital Markets estimates that based on Biomet's results, the knee market increased 2.5% in the first three months of 2015 with Biomet losing a bit of market share to 13.8% from 14.2% year-over-year. She also estimates the hip market increased 2.4%, Biomet losing 0.1% share.

Biegelsen said his information suggest that the reconstructive market is stable and expects market growth in 2015 to be similar to 2014's 3.3%. He added that he sees Biomet's results as consistent with recent market results that show growth in the U.S. market, but international markets remain challenged.

Biomet's growth slowed from the prior quarter in all of its three geographic regions and in four of its six product categories, said Mike Matson of Needham & Company. "While Biomet's recon growth was stable with the prior quarter, we suspect that it was slower than market growth and that Biomet lost share in knees and maybe hips as well possibly due to disruption ahead of its merger with Zimmer.

Johnson & Johnson's DePuy Synthes will be the next orthopedic company to report on April 14.

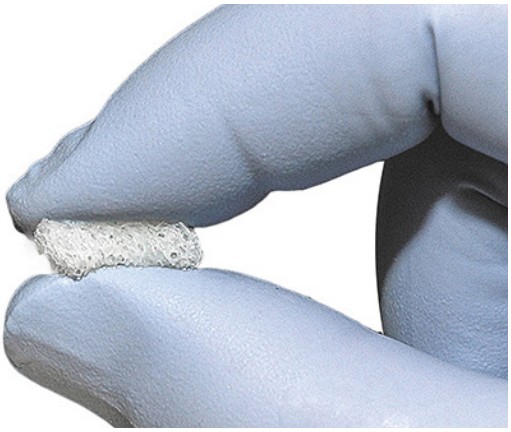
Dane's Smilin'

So the company that Dane Miller built will leave the orthopedic playing field as a stand-alone company just as Miller passed away. He must be smiling as most of his old employees will likely get to remain in their beloved home town.

Good night Dane. Good night Biomet. — *WE*

Bacterin Gets Patent for OsteoSponge

Bacterin International Holdings, Inc. has been issued U.S. Patent No. 8,992,964 by the U.S. Patent and Trademark Office for its OsteoSponge human demineralized cancellous bone product.



OsteoSponge/Bacterin International Holdings, Inc.

According to an April 6, 2015 company announcement, the patent entitled, "Process for Demineralization of Bone Matrix with Preservation of Natural Growth Factors," includes claims that cover "certain demineralized bone matrixes containing minimum levels of bone morphogenetic protein-2 (BMP-2)."

These claims are included in the company's OsteoSponge product line. The company says it also has pending continuing applications in the U.S. to pursue protection on other aspects of its bone demineralization technology.

The OsteoSponge technology allows for the allograft comprised of human bone to become compressible, while, claims the company, "maintaining the spectrum of native growth factors inherent to bone."

The company further claims that this unique combination of properties has allowed clinical investigators to show fusion rates greater than 97% in peer-reviewed, published studies. Bacterin claims to be the first company to commercialize a compressible demineralized bone matrix (DBM) sponge marketed specifically for its handling characteristics, osteoconductive architecture, and osteoinductive properties for orthopedic bone grafting applications.

OsteoSponge is a form of DBM made from 100% bone and provides a natural scaffold for cellular ingrowth and exposes bone-growth-inducing proteins to the healing environment. According to the company, the "malleable properties" of the product enable it to fill and conform to irregular bony defects. "Due to its shape memory characteristics, OsteoSponge will expand to completely fill a void after graft placement. The unique mechanical and biological properties make OsteoSponge an ideal bone graft for use with spinal fusion devices, in arthrodesis, or in fracture sites."

Bacterin develops, manufactures and markets biologics products to domestic and international markets. These products, according to the company, are used in a variety of applications including "enhancing fusion in spine surgery, relief of back pain, promotion of bone growth in foot and ankle surgery, promotion of cranial healing following neurosurgery and subchondral repair in knee and other joint surgeries." — *WE*

Benvenue Medical Signs Kiva Agreement With Novation

Benvenue Medical, Inc. has announced that it has signed a group purchasing agreement for the Kiva VCF Treatment System with Novation. The three-year contract means that the Kiva System can be offered to the more than 100,000 members and affiliates of VHA Inc., UHC, Children's Hospital Association and Provista served by Novation.

The Kiva System is indicated for the reduction and treatment of spine fractures in the thoracic and/or lumbar spine from T6-L5. According to the March 30, 2015 news release, Kiva was selected through the Novation Innovative Technology program, which is designed to ensure that members have access to innovative health care technology. The rigorous process includes review by a clinical member council or task force to determine whether the technology represents incremental advantage for members. The Kiva System is the first clinically proven new approach to the treatment of vertebral compression fractures (VCFs) in over a decade.

"We are committed to providing the health care facilities we serve new technologies that are clinically validated and cost-effective," said Olya Carter, RN and Senior Clinical Manager at Novation, in the March 30, 2015 news release. "The decision to offer the Kiva System was based on compelling treatment effectiveness data from multiple clinical studies."

"Kiva has met the high bar set by the Novation Innovative Technology program by providing improved patient outcomes and a reduction in the economic burden to the healthcare system, compared with balloon kyphoplasty," said Benvenue CEO Robert Weigle. "We are pleased to offer Kiva through the Novation portfolio, which serves nearly half of all surgeries performed in the U.S."

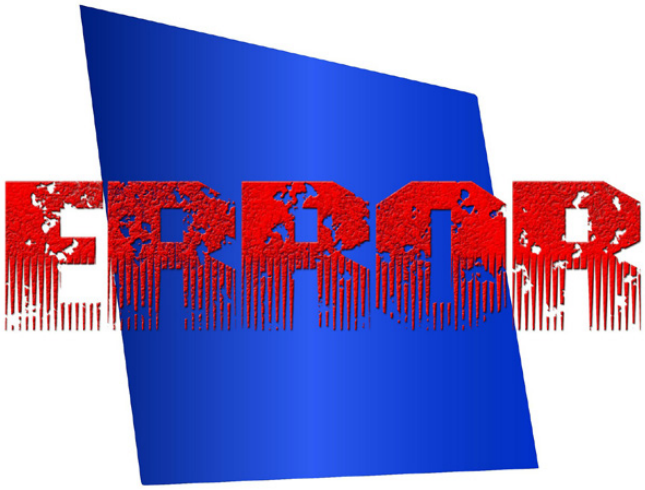
According to the company Kiva has been demonstrated in at least three comparative studies with a total of more than 500 patients, to meet or exceed the performance of balloon kyphoplasty.

Weigle told *OTW*, "Our new relationship with Novation opens so many doors for Kiva, and the Innovative Technology Program validated that Kiva is a new option to treat VCFs which presents advantages for Novation's members. We are confident that Kiva will live up to these expectations throughout our three-year contract and beyond." — *EH*

Benvenue Medical, Inc.

LEGAL

Made in China, Not U.S. – Medtronic Settles False Claims Charges



Pixabay.com

Dublin-based Medtronic plc has agreed to pay the U.S. government $4.4 million to settle charges that the company deliberately brought spinal surgery devices in from China, relabeled them "Manufactured in Memphis, Tennessee," and then sold them to the government for use in U.S. soldiers and veterans.

In an April 2, 2015 Department of Justice (DoJ) press release, the government said the agreement settled allegations that the company violated the False Claims Act by "making false statements to the U.S. Department of Veterans Affairs (VA) and the U.S. Department of Defense (DoD) regarding the country of origin of certain Medtronic products."

The government also said the claims resolved by the settlement are only allegations and no determination of liability had been reached.

Medtronic Implicates Third-Party Suppliers

The *Star Tribune* of Minnesota reported on April 2, 2015 that Medtronic spokeswoman Cindy Resman said that although the company has since improved its country-of-origin dis-

closures in government contracts, it "makes no admission that any of its activities were improper or unlawful."

Made in China and Malaysia

The settlement focused on "a limited number of accessories and surgical instruments used in spinal surgeries that were provided to Medtronic by third-party suppliers and were manufactured in China or Malaysia. The overwhelming majority of Medtronic's products are manufactured in the United States or its trading partners, such as Mexico or Ireland," she said in an e-mail to the newspaper.

"Domestic manufacture is a required component of many military and Veterans Administration contracts," said U.S. Attorney Andrew M. Luger of the District of Minnesota. "Congress has mandated that the United States use its purchasing power to buy goods made in the United States or in designated countries. We take that mandate seriously and will not hesitate to take appropriate legal action to ensure compliance."

According to the settlement agreement, between 2007 and 2014, Medtronic sold the VA and DoD products it certified would be made in the U.S. or other designated countries. The requirement is part of the Trade Agreements Act of 1979 (TAA). The government alleged that Medtronic sold the VA and DoD products manufactured in China and Malaysia, which are prohibited countries under the TAA.

The specific Medtronic products at issue included anchoring sleeves sold with cardiac leads and used to secure the leads to patients, certain instruments and devices used in spine surgeries, and a handheld patient assistant used with a wireless cardiac device. The agreement covers the period from January 1, 2007 to December 31, 2013, and for one device (the handheld patient assistant), the period from January 1, 2014 to September 30, 2014.

Medtronic In Settlement Mode

The country of origin settlement, according to the *Tribune*, is the third federal lawsuit Medtronic has settled with DoJ since moving its headquarters to Dublin, Ireland, in late January.

On February 5, 2015, according to the *Tribune*, Medtronic subsidiary ev3 Inc. agreed to pay $1.25 million to settle allegations that its corporate predecessor, Fox Hollow Technologies Inc., encouraged 12 hospitals to overbill Medicare for atherectomy procedures. On February 6, 2015, the company agreed to pay $2.8 million to settle claims that it caused "dozens" of doctors to bill Medicare for investigational neurostimulation procedures that were not reimbursable.

Whistleblowers Strike Again

The most recent settlement resolves allegations originally brought in a lawsuit filed by three whistleblowers under the qui tam provisions of the False Claims Act. The relators will receive a total of $749,700 of the recovered funds.

The underlying case is *United States of America ex rel. Samuel Adam Cox, III, Meayna Phanthavong, and Sonia Adams v. Medtronic, Inc., Medtronic USA, Inc., and Medtronic Sofamor Danek USA, Inc., Civil No. 12-cv-2562 (PAM/JSM)*. Cox, according to the *Tribune*, was the same whistleblower who made similar allegations against London-based Smith & Nephew. That case was resolved in September 2014, with an $11.3 million settlement. Smith & Nephew also denied any wrongdoing. — *WE*

Prosecutors Increasing Medical Device Industry Scrutiny

Scales of Justice / Source: Pixabay.com

Three U.S. Attorneys recently told a group of compliance officers that they are placing an increased emphasis on medical device manufacturer misconduct.

Increased Emphasis and Coordination

The prosecutors from California, New Jersey and Tennessee, according to Tom Sullivan of *Policy and Medicine*, said the reasons for the uptick are that there are a number of areas of the country where prosecutors had not given such cases a high priority. Ben Wagner of the Eastern District of California said that his office is just getting through a lot of mortgage fraud cases from a few years ago. White collar prosecutors will be looking for new cases. He also noted that better coordination between the FBI, HHS (Department of Health and Human Services), and other agencies have allowed for more streamlined enforcement.

Whistleblowers Up Their Games

Elizabeth Tonkin of the Eastern District of Tennessee said that as qui tam whistleblower cases have been successfully settled, more whistleblower cases are coming to her office and she has an obligation to investigate them. She says a lot of qui tam relators have done their homework.

More Misconduct

Jacob Elberg of New Jersey told the compliance officers that based on the cases he and other prosecutors are see-

ing, they "continue to have the feeling that there is more misconduct that isn't being addressed." The medical device industry breeds a "whole range of misconduct," he noted, including improper payments, kickbacks, and off-label activity. Sullivan wrote that Elberg believes that prosecuting such behavior is important for the companies that are doing the right thing. "It's only fair" to scrutinize smaller companies that might profit by not following the rules the larger companies have been bound to for quite some time. Sales reps, for example, shouldn't have to lose out on business to other reps that rely on kickbacks to sell their devices. Elberg wants companies that follow the rules to know that Department of Justice (DOJ) is always interested in tips about such misconduct.

Docs Not Spared

When the prosecutors were asked why they only seem to go after the companies and not the surgeons, Sullivan said that Elberg "took issue with" that and said his office has convicted more than 60 doctors over the last few years, many related to kickbacks in the laboratory referral setting. Elberg told the audience that if a doctor is refusing to do business without a kickback payment side deal, companies should proactively bring it to the attention of the DOJ.

The prosecutors said they would love to know about physicians who are insisting on bribes. They agreed that such physicians, as well as those that reprocess single use-devices without following FDA protocol, or that import cheaper, non-FDA approved devices, are hurting med device companies.

They also pointed out, according to Sullivan, that it takes longer to prosecute physicians under a criminal statute. Arguing over what is "medically unnecessary" in front of a jury is a tough litigation challenge. But, said Tonkin, the government has the ability to assess penalties directly against physicians who are accused of kickbacks, without the physician being prosecuted separately.

The Open Payments and Medicare payments data streams are also new tools that allow prosecutors to track situations where doctors are implanting medical devices of a certain type where the area's demographics don't seem to support that level of use. They said they are getting better at tracking the needle in the haystack.

Device Company Compliance Expectations

When asked whether or not the government would also go after the device companies that sold the doctors the implants, the prosecutors said that companies should already be monitoring their customers for doctors who purchase and/or utilize a high number of devices—both from a business perspective and a risk-management perspective regarding off-label use. To avoid liability, Elberg said the government is going to expect the company to start asking questions about outlier implant use. To say the doctor was asking for a lot of product and we're a for-profit company, isn't going to fly with prosecutors.

The take-away message from the prosecutors to the compliance officers seemed to be that if your company is doing things right and you have competitors who are competing unfairly, go to the DOJ and sign them up as your new partner. — *WE*

LARGE JOINTS

Zimmer Recalls 11,658 Persona Knee Parts

Zimmer Holdings Inc. has recalled 11,658 parts used in its Persona Trabecular Metal Tibial Plate/Persona TM Tibia knee implant systems.

FDA Recall Notice/FDA

According to the Food and Drug Administration (FDA), Zimmer is initiating the voluntary global recall following an increase in complaints of "radiolucent lines and loosening." All sizes and lots of the affected devices are being removed from distribution. In the U.S., the part was distributed to a number of VA Medical Centers in states including South Dakota, Georgia, Alabama, Massachusetts, New York, Ohio, Indiana, Pennsylvania, Missouri and California.

It's a Class II recall, which means the FDA believes the product can "cause temporary or medically reversible adverse health consequences."

Problems associated with this implant can cause serious complications and patients can face the risk of loosening of their tibial component. Indications of loosening include radiolucent lines on imaging tests, which are large gaps between the device and bone. Loosening can cause pain and significant mobility problems, and can require the patient to undergo additional surgery

to remove and replace the loose tibial component.

Urgent Medical Device Recall notices were issued to affected distributors, hospitals, and surgeons on February 16, 2015 via mail. Customers were asked to review the notification and ensure affected personnel are aware of the contents. All affected product are to be located and quarantined immediately. The Inventory Return Certification Form should be completed and returned along with the recalled product. Customers may contact the following with any questions: 1-877-946-2761 between 8:00 am and 5:00pm EST.

The FDA Notice can be read here: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=133978

Introduced in 2013

Zimmer introduced, "Persona - The Personalized Knee System", at the 2013 American Academy of Orthopaedic Surgeons annual meeting. The company said the new system "ushers in a new era in total knee replacement, combining personalized implants with intelligent instrumentation to provide surgeons with a new level of intraoperative precision to customize the best fit for their patients. — *WE*

Six-Point Scale Predicts Joint Replacement Outcomes

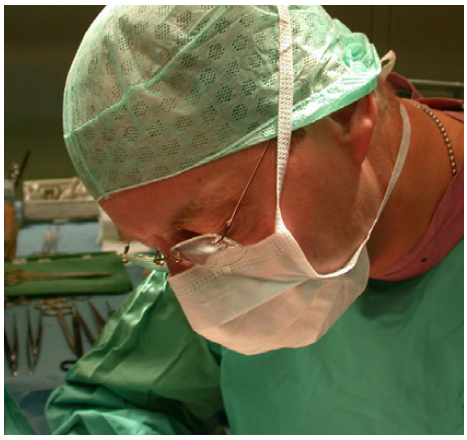
Who is at risk for complications following joint replacement surgery and which patients will sail smoothly through the process without incident? Researchers at the Perelman School of Medicine at the University of Pennsylvania conducted two tests to find out.

In the first test, investigators examined the cases of 1,012 patients who underwent primary total hip and knee replacement surgery over a 10-month period. They found that 70 patients had developed serious complications, most of which were cardiopulmonary in nature, including pulmonary embolism and cardiac arrhythmia. Of these, 11 suffered setbacks within 24 hours of their surgery, and 59 experienced complications just 24 hours later.

Doctors realized that if these 59 patients who experienced compilations had undergone same-day or short-stay surgery, and had been recovering at home when the complications occurred, they would have been at serious risk of injury.

As a result of the findings, the Penn team developed the six-point scale to determine a patient's candidacy for same-day or short-stay total joint replacement. Patients without a history of chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease, or cirrhosis have only a 3.1% probability of developing late, serious complications following joint replacement surgery.

However, patients with just one risk factor have nearly a 10% risk of complication, a risk that is compounded by the addition of other risk factors. Thus, patients with even one of these risk factors should not undergo outpatient or overnight total hip and total knee replacement. Instead they should be admitted to the hospital for traditional-duration surgery and recovery.



Wikimedia Commons and Dschwen

In the second study doctors examined 738 patients who had undergone total hip and knee replacement and found that patients who required admission to intensive or critical care units after surgery were likely to have a history of chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease, chronic kidney disease, or suffering blood loss of more than 1,000 milliliters during surgery or requiring vasopressors during surgery.

Based on the findings, the investigators developed a weighted Penn Arthroplasty Risk Score to predict which patients would require intensive or critical care intervention after knee or hip replacement.

Gwo-Chin Lee, M.D., senior investigator on both studies and an assistant professor of orthopedic surgery said, "Total joint replacements are very common procedures, but they can also pose significant health risks to certain populations, such as seniors. These two studies have provided us with better, more systematic and accurate ways of predicting before and after surgery, which patients are at greater risk for complications, allowing us to more accurately assess their conditions, and determine the appropriate course of treatment, care, and rehabilitation."

He added, "Given the increased national emphasis on quality metrics and the need to ensure patients recover well following joint replacements, there is a need to better identify and predict post-operative complications so we can intervene and provide timely follow-up care," — *BY*

Joint Replacement Surgery Easier on Women

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New research from Canada, reported in *Arthritis Digest*, reveals that women have fewer complications than do men after knee and hip replacements. Men also face higher odds than women that they will need revision surgery in a Canadian hospital.

Researchers looked at eight years of records for 37,881 total hip replacements of which 53.8% were female and 59,564 total knee replacements, of which 60.5% were female. Women who had hip replacements were significantly older than were the men—70 years versus 65 years—but the average age for both sexes for knee replacement was 68 years. Many of the women who went in for joint replacements were described as being frail.

Following the surgery, men were 15% more likely than women to return to the hospital's emergency department within 30 days of their joint replacement surgery. Men were also from 60% to 70% more likely to have a heart attack within three months of receiving a joint replacement. Men were also 50% more likely to require a revision arthroplasty within two years of receiving their total knee replacement.

Lead study author Bheeshna Ravi, M.D., said, "In this study, we found that while overall rates of serious complications were low for both groups, they were lower for women than for men for both hip and knee replacement, particularly the latter." — *BY*

Pain Killer Offers Cost Savings, Patient Comfort

In a study of 2,248 hip and knee replacement patients, those treated with the pain killer Exparel (bupivacaine liposome injectable suspension) reported significantly lower pain scores. According to the manufacturer, Pacira Pharmaceuticals, Inc., in a presentation at the annual meeting of the American Academy of Orthopaedic Surgeons (AAOS), patients treated with Exparel were more likely to report having "zero pain" during their hospital stay and were associated with lower hospital costs.

More than 1.1 million joint replacements are performed annually in the U.S. and post surgical pain is usually managed with regional nerve blocks and systemic opioids. In this study half of the patients received periarticular injections (PAI) with bupivacaine HCl, with or without ketorolac, and morphine, while the other half received PAI with Exparel.

The primary outcomes measured were Visual Analog Scale (VAS) pain scores and the percent of VAS pain scores that were zero, meaning patients reported "no pain." In addition researchers compared length of stay, patient-reported satisfaction and per patient costs for supplies and pharmaceuticals between the two treatment groups.

The researchers found average cost savings of $1,246 per patient, which resulted in an overall hospital savings of over $1.5 million, predominately attributed to eliminating the need for femoral nerve catheters, knee immobilizers, and patient controlled analgesia pumps to deliver IV opioids.

John Barrington, M.D., orthopedic surgeon at Texas Center for Joint Replacement in Plano, Texas, said, "Getting patients on their feet and moving is critical to optimizing long-term treatment outcomes after hip or knee surgery, and the ability to provide a single-dose long-lasting alternative to opioids and catheter-based regional nerve blocks—which can negatively impact ambulation and the patient recovery experience—is a major advantage for orthopedic patients. Our analysis found that the use of Exparel can improve both pain control and patient satisfaction, while resulting in a meaningful cost savings per patient." — *BY*

Wikimedia Commons and Dave Haygarth

SPINE

Avoid Acetaminophen? New Study Questions Effectiveness, Safety

New research from Australia has found that paracetamol (acetaminophen) doesn't work when it comes to reducing pain, disability or improving quality of life for patients with low back pain or osteoarthritis of the hip or knee. This study, a review of 13 randomized controlled trials, also found that acetaminophen may cause problems for the liver.

Wikimedia Commons and Michelle Tribe

According to the study, just published in the *British Medical Journal*, paracetamol is no better at treating low back pain than a placebo. Lead author, Gustavo Machado—of The George Institute and the University of Sydney—says the results of this systematic review provide cause to review guidelines that endorse paracetamol for back pain and osteoarthritis.

"Use of paracetamol for low back pain and osteoarthritis was also shown to be

associated with higher risk of liver toxicity in patients," said Machado in the March 31, 2015 news release. "Patients were nearly four times more likely to have abnormal results on liver function tests compared to those taking placebo pills."

Senior author Associate Professor Manuela Ferreira of the George Institute for Global Health and the University of Sydney said, "…For example, last year The George Institute showed that paracetamol does not speed recovery or reduce pain for acute low back pain." "This latest research, the most comprehensive systematic review of its kind, reaffirms this with an even larger, global patient base, and has for the first time also established that the effects of paracetamol for knee and hip osteoarthritis are too small to be of clinical importance."

Machado told *OTW,* "Low back pain and lower limb osteoarthritis are the major causes of disability worldwide and paracetamol is commonly prescribed for these conditions. In addition, paracetamol is the most used over-the-counter medication to treat back pain and osteoarthritis. Our study revealed that paracetamol is ineffective for patients with low back pain and only provides small benefits for osteoarthritis in terms of pain reduction and improvement of function. These results were quite surprising considering that clinical guidelines often recommend paracetamol as the first line analgesic medication based on the view that it is a safe, effective and a cheap medicine."

"We believe that our results provide a strong argument to reconsider the endorsement of paracetamol in clinical guidelines of back pain and osteoarthritis. Future research therefore should focus on the effects of this medication in other disabling conditions." — *EH*

Spinal Implants Set Off Airport Alarms

Airport security alarms went off when children who had cobalt chrome spinal fusion implants in their backs tried to go through security. Twenty-four percent of 50 pediatric spinal fusion patients set off TSA metal detector alarms, according to Regina P. Woon, MPH ,of Children's' Hospital in Los Angeles who reported on the events at the 2015 annual meeting of the American Academy of Orthopaedic Surgeons (AAOS) in Las Vegas. None of those with stainless steel implants triggered alarms, she said.

Sarah Wallan, staff writer for *MedPage Today*, reported that the children who set off the alarms in a U.S. airport ranged in ages from 4 to 22. Their average age when they had their surgery was 14. All of the youth underwent spinal surgery between 2004 and 2013.

Wallan reports that out of 28 patients with cobalt chrome rod in their backs, 18% set off the archway metal detectors, and 17% triggered full-body scanner alarms.

Previous research, reported by Wallan, found that roughly half of all orthopedic implants set off metal detectors in airport settings. When compared with stainless steel, cobalt chrome and titanium implants were believed to be more likely to trigger the alarm. However, other researchers report that t titanium did not set off any alarms at walk-through airport metal detectors. — *BY*

Wikimedia Commons and Terence

SPORTS MEDICINE

ACL Failure Rates in Young Athletes: Autograft Outshines Allograft

New research from Canada has found that when it comes to anterior cruciate ligament (ACL) repair in younger athletes, those patients receiving their own tissue fare MUCH better. The study, published online in *Sports Health: A Multidisciplinary Approach*, utilized a systematic review of 1,016 young, very active patients to compare ACL failure rates using allograft versus autograft tissues.

"This is the first review to examine young, active patients and how they perform following an ACL surgery using allografts (tissue from a cadaver) or autografts (patient's own tissue). In our analysis, the pooled failure rate for autografts was 9.6% and 25% for allografts," said lead author, David Wasserstein, M.D., M.Sc., FRCSC from the University of Toronto, in the March 31, 2015 news release.

Asked about those surgeons who still use allografts, Dr. Wasserstein told *OTW,* "I think we should clarify that there are still indications for the use of allograft in primary ACL reconstruction, however, this study showed that when used in young and highly active patients, they are being asked to assume an unacceptable level of risk for failure. There may be 'holdouts' for the use of allograft in this patient population for two main reasons—some surgeons may not be aware of this data, and allograft does have some practical advantages. With allograft there is less initial recovery time for the patient, and for the surgeon there is shorter operative time."

As for how this work is being received, Dr. Wasserstein noted, "In my own practice, and among the MOON (Multicenter Orthopaedic Outcomes Network) knee group (the group of surgeons that produced some of the initial data warning about this risk) this is actually old news. Readers should have a look at the article by Kaeding et al. in *Sports Health* (2011) and *AJSM* (2015). I am not entirely sure how the rest of the community perceives this topic, but hopefully folks will listen to the message. Some may hold on to the notion that not all allografts are equal (i.e., fresh frozen or minimally treated grafts are 'safe'), but I would argue that while the data is less clear on that topic, the onus of proof has now completely shifted to allograft users in this patient population to demonstrate the safety of those types of grafts before they continue to use them."

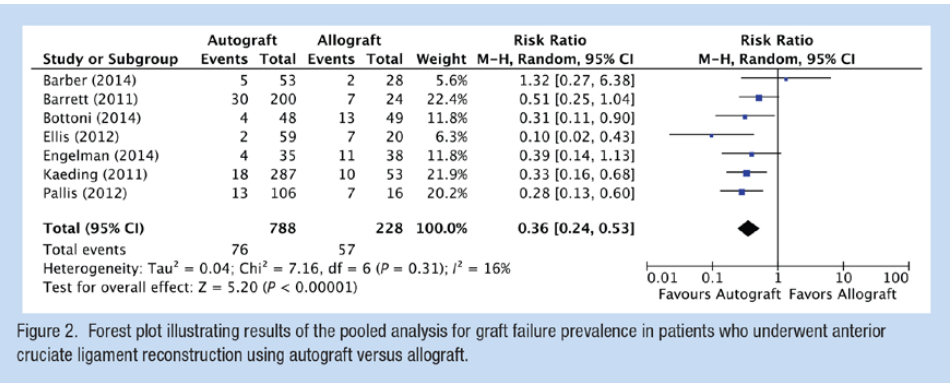

Figure 2. Forest plot illustrating results of the pooled analysis for graft failure prevalence in patients who underwent anterior cruciate ligament reconstruction using autograft versus allograft.

Study courtesy Sports Health: A Multidisciplinary Approach and David Wasserstein, M.D., M.Sc., FRCSC

"Systematic reviews like this study are an excellent way to distill knowledge, but they depend on the hard work of those creating knowledge through primary research and I salute the efforts of my colleagues engaged in those endeavors." — *EH*

PEOPLE

Andrew J. Weiland, M.D. Receives Tipton Leadership Award From AAOS

Andrew J. Weiland, M.D., an attending orthopedic surgeon at the Hospital for Special Surgery, has been honored with the 2015 William W. Tipton, Jr., M.D., Leadership Award by the American Academy of Orthopaedic Surgeons (AAOS).

Andrew J. Weiland, M.D., courtesy Hospital for Special Surgery

According to AAOS, the "Tipton Leadership Award recognizes Academy members who have demonstrated outstanding leadership qualities that have benefitted the orthopaedic community, patients, and/or the American public. The award honors and celebrates the life, accomplishments and qualities of the late William W. Tipton, Jr., M.D.,

an orthopaedic surgeon, educator and former AAOS chief executive officer."

Dr. Weiland is professor of orthopedic surgery and professor of surgery (plastic) at the Weill Cornell Medical College. He has been a visiting professor in almost all 50 states, has taught hand and microvascular surgery to fellows and residents for nearly 40 years, and has authored more than 250 research studies.

While at the American Board of Orthopaedic Surgery (ABOS), Dr. Weiland was directly involved in the creation of a Subspecialty Certification in Hand Surgery, a first for orthopedic surgery, requiring the collaboration of three boards: ABOS, the American Board of Plastic Surgery, and the American Board of Surgery.

"Dr. Weiland's diplomacy was a key ingredient in making this happen," said Peter J. Stern, M.D., the Norman S. and Elizabeth C.A. Hill professor and past chairman of orthopedic surgery at the University of Cincinnati College of Medicine, in the March 26, 2015 news release. "He understands the importance of respect for dissenting opinions, building consensus through open discussions, listening and acknowledging the concerns of others, and being inclusive rather than exclusive."

Most recently, his residents, fellows and colleagues established the Weiland Medal (within ASSH) to annually recognize a mid-career scientist who has made substantive contributions to hand surgery.

Asked what this award means to him, Dr. Weiland told *OTW,* "It is a tremendous honor to be recognized by AAOS for my contributions to orthopaedic surgery. My love and passion for our specialty is what has motivated me in addition to the privilege of having worked with outstanding individuals in the various organizations that I have been involved with. During my service with the Academy, I worked closely with Bill Tipton while I was on the council of education and treasurer and had the highest respect for his leadership skills and cherished his friendship."

As for what leadership experience he is most proud of, Dr. Weiland stated, "The leadership experience I am most proud of is working with residents and fellows over the last 40 years and playing some part in instilling in them the passion I have for our specialty. There is no greater satisfaction then seeing one of your students contribute to orthopaedics and become a leader in our field." — *EH*

Dr. Lovejoy's Sustainable Humanitarian Work Honored by AAOS

John Lovejoy Jr., M.D., is a retired orthopedic surgeon. But he's not done being a physician.

While serving in the U.S. Navy during the Vietnam War, he saw how he could make a big difference in improving healthcare in the developing world. This was not unusual. His father, also an orthopedic surgeon, was a noted humanitarian and during the holidays father and son would send out medical bills to patients in financial straits with a note that said "Merry Christmas, Paid in Full."

But it was in the Caribbean where Dr. Lovejoy would leave his biggest mark in a story reminiscent of the parable of teaching a starving person to fish.

2015 AAOS Humanitarian Award

For that work, the American Academy of Orthopaedic Surgeons (AAOS) presented Dr. Lovejoy with the Humanitarian Award during the Ceremonial Meeting on March 26, 2015 at the AAOS annual meeting in Las Vegas.

For more than 40 years Dr. Lovejoy, of Jacksonville, Florida, travelled to Haiti, the poorest nation in the Caribbean, to provide medical care. He also frequently travelled to the island of Grenada to upgrade medical equipment, build an arthroscopic system and create an exchange program to bring Grenadian surgeons to the U.S. for training.

Work in Haiti

But it was in the aftermath of the killer earthquake in Haiti in 2010 that he really made a difference. According to *AAOS Now*, five days after the disaster, Dr. Lovejoy and his surgical team returned to Haiti to provide medical relief efforts at Hôpital Sacré Coeur. His team transformed the 73-bed hospital into a more than 600-bed facility similar to a mobile Army surgical hospital (MASH) unit.

John Lovejoy, Jr., M.D./AAOS NOW

On an average trip to Haiti, Dr. Lovejoy and team saw approximately 50 to 100 patients and performed 20 to 30 surgeries in a week. After the earthquake, the surgical team, including his son

Dr. John F. Lovejoy, a third generation orthopedist, operated on more than 180 cases that first week and more than 150 cases with approximately 400-500 patients during a second trip two weeks later.

What really got to him in Haiti was seeing all the amputations in children because of delays to immediate medical care. "There were 50,000 amputees [in Haiti] and 10,000 more after this earthquake. And, there are zero certified prosthetists in the country," Dr. Lovejoy told *AAOS NOW*.

He had to teach the Haitians how to help themselves. So when he got back Jacksonville, he designed, funded, and built a state of the art prosthetic lab and shipped it to the hospital. He recruited U.S. orthopedic teams to teach and correct limb deformities, and trained local orthopedists to deliver a higher level of care.

Train Haitians to Treat Haitians

He trained Haitians through the Crudem Foundation and personally sponsored two Haitian students' enrollment in a three-year college degree program at Don Bosco University in Prosthetics and Orthotics. The students worked in the prosthetic lab learning the trade, and graduated in February 2015. His colleague Dr. William A. Sims said Dr. Lovejoy and teams also planned, designed and built a physical therapy building and program adjacent to the hospital.

To this day, amputees at the hospital are fitted with prostheses, and Haitians continue to train to become certified prosthetist orthotists. Dr. Lovejoy told *AAOS NOW* that "To make things sustainable, we needed to train Haitians to treat Haitians. We've given them the tools. We've given them the facility and the educational opportunities so they can learn the skill, and then treat their own people."

A Family Affair

In nominating Dr. Lovejoy, John S. Kirkpatrick, M.D., wrote: "Dr. Lovejoy selflessly contributes his time and resources to benefit the less fortunate and mentor future orthopedic surgeons."

It doesn't look like the Lovejoy family's humanitarian efforts will end any time soon. Dr. Lovejoy's son is a pediatric orthopedic surgeon at Nemours Children's Hospital in Orlando, Florida, who accompanies his father on medical missions to Haiti.

"As my children grew up, I began to involve them in my humanitarian efforts. Like me, they appreciated all they had when they saw how others struggled for existence," Dr. Lovejoy told *AAOS NOW*. "My wife supported me and encouraged the kids' involvement. Working together on these projects drew us closer together." Over the years, he estimates he has recruited more than 500 orthopedic surgeons and other medical practitioners to participate in medical missions.

"Orthopedic surgeons are very giving people. I encourage them to give back to their communities and help others who cannot afford their care," he said. — *WE*

Orthopedics This Week I RRY Publications LLC

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