VOLUME 10, ISSUE 5 | FEBRUARY 11, 2014

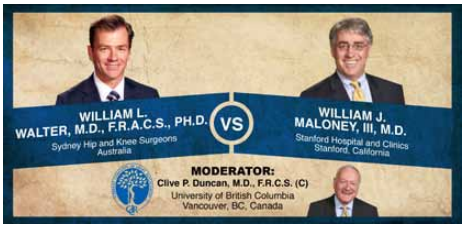
Orthopedics This Week

WEEK IN REVIEW

4 Spine IPOs: Multiplying Like Rabbits >> K2M announced last week that it is ready to go public. If successful, investors will have seven (yes!) seven public spine companies to choose from. How will K2M stack up? Pretty well we think. Here are a few details.

9 DOJ's New "Probation Lite" Strategy >> A shift from traditional Corporate Integrity Agreements to "Probation Lite" may be the government's next effort to curb corporate recidivism in the medical devices and pharmaceuticals industries. The nation's top prosecutor made waves recently as he outlined a new strategy. We've got it here.

14 Walter v. Maloney: Dual Mobility Poly Liner >> "Ceramic bearings are stable and popular worldwide…Australia (26%), France (43%)," states Bill Walter. Bill Maloney counters, "There is interest in CoC because it's a very low wear bearing surface. But is that relevant today with the other, lower cost bearing options we have? Probably not."



18 Landmark Agreement on Joint Infection Protocols // NFL, GE Tap UPMC to Study Concussions // Finally! THE Book on Failed ACL Reconstruction >> Four hundred participants from 52 countries came together and hashed out the first comprehensive infection protocols. This landmark accomplishment will affect every surgeon, every hospital. Concussions and the NFL. Big issue. Solution? The University of Pittsburgh Medical Center. And Robert G. Marx, M.D. from HSS has written THE book on failed ACL reconstructions.

BREAKING NEWS

22 Record Number of **Healthcare Fraud Prosecutions** in 2013

Judge Approves $56 Million **Biomet Metal Hip Settlement**

Wright Acquires **Solana, OrthoPro**

Home Plate – **Baseball's Danger Zone**

$24k for **Hip**, $21k for **Knee**

Hospitals Cut Ortho Costs, Grow Earnings

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Smith & Nephew's purchase of ArthroCare brought new buyers into SNN. Price paid was high, but leveraging SNN's existing distribution should yield strong, long-term returns. Operationally, the orthopedic industry is enjoying robust demand (perhaps more than CEOs expected) for their implants. Combine that with a steady pace of consolidation and shareholders should continue to expect that 2014 will be a good year.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	15.71%	3.13%	SYK is still the 3rd least expensive equity in orthopedics; 2013 was a solid year and now, with MAKO, SYK's long-term prospects look even better.
2	2	Globus Medical	28.29	17.93	With an 18% pop in the last 30 days, GMED's equity valuation is getting close to nose-bleed territory.
3	6	Smith & Nephew	20.25	5.35	Buys ArthrCcare—a great franchise—and announces rising profit margins. This is the most excitement SNN has generated in, well, a long time. Up 3 spots.
4	3	Zimmer	27.31	(3.02)	Still banging out terrific operating margins and clearly is gaining share in recon, especially knees. And it is the 2nd cheapest (after OFIX) ortho stock.
5	5	NuVasive	6.30	2.42	Like GMED, NUVA defies gravity when it comes to valuation. Both of these firms are executing extraordinarily well.
6	7	Symmetry Medical	6.50	1.35	Has yet to report Q4, 2013 sales and earnings. Wall Street consensus is saying SMA will have down sales and earnings.
7	4	ConMed	10.37	(1.77)	SNN pays 5x sales for MIS leader ArthroCare. The other company with a significant MIS product portfolio is CNMD. Its PSR is 1.54x.
8	10	Medtronic	28.84	(8.63)	Low single-digit sales growth and, most analysts expect, down earnings for the January quarter. Investors need a catalyst to get excited about MDT.
9	NR	Johnson & Johnson	26.58	(4.38)	Back on the Power Rankings as OFIX exits. The recent market sell-off has improved JNJ's relative valuation.
10	8	Integra LifeSciences	11.77	(8.86)	Buys DuraSeal from Covidien and the market yawns. We're watching the March quarter. Could be nice upside surprise coming.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$1.10	$177	45.19%
2	Aurora Spine	ASG	$4.75	$74	39.88%
3	Globus Medical	GMED	$23.35	$2,177	17.93%
4	Baxano Surgical Inc	BAXS	$1.31	$59	15.94%
5	Alphatec Holdings	ATEC	$2.30	$224	14.43%
6	ArthroCare	ARTC	$49.53	$1,406	6.36%
7	Smith & Nephew	SNN	$75.64	$13,508	5.35%
8	Stryker	SYK	$79.43	$30,058	3.13%
9	NuVasive	NUVA	$35.91	$1,602	2.42%
10	Bacterin Intl Holdings	BONE	$0.54	$28	1.66%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	$6.85	$709	-13.73%
2	CryoLife	CRY	$9.61	$265	-11.18%
3	Orthofix	OFIX	$20.67	$402	-10.40%
4	Integra LifeSciences	IART	$45.08	$1,448	-8.86%
5	RTI Biologics Inc	RTIX	$3.12	$176	-8.77%
6	Medtronic	MDT	$55.59	$55,498	-8.63%
7	Exactech	EXAC	$22.25	$301	-7.29%
8	Johnson & Johnson	JNJ	$90.04	$254,042	-4.38%
9	Tornier N.V.	TRNX	$18.86	$914	-3.28%
10	Zimmer Holdings	ZMH	$94.49	$16,156	-3.02%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$20.67	$402	8.30
2	Medtronic	MDT	$55.59	$55,498	14.95
3	Zimmer Holdings	ZMH	$94.49	$16,156	16.44
4	Johnson & Johnson	JNJ	$90.04	$254,042	16.44
5	Stryker	SYK	$79.43	$30,058	18.94

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$35.91	$1,602	94.50
2	Symmetry Medical	SMA	$9.76	$364	49.19
3	ArthroCare	ARTC	$49.53	$1,406	31.72
4	Integra LifeSciences	IART	$45.08	$1,448	28.77
5	CryoLife	CRY	$9.61	$265	24.81

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$20.67	$402	1.19
2	Globus Medical	GMED	$23.35	$2,177	1.39
3	Exactech	EXAC	$22.25	$301	1.49
4	ConMed	CNMD	$42.72	$1,180	1.67
5	Zimmer Holdings	ZMH	$94.49	$16,156	1.71

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$35.91	$1,602	7.68
2	CryoLife	CRY	$9.61	$265	6.20
3	Symmetry Medical	SMA	$9.76	$364	4.10
4	Integra LifeSciences	IART	$45.08	$1,448	3.92
5	Smith & Nephew	SNN	$75.64	$13,508	2.82

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	$0.54	$28	0.85
2	Orthofix	OFIX	$20.67	$402	0.87
3	Symmetry Medical	SMA	$9.76	$364	0.89
4	RTI Biologics Inc	RTIX	$3.12	$176	0.99
5	Alphatec Holdings	ATEC	$2.30	$224	1.14

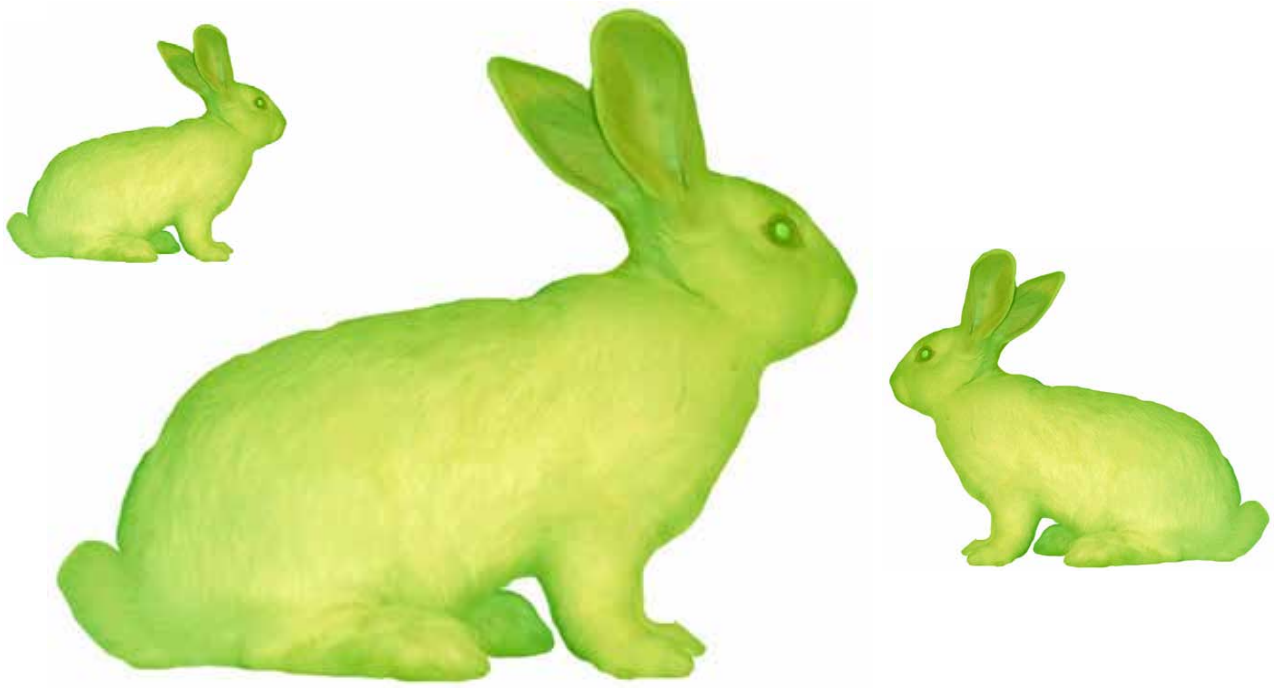
HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.10	$177	43.35
2	MiMedx Group	MDXG	$6.85	$709	26.20
3	Globus Medical	GMED	$23.35	$2,177	5.64
4	Baxano Surgical Inc	BAXS	$1.31	$59	4.06
5	ArthroCare	ARTC	$49.53	$1,406	3.81

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

Spine IPOs: Multiplying Like Rabbits

BY ROBIN YOUNG



Wikimedia Commons and Conita

On its 10th anniversary, Virginia-based spinal implant company K2M, Inc. announced that it had filed in January a "confidential" S-1 with the Securities Exchange Commission (SEC) which signals the company's clear intent to "go public" or sell shares of its common stock to the general public.

Interestingly, the filing is "confidential." Prior to 2012, all S-1 filings were available for public scrutiny. But K2M's S-1 filing comes under a new provision of the JOBS Act passed in 2012 which allows small companies to submit draft registration statements for *confidential* review by the SEC. No public disclosure—outside of a simple press announcement.

If K2M successfully floats this offering there will be seven public spinal implant companies—making spine the orthopedic sector with the most public companies.

The other pure, public spine companies are, in order of 2013 revenues:

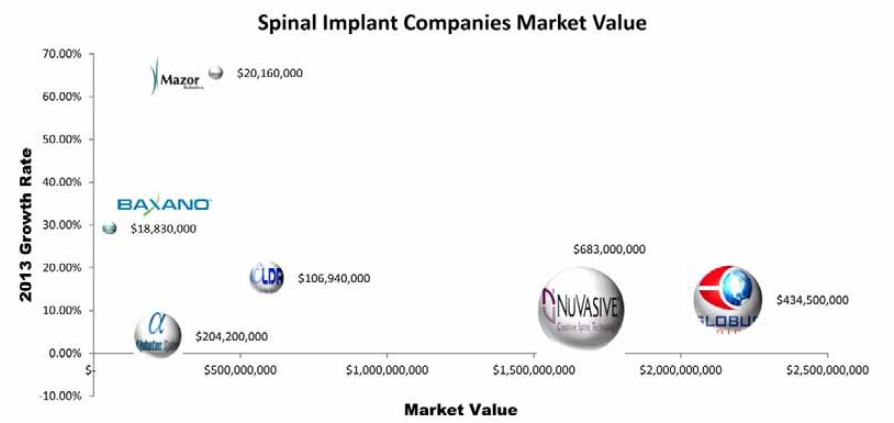
1. NuVasive, Inc. ($683 million)
2. Globus Medical, Inc. ($434 million)
3. Alphatec Holdings, Inc. ($204 million)
4. LDR Holding Corporation ($107 million)
5. Baxano Surgical, Inc.($19 million)
6. K2M, Inc. (unknown)
7. Aurora Spine Corporation (unknown)

Valuation

Investors have put a very wide range of prices on spinal implant companies. At the low end of the range is Alphatec which investor's judge is worth 1.08x sales. At the high end is Globus Medical which carries a price to sales valuation of 5.5x.

The following chart illustrates this range. *(See chart on page 5.)*

The little company at the top of the sales growth rate scale is Mazor Robotics Ltd. For 2013 Mazor's sales jumped nearly 70% (from a low base) and investors—looking no doubt at MAKO Surgical Corp.'s buyout by Stryker



Source: RRY Publications LLC

Corporation—decided that Mazor was worth something in the neighborhood of $400 million (nice neighborhood).

LDR Spine, riding the momentum from its PMA (premarket application) approval for Mobi-C disc, is now valued at more than a half a billion dollars. Alphatec Spine, with twice the sales of LDR Spine, has less than half the valuation. Of course, we do expect that Alphatec's 2013 sales growth rates will be higher than Wall Street's analysts are expecting. According to a consensus of those analysts who cover Alphatec, sales this year are expected to rise just 4%. That seems extremely unlikely. Alphatec's sales for the first nine months of 2013 increased 5.6%. Sales for the third quarter were up 7.2%. It would, as a result, hardly surprise us if Alphatec's full year sales growth rate was almost double the Street's consensus.

Each company's valuation appears to reflect the unique characteristics of each firm—not necessarily an overall excitement about spinal implants or the market to treat back pain. In fact, on a macro basis, the market to treat back pain continues to experience reimbursement and regulatory headwinds which should give most investors pause.

This Class of Entrepreneurs

If any one thing distinguishes these spinal implant companies it is that almost all of these companies are still headed up by their founder and each CEO is a compelling entrepreneur in their own right.

- Alex Lukianov—Founder and CEO, NuVasive
- David Paul—Founder and CEO, Globus Medical
- Christophe Lavigne –Founder and CEO, LDR Holdings

- Ori Hadomi—Co-Founder and CEO, Mazor Robotics

The two companies with the lowest valuations are no longer being run by their founders.

K2M, which may soon join this group of public spinal implant companies, is similarly led by its co-founder, Eric Major.

A Little K2M Background

In 2003, John Kostuik, M.D., former president of NASS, SRS and chief of orthopedics at Johns Hopkins, was in his 69th year and contemplating life after academia when he sat down with one of his former fellows, Tom Errico, M.D., and said: "Tom, I'm looking for something to do."

Dr. Errico thought about it, asked a few questions then strung together these five fateful words; "Maybe we should start a company."

Physicians starting companies is not really a good idea. It's like putting sharp objects in the hands of businessmen. Nine times out of ten they'll hurt themselves. But Drs. Kostuik and Errico de-risked their notion by calling a friend—the former CEO of American OsteoMedix and sales executive for Interpore Cross, Aesculap, Inc. and Synthes Spine—Eric Major.

Major, like Kostuik, was also looking for something to do.

Eric Major had just sold his supplier of VCF products to Interpore Cross. So he knew a thing or two about starting, running and selling businesses. In those days spine was a hot area for investment. Lots of entrepreneurs were throwing up shingles offering spinal implant products for sale.

But Kostuik and Errico didn't want to start a spine business like other guys. They had something else in mind. Eric Major (later with his brother Lane Major) liked what they heard.

Surgeon-Focused, Education-Centered

"I insisted that our company's product development be surgeon focused. Right from the start Tom and I insisted that we have a large scientific board and that we put them to work. Our initial scientific board was 16 surgeons, half from academia and half from private practice. Later we grew it to 20 surgeons and we made them come to our offices four times a year and hold conference calls with us every two weeks!" remembers Dr. Kostuik.

"The other thing I insisted on was an educational forum. I'd always been an admirer and active participant in the AO spine educational programs and

I felt that an educational forum combined with a strong data acquisition program was essential."

With that, Kostuik and the two Majors (Eric and Lane) went to work under the banner, "K2M."

That first year the scientific board swamped the employees—16 to 5. The first product was no surprise, a pedicle screw. It took ten months to get it through the FDA and ready for market. Ten million in seed money came from family, friends and a few surgeons. While it was a great start, there was one critical question remaining—what would be the company's product platform?

Back to the Future

"I had always been involved in adult deformity." – Dr. John Kostuik, former president of SRS.

In 2004, deformity was old news. Scoliosis? Is anyone still doing those surgeries? No, the action in 2004 was intervertebral body implants—cages or motion preserving implants like Charité and ProDisc. In 2003 and 2004, Synthes, DePuy, Stryker and virtually every private equity firm on Wall Street laid hundreds of millions of dollars on the table to pay for motion preserving implants to treat degenerative disc disease.

Deformity? Who does deformity?

So while innovation to treat spine disease was zigging to DDD (degenerative disc disease), the small team assembled by the Majors and Kostuik, zagged. Relying on their scientific advisory board, they realized that the issue wasn't deformity, per se, it was the complexity of the surgery itself. And there had not been a significant new innovation in this area since Cotrel-Dubousset.

K2M became the company dedicated to making complex spine surgery less complicated, more consistently successful and less morbid.

Innovations for Complex Constructions

Between 2004 and 2010, K2M introduced a series of major innovations for spine surgeons who are tackling particularly complex constructions.

The first platform system from K2M was the Denali system which was a top-loading spinal system featuring off-axis screw height adjustment and offering a complete array of screws, rod connectors, and hooks, coupled with easy-to-use instrumentation.

One surgeon who'd used K2M's products wrote this on an anonymous blog a year ago: "The system is incredible. I am a deformity surgeon and I 'gave it a go' to see what all the talk was about. I thought I would use it once and that it would be a joke. How wrong I was. It is incredibly powerful and fast. I can do monster reductions very quickly, far easier that the previous system that I used. I had to do a revision using my old system last week—what a nightmare. It reminded me what a frameshift this pedicle screw is."

Gil Tepper, M.D., who is the founder and president of the Spine Institute at Miracle Mile Medical Center in Los Angeles, characterizes K2M this way. "At K2M, spine surgeons from diverse backgrounds and interests collaborate extensively and work closely with engineers to facilitate innovations as well as improvements in the logistics and approach to various spinal surgical techniques. The collaboration involves didactic sessions and cadaver workshops. It's truly cooperative patient and procedure centered and data driven."

By 2010, K2M's sales had grown to, we estimate, well over $100 million.

Welsh, Carson

"When we first started out we thought we would do a couple of innovative things and then get bought out." – John Kostuik.

It didn't quite happen that way. None of the major orthopedic companies bought K2M—although they did come knocking. No, the firm that finally convinced the Majors, Kostuik et al. to transfer majority ownership was Welsh, Carson (WCAS)—the largest private equity firm in medicine.

At a time when hospitals are demanding lower prices, Medicare (CMS) is cranky, the FDA is flailing around, several small spine technology firms have left the pitch and one of the most important new technology initiatives—motion

preservation implants—was mugged in the alley, Welsh, Carson decided to invest in spine.

Either these guys were smart or they weren't paying attention to the headlines. In fact, WCAS had built its business by laying shrewd bets on strong jockeys who knew how to ride a thoroughbred company to the finish line.

WCAS's purchase of a majority share of K2M closed in July 2010.

A Very Fine Neighborhood

With Welsh, Carson on board, K2M has kicked in the afterburners. Since 2010, K2M has grown to 750 employees, built a portfolio of more than 55 products and opened up the international market.

What's next? Obviously, an S-1 filing.

We can't imagine why the SEC wouldn't quickly approve this. And we look forward to reading how much progress the K2M and WCAS team have made since 2010. In terms of how K2M will stack up as a public company, if we were to guess, we'd expect it would be somewhere in the neighborhood of LDR, NuVasive and Globus.

Which is a very fine neighborhood, indeed. ♦

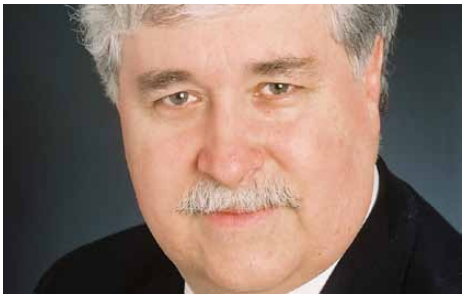
DOJ's New "Probation Lite" Strategy

BY WALTER EISNER

Corporate Integrity Agreements (CIAs) are the cornerstone of the Department of Justice's (DOJ) attempts to keep device companies and pharmaceutical companies on the straight and narrow.

Problem is, companies continue to get into hot water with prosecutors and their effectiveness is hard to measure.

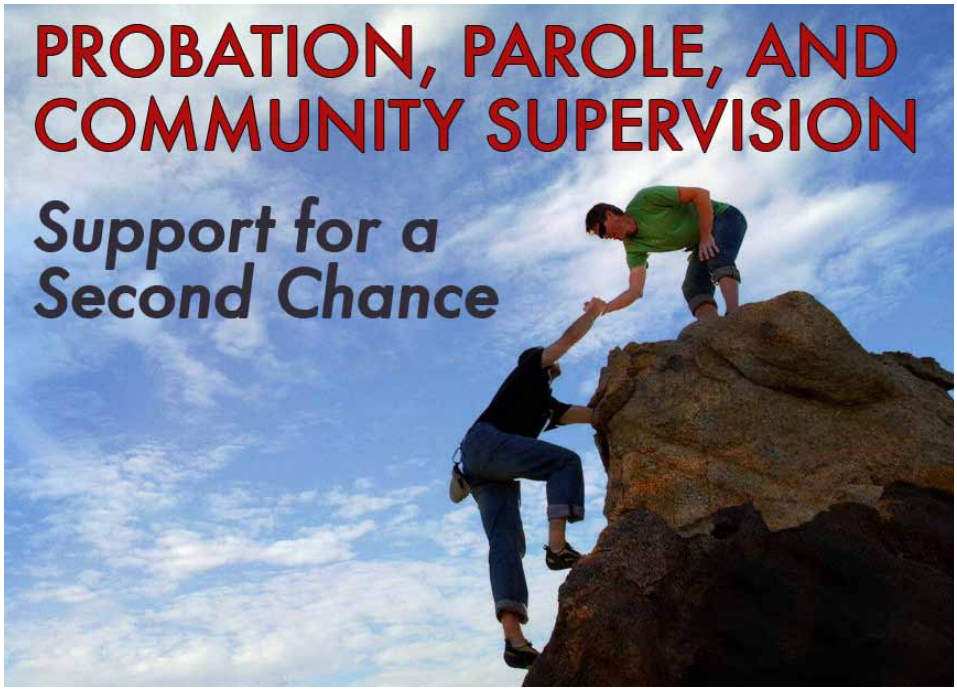
"Unfortunately there is insufficient objective data demonstrating that CIAs are actually reducing non-compliance," University of Minnesota law professor and counsel to Faegre Baker Daniel LLP (FBD), Ralph Hall told *OTW* on February 4, 2014.



Ralph Hall, J.D./University of Notre Dame

"Fines are steadily increasing and even companies under CIAs continue to be the subject of enforcement actions. No one really knows which elements of a CIA are making a difference in either encouraging compliance or creating effective disincentives to non-compliance. Currently there is no agreed way to measure the level of compliance within a company and so we don't know what works."

The nation's top healthcare crime prosecutor, U.S. Assistant Attorney General Stuart Delery, seems to agree with Professor Hall.



www.appa-net.org and RRY Publicaitons LLC

"Probation Lite"

In a keynote address to pharmaceutical compliance officers in Washington, D.C., on January 29, 2014, Delery, head of the DOJ's Civil Division, said the department is "not interested in merely collecting a large fine and moving on to the next case. We strive to give companies the incentives—and the tools—to craft better compliance practices in the future."

U.S. Assistant Attorney General Stuart Delery/ Department of Justice

Tom Beimers, also of FBD and a former prosecutor in Delery's division, told us that Delery appeared to signal a shift of emphasis in DOJ's fraud prevention efforts. "Whereas DOJ's focus in the past several years has centered on large dollar settlements in high-profile off-label marketing cases, Delery emphasized 'renewed emphasis on identifying non-monetary measures that will

Tom Beimers/ Faegre Baker Daniel LLP

help DOJ to prevent the recurrence of misconduct.' This approach is in contrast to prior speeches, in which DOJ highlighted efforts to create disincentives through more enforcement activities, particularly with respect to individuals."

He added, "Until the next major settlement, the precise meaning of Delery's speech will remain speculative, but a shift from traditional CIAs to something along the lines of 'probation lite' may be DOJ's next effort to curb what it views as a corporate recidivism problem."

$20 billion in Settlements

Delery noted that since 2009, judgments and settlements under the False Claims Act (FCA) and Food, Drug and Cosmetic Act (FDCA) have totaled over $20 billion. "But monetary results tell only part of the story," said Delery.

"We have pursued doctors who perform unnecessary procedures to increase their bills, like a Florida dermatologist who performed thousands of unnecessary skin surgeries, participated in an illegal kickback scheme, and ultimately paid one of the largest FCA settlements ever by an individual—$26.1 million. We have gone after the manufacturers of defective medicines or medical devices, as in our criminal and civil cases against a Boston Scientific subsidiary for knowingly selling defective cardiac defibrillators."

He said that when the focus is on financial recoveries, or on a specific investigation, it is easy to think of government and industry as adversaries. "But when the goal is ensuring that Americans can trust the drugs they take and the medical advice they receive, it is clear that we are on the same side."

Expanding Corporate Integrity Agreements

Historically, when a drug or device company resolved FCA liability through a settlement, Beimers said the agreement was contingent upon entering into a CIA with the Office of Inspector General (OIG). Those agreements first appeared in the early 1990s and were originally limited to training and education requirements.

Over the years the scope of the agreements expanded, with additions including third-party auditing and monitoring provisions and the mainte-

nance of databases reflecting payments to healthcare providers.

In recent years, Beimers says CIAs have introduced further enhancements. Management and board certifications required companies to certify compliance with a broad range of federal rules and laws, creating a cascade effect of additional compliance functions and necessitating the addition of compliance personnel.

Recent agreements, according to Beimers, have also mandated the retention of third party experts, the monitoring of various marketing activities (such as speaker programs), and transparency requirements, such as posting payments to physicians and disclosing the results of clinical trials. "Despite this expansion, the government frequently notes that the same companies are entering into a second or even third FCA settlement."

New Post-Settlement Oversight and Monitoring Model

Against that backdrop, Beimers believes Delery's speech may signal DOJ's intention to take a more active role in crafting post-settlement oversight and monitoring arrangements. "There have been hints in this direction over the past two years."

Delery pointed in particular to India-based Ranbaxy Laboratories Limited, which has experienced notorious manufacturing problems at many of its facilities. Those problems led to a major FCA settlement. Because Ranbaxy is subject to a strict consent decree with FDA, the agency has been able to act quickly when additional manufacturing issues were discovered.

Beimers says it is notable that Ranbaxy did not enter into a CIA with OIG as a condition of its settlement. "This may be a function of the relative lack of expertise within OIG when it comes to supervising manufacturing practices and quality systems issues."

However, OIG does have a CIA with GlaxoSmithKline plc (GSK), based on violations of Good Manufacturing Practices regulations.

That CIA, which Beimers says tops out at over 100 pages, contains detailed provisions governing GSK's manufacturing practices. "Some commentators have noted that the monitoring of these terms is rather far afield from the type of training and monitoring provisions that are typical of OIG agreements. That manufacturing practices oversight is more appropriate to FDA's mandate may explain why DOJ is highlighting the Ranbaxy settlement structure as a model going forward."

In a 2012 settlement with Abbott Laboratories for the off-label marketing of the atypical anti-psychotic Depakote, Beimers said DOJ supplemented the traditional CIA with probation. The probation terms require that Abbott submit some of the same information typically required by CIAs directly to DOJ.

"But the conditions of probation go well beyond the standard CIA requirements, and include a requirement that Abbott report any probable violation of the FDCA to the government, and put into place controls to ensure transparency around grant making and clinical trials," said Beimers.

Delery told the compliance officers that industry and government shared the same interests in assuring safe products and assuring competition on a level playing field. He outlined three ways the interests of the government align with corporate interests.

Ethical Culture, Not Programs

First, he said there is a common interest in promoting an ethical corporate culture instead of maintaining a compliance program in name only. "A common thread in many of our cases is that numerous individuals—ranging from executives to safety technicians—saw signs that misconduct was taking place and did not act."

He said this demonstrates how a company can have the tools it needs to avoid violations of law, and yet have such violations happen anyway. "To be sure, Ranbaxy's compliance operation could have done more than it did—its auditors, for instance, said that the company badly needed cGMP [current Good Manufacturing Practices] training; that training never happened. But policies alone are not enough."

That is why the government has put a renewed emphasis on identifying non-monetary measures that will help to prevent the recurrence of misconduct, said Delery. "That happened with Ranbaxy, where an earlier civil consent decree called, among other things, for the company to establish an Office of Data Reliability that would work with its manufacturing, testing, approval, and compliance operations to ensure that all future drug applications are audited for accuracy before submission."

Personal CEO Responsibility

In the $1.5 billion criminal and civil resolution in 2012 with Abbott Lab, Delery said DOJ crafted a resolution designed to ensure high-level accountability for the company's compliance efforts. It imposes a term of probation for five years which requires Abbott to report any probable violations of the FDCA, and requires that its CEO personally certify compliance with this reporting requirement. In addition, Abbott's board of directors is required to review the efficacy of the company's compliance effort.

"And," added Delery, "it demands that Abbott institute policies to ensure that its scientific research and publications foster increased understanding of scientific, clinical, or healthcare issues."

Knowing the Line

The second common interest is in having transparency about the conduct the government is investigating. "We must be clear about what misconduct gave rise to a criminal or civil resolution."

Delery said the government will distinguish conduct that is lawful and even beneficial from conduct that is illegal and harmful. "For example, we recognize the value of giving doctors the freedom to decide, in consultation with their patients, what treatments to use. And we acknowledge the importance of an open dialogue in which companies and physicians share truthful information about a product's likely effects."

But where a company crosses the line and distributes its products intending them to be used in ways that are not approved as safe and effective by the FDA, the government will act aggressively.

Level Playing Field

Third, Delery says there is a common interest in ensuring that corporate compliance is a winning business strategy. The government will pursue companies that seek an unfair advantage by breaking the law. They want to ensure that companies that are committed to doing things right have the opportunity to compete on a level playing field.

"We want to make clear that the decision to come forward is the right one. When a company or individual acts responsibly by timely and voluntarily disclosing unlawful conduct, we will give serious consideration to that disclosure in deciding whether or how to charge or resolve the matter. Likewise, we will credit actions taken once the government has started to investigate."

What to Expect

Delery says the government rejects the "pernicious idea" that a company can succeed by violating the law and treating healthcare fraud enforcement as a cost of doing business. "We continue to insist on resolutions that eliminate any economic incentive to engage in and attempt to conceal unlawful conduct. We continue to seek criminal penalties, against both companies and individuals, under appropriate circumstances. We continue to demand accountability by vigilantly enforcing federal laws against those who seek an unfair advantage at the expense of patients and taxpayers." ♦

OP-1® PUTTY from Olympus Biotech.

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IMPORTANT SAFETY INFORMATION

HUMANITARIAN DEVICE

OP-1 PUTTY is authorized by Federal law for the repair of symptomatic, posterolateral (intertransverse) lumbar spine pseudoarthrosis in patients for whom autologous bone and/or bone marrow harvest are not feasible or are not expected to promote fusion and who have at least one of the following compromising factors: osteoporosis, diabetes or nicotine use. The effectiveness of OP-1 PUTTY for this use has not been demonstrated.

- Brief summary of contraindications and warnings:
- OP-1 PUTTY is contraindicated in patients who (1) are pregnant (2) have or have had a malignancy (3) are skeletally immature (4) are pregnant or want to become pregnant within 2 years of treatment (5) have a known hypersensitivity to the active substance or to collagen (6) have an autoimmune disease or immune suppression (7) have been previously treated with OP-1 IMPLANT or OP-1 PUTTY.
- The use of OP-1 PUTTY may result in (1) the formation of localized ectopic or heterotopic bone outside of the treatment site (2) development of an immune response against BMP-7 or Type I collagen.
- There are no adequate well controlled studies of OP-1 PUTTY in (1) pregnant women (2) patients with autoimmune disease or immune suppression (3) patients with renal impairment.

Please see the package insert for the complete indication, contraindications, warnings, precautions, adverse events and other important medical information.

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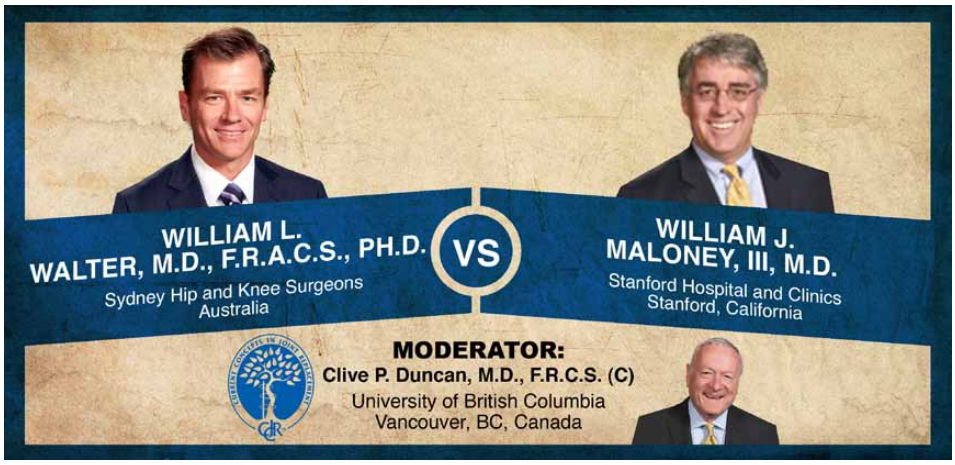
Walter v. Maloney: Dual Mobility Poly Liner

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

"Ceramic bearings are stable and popular worldwide…Australia (26%), France (43%)," states Bill Walter. Bill Maloney counters, "There is interest in CoC because it's a very low wear bearing surface. But is that relevant today with the other, lower cost bearing options we have? Probably not."

This week's Orthopaedic Crossfire® debate is "Ceramic-on-Ceramic Hip Arthroplasty: A New Standard." For the proposition is William L. Walter, M.D., F.R.A.C.S., Ph.D. from Sydney Hip and Knee Surgeons in Australia; against the proposition is William J. Maloney, III, M.D. from Stanford Hospital and Clinics in California. Moderating is Clive P. Duncan, M.D., F.R.C.S. (C) of the University of British Columbia.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Walter: "It's not really a new standard as ceramic bearings have been around since the early 1970s. In many countries ceramic bearings have been the standard for a long time. In Australia 26% of our primary hip replacements are ceramic-on-ceramic (CoC); in France it's 43%; the U.S. has one of the lowest uses of CoC in primary hip replacements (<15%). And the Australian registry shows us that use of this bearing has been stable for about 10 years."

"In our own practice we've done over 4,000 CoC hip surgeries. Looking at the first 300 cases we published, our 10-year data shows survival with any revision for failure was 98% at 11 years. There were no failures after four years, so with ceramics—compared to the old poly—we've eliminated late failures due to wear. We did see some periprosthetic fractures early, as well as some early loosening. Out of those 300 hips, 0.6% were squeaking, but none of those were revised. Looking at the 4,000 CoC hip surgeries from 1998 – 2010 we had 55 retrieved with ceramic heads; they were retrieved for reasons unrelated to the bearing (only two for squeaking). And we analyzed the wear of these bearings, and published that in 2012."

"In ceramic bearings you don't get concentric wear, you get stripe wear or edge loading pattern. We've measured wear volumes and found no measurable concentric wear, but edge loading wear occurs in 84% of our retrievals. The median wear rate is 0.2mm^3 per year. Stripes that slope down have bigger wear and those that slope up have less wear. The down sloping ones are due to anterosuperior edge loading, which is less common; posterior edge loading is more common and it produces lower wear."

"We've also related the width of the wear stripe to the volume, and we've measured the acetabular component position for anteversion and inclination. We found that it's a combination of high anteversion and high inclination that leads to anterosuperior edge loading, while low anteversion and low inclination leads to posterior edge loading."

"We did a logarithmic scale showing the wear of metal-on-metal with edge loading, metal with concentric wear, the Biolox Forte and the Biolox Delta… the last one has very low wear. Our data on revisions for osteolysis showed that ceramics had only one revision for osteolysis. Paradoxically, it may not be the ceramic debris that causes the osteolysis here. Looking at the histology, with the ceramic bearings we see there is mild synovitis. Compare that to poly where you have pseudotumors, visible debris, synovitis…and metal-on-metal where you also have necrosis."

"With ceramic the tissues around the hip are very benign. We do see some yellow grainy debris in the macrophages; in the case with osteolysis there is black debris in the hip. When we looked at it in more detail we saw that this was not

alumina, but it was titanium. So paradoxically in ceramic the wear debris that causes osteolysis is the titanium from impingement or from the tapers."

Dr. Maloney: "The title is, 'A New Standard.' The dictionary says that 'standard' is something established by authority, custom, or general consent. This is clearly untrue for CoC THA [total hip arthroplasty]. Is there any indication for CoC THA today?"

"There is interest in CoC because it's a very low wear bearing surface. But is that relevant today with the other, lower cost bearing options we have? Probably not. When you examine the wear data on conventional poly with ceramic, it probably makes a significant difference…especially when you're comparing ceramic on old polyethylene or metal on old polyethylene with modern CoC. But when you look at highly crosslinked polyethylene (HCLP) it almost doesn't matter what bearing surface you use…it's hard to generate wear that will lead to lysis."

"We did a study looking at retrieved femoral heads in revision hip surgery. If you look at roughness of femoral heads up against conventional poly, as the femoral heads get rougher the wear volume increases, thus increasing the risk for osteolysis and loosening. However, when you take the same femoral heads at five million cycles against HCLP, it was less than 0.1 mg of wear."

"The negatives of CoC? One of the biggest is value…and whether you live in China, Australia, or the U.S., we're going to have to bring the cost of implants down. I was told that in China it costs more than $1,000 extra to do a CoC THA. To justify that you must reduce the revision risk. The revision rate in the U.S. with different bearing surfaces, comparing metal-on-plastic with CoC it's clear that with regard to revision rates there's no difference between metal-on-plastic and CoC. That is despite the fact that both bearing surfaces are used at high and low volume hospitals and in young and old patients."

"Registry data from Australia shows that the best performers are ceramic on poly and metal on poly. There is an increasing interest in the use of ceramic femoral heads in the U.S. because of possible taper corrosion. Until we figure that out I'm using ceramic heads in my younger patients."

"We have ten-year data on HCLP from our center on patients under the age of 50; there are no revisions for osteolysis and one case of osteolysis that you cannot see on an X-ray. There is some CT scan data showing some small osteo-

lytic lesions; people are saying, 'That's osteolysis caused by HCLP.' Remember, osteolysis can be caused by fluid pressure, and we don't have the same data on CoC. The good news is that large ceramic heads do better than small ceramic heads."

"But it's a more demanding procedure, and if you get it in wrong you're going to have an increased risk of problems. As for breakage, you can't predict who is going to break. The new Delta ceramic is much better; it's a harder material and the fracture risk will continue to decrease. Part of the risk of fracture is that we surgeons don't assemble it right."

"The other issue is squeaking. Patients who squeak don't like it. I will close by saying, 'you can squeak by with CoC, but it's not the new standard.'"

Dr. Walter: "Dr. Maloney showed lab studies of polyethylene, but what they don't include is oxidation in vivo. There is work from Harvard showing that the HCLP we've been using for 10 years reoxidizes and returns to the higher wear state. We heard 5 – 10 years ago that HCLP was going to be 'the answer,' but now there's a strong scientific argument that this isn't enough…that it needs to be laced with vitamin E to stop the free radical formation. Regarding revision rates, all of the data that was presented was less than 10 years; when you're using a CoC bearing you're thinking about 30 – 40 year survival of the hip. We're looking to put a hip in our young patients that will last many decades…and we don't have the data in terms of revisions, either from the registries or from small studies, about how the HCLP will be long term. But we do know that CoC bearings have lower wear, so we expect them to last longer (20/30/40 years)."

Dr. Maloney: "Retrieval data is being re-evaluated as it relates to what actually is oxidizing in that material. We certainly haven't seen it clinically in terms of 10-year data from Sweden and 8 – 10 year data from the U.S. The clinical significance of that is questionable and probably not relevant. We always say, 'We have a 30/40 year hip.' I've been doing this for 25 years and I've never seen a good 30 or 40 year paper; we keep changing things. So the implants that Bill is putting in today aren't the implants he put in 10 years ago. And if you're paying for this operation in today's world you going to look at a justification for increased cost. If you examine the 10 year revision data for bearing surfaces—metal-on-plastic, ceramic-on-plastic, or CoC—they are not different."

Moderator Duncan: "Bill, what about the revisability of the failed ceramic."

Dr. Walter: "We've had about 4,000 CoC bearings and have had three liners break and no femoral head breaks."

Moderator Duncan: "But the ones that have been referred into you perhaps because there was edge loading or something."

Dr. Walter: "If you have a broken ceramic head you need to revise the stem because the head taper will be damaged and you can exchange the ceramic insert. If you have a ceramic breakage on the acetabular side then you need to revise the cup, and you can retain the stem and change the head."

Moderator Duncan: "So you change the stem because the trunion has become damaged by the fractured head?"

Dr. Walter: "Correct.

Moderator Duncan: "You can't use a titanium adaptor?"

Dr. Walter: "We've never revised a broken ceramic head because we've never seen one. Because of the soft metal head articulating against the fragments of ceramic it damages the taper much more severely than with corrosion or another form of failure. In that situation I would study the head, and if the patient had been walking on it with a broken head then it would be too much damage to the trunion."

Moderator Duncan: "Bill, if you have a young active patient who requires a 28/32mm head are you going with that? Or is it when you're faced with a 36mm head and your large patient favors that so as to reduce the risk of instability?"

Dr. Maloney: "I haven't used a 28mm head in more than five years, so I would use a ceramic 32mm head in a young, active patient; in an older patient I'd use a cobalt chrome head. For 36mm I tend to use mostly ceramic…and that's solely for the taper corrosion issue. In our own practice we've got about 1,000 36mm heads in and I've not seen a case of taper corrosion. And assembling it wet through small incision surgery is a risk factor with cobalt chrome on titanium."

Moderator Duncan: "Bill, what's happened to vitamin E poly? We're not hearing about this lately."

Dr. Maloney: "We did a randomized clinical trial (RCT) and we just got the five-year results. As you might expect it's looking good…the same as the Longevity or other HCLPs that we have RCT data on. It tends to bed in at about a year and after that it flattens out; at five years we're measuring no wear from the one to five year standpoint." ♦

Please visit www.CCJR.com to register for the 2014 CCJR Spring Meeting, May 18 - 21 in Las Vegas, Nevada.

Landmark Agreement on Joint Infection Protocols // NFL, GE Tap UPMC to Study Concussions // Finally! THE Book on Failed ACL Reconstruction >>

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

Landmark Agreement on Joint Infection Many have tried, few have succeeded. However, Javad Parvizi, M.D., director of research for The Rothman Institute in Philadelphia, has managed to get orthopedic surgeons from around the globe to agree on not one, but 207 issues! Dr. Parvizi tells *OTW*, "Finally, after years of trying to obtain consensus on infection-related issues, we have succeeded. Our recent meeting drew 400 participants from 52 countries; we developed 207 infection-related questions, voted on each one, and then made recommendations to establish 'set in stone' protocols for surgeons worldwide. We then published these recommendations in several journals, and printed and distributed 15,000 copies of the resulting book that is being translated into more than 20 languages."

United States Navy

"Incredibly, we were able to arrive at a consensus on 203 of the 207 questions. One of the main areas of consensus was to reach a definition for PJI [periprosthetic joint infection]. Infection of a joint usually presents with pain and relying on isolation of an infecting organism from the joint cannot be relied on as a gold standard. Thus, there are so many different definitions of what constitutes PJI. The consensus meeting accomplished the difficult task of reaching an acceptable definition. The Centers for Disease Control (CDC) will adopt our definition of periprosthetic joint infection moving forward. This is very exciting because many of the things we do in clinical practice vary greatly from place to place; that will no longer be the case when it comes to joint infection."

"Some of the questions we addressed included, "'Should you change gloves during surgery and if so, how often?' 'Which antibiotics should be administered to patients prior to surgery and for how long?' There were four questions that did not reach a consensus. One was, 'What type of dressing should be used after surgery?' It turns out that surgeons feel pretty wedded to the dressing they are accustomed to, and it works in their hands so they did not want to make a change. We attempted to get people to switch to occlusive dressings, but despite evidence to the contrary, some are still under the impression that a regular change of dressing is necessary. Another point that did not reach a consensus was the use of tantalum. There is some research showing that tantalum can provide protection against infection, but not everyone was in agreement on this issue."

"As a follow-up to the meeting, each participating country has organized a consensus dissemination meeting. Our biggest goal is to determine if the implementation of these consensus items will make a difference in surgical site infec-

tions. We are working with the CDC to measure the impact of the consensus, focusing on which regions of world can be most impacted by these guidelines."

"It's interesting to note that some of the questions we discussed don't lend themselves to level 1 studies. For example, 'Should one do the joint replacement in a laminar flow room?' or 'Should you add antibiotics to the irrigation solution? Not everything we know and practice in medicine has been developed as a result of level 1 studies. Many of our practices are in fact based on the observation of scholars and great thinkers from the past. For example, there is no level 1 study on the use of glove during surgery. Would anyone dare do a randomized, prospective study evaluating this issue? There are many other related issues in medicine that cannot be subjected to randomized, prospective study and requires the cumulative wisdom of experts. The meeting we held was intended to do this exactly. We have accomplished an important step in improving care for our patients in terms of minimizing infection in orthopedics with all its dreaded consequences. Going forward, the consensus guidelines should make a significant impact on patient care."

Finally! THE Book on Failed ACL Reconstruction What major resource can surgeons avail themselves of when dealing with a failed ACL [anterior cruciate ligament] reconstruction? Until now, none. Robert G. Marx, M.D. is an orthopedic surgeon on the Sports Medicine and Shoulder Service at Hospital for Special Surgery (HSS). He has recently written a textbook—"Revision ACL Reconstruction: Indications and Technique"—that tackles this challenging problem. Dr. Marx, also a professor of Orthopedic Surgery and a professor of Public Health at Weill Cornell Medical College, tells *OTW*, "I was approached by Springer to write this book after I delivered a presentation on failed ACL reconstructions; the editor indicated that there was no textbook that could serve as a reliable resource for orthopedic surgeons regarding such cases. It was an incredible learning process as it became clear that no matter how 'expert' one is at something, there is always more to be learned. For example, the chapter on revising failed double bundle reconstruction was particularly enlightening and interesting because the author (Freddie Fu, M.D.) had a significant amount of experience with these surgeries, something that isn't normally the case. He provided vital guidelines on when to revise a double bundle to a single bundle revision and when it may be better to revise a double bundle to another double bundle."

"By including authors from every continent we were able to gather different points of view. For example, in Japan

they use a different technique—a rectangular femoral socket. Patients there are often smaller so these surgeons have more experience with small stature patients; their techniques for smaller people are unique."

"The critical thing with revision ACL reconstruction is that each patient is often very different. Some cases can be very simple, whereas others are quite challenging because of the technical considerations (prior tunnel placement or expansion, location of prior hardware, type of hardware etc.). Because of this you must have a lot of different techniques that you are comfortable with. And you must not only have a plan, but you must be ready to alter your plan. The fact that we have so many authors from different countries is especially valuable for revision ACL reconstruction because these cases require these cases benefit from a wide variety of approaches."

UPMC Tapped by NFL, GE to Study Concussions To whom did the NFL turn to further the science of brain injury? The University of Pittsburgh Medical Center (UPMC). Michael Collins, Ph.D. is director of the UPMC Sports Medicine Concussion Program. He tells *OTW*, "When the NFL and GE decided to work together to fund research on diagnosing concussions they put out a call for proposals. Out of the 402 they received only 16 were funded. This work is so important because to date we have had no imaging or biomarker to delineate concussions. We have been utilizing a neurocognitive test but, while that information is very useful and of significant importance from a functional standpoint, it is an indirect measure of brain function and only one tool in our concussion medicine kit."

"Our project involves an advanced imaging high definition fiber tracking that is based on standard MRI sequences. Traditional imaging cannot reveal subtle damage that can be caused by a mild traumatic brain injury. Using advanced computational methods we will be able to look at the white matter in the brain and determine—with great sensitivity and specificity—if there is a fracture or breakage of any sort. At this point we are not looking at use for the playing field, but within the first seven days after an injury. If a child is injured and a diagnosis of concussion is reached, then we will conduct a functional assessment, employ the fiber tracking, follow them, and reimage them when they return to

play. We will begin enrolling patients in about two weeks and expect to have preliminary results in approximately six months."

"If you have a knee problem we can rely on evidence-based ways to determine the prognosis, who will be quickest to recover, etc. Our goal is to make brain injuries just like any other injury. Every step that we've taken is scientifically geared toward understanding the phenomenology of this issue."

"In 2000 when Freddie Fu, M.D. recruited my colleagues and I [sic] to UPMC no one was focusing on concussions. Dr. Fu could see that this issue would only increase in importance, and he had foresight to bring our program into the sports medicine division. At UPMC we have the largest concussion program in the world, with over 20,000 patient visits annually. This work will go a long way towards increasing the safety of our most popular national sport."

Robert A. Kayal, M.D. Receives Compassionate Doctor Award Robert A. Kayal, M.D., founder, president, and CEO of Kayal Orthopaedic Center in New Jersey, has been awarded the Compassionate Doctor certification. This recognition is given by Vitals, a doctor review site where patients can provide online reviews and vote for their favorite doctors.

The award is given to doctors who go above and beyond in treating their patients with kindness. The award is based on a doctor's overall and bedside manner scores. Doctor Kayal serves on the medical staff at The Valley Hospital, The Hackensack University Medical Center, Chilton Hospital and is the Director of Orthopaedic Surgery at Patient Care Associates. ♦

COMPANY

Wright Acquires Solana, OrthoPro

Wright Medical Group, Inc. has announced the acquisition of both Solana Surgical, LLC and OrthoPro, LLC.

Robert Palmisano, president and chief executive officer of Wright, commented in the January 30, 2014 news release, "The acquisitions of Solana and OrthoPro are excellent fits for our Extremities business, enabling us to add a base of fast-growing extremity revenue that we can effectively grow on a go-forward basis. Both of these transactions meet our criteria of being accretive to revenue growth and adjusted EBITDA. In addition, products from both companies will complement our existing foot and ankle portfolio and include several specialized products that expand our extremities product offering. Both companies have a reputation for leading innovation, and we anticipate that their products will help expand Wright's position as the definitive technology leader in the foot and ankle market."

Alan Taylor, chief executive officer of Solana, added, "We are delighted to partner with a company that shares Solana's commitment to building a high-growth Extremities business. We believe that Wright Medical, with its global leadership position in the foot and ankle market and expertise in medical education and product development, is the ideal partner to accelerate our growth and realize the full potential of Solana's products around the world. We look forward to an exciting future and the continued success of our business as part of Wright Medical."

Dustin Leavitt, chief executive officer of OrthoPro, commented, "This combination will provide the opportunity for further expansion of OrthoPro's innovative products to support market growth and procedure penetration worldwide. We look forward to advancing our foot and ankle business with the recognized leader in the foot and ankle market."

Lance Berry, CFO for Wright, told OTW, "The acquisition of Solana Surgical and OrthoPro are right in line with our stated strategy to pursue targeted M&A to accelerate growth opportunities and profitability in Wright's extremities business. Both companies have excellent products that will fit well with our current product portfolio."

—EH (February 5, 2014)

Logos courtesy of Wright Medical, OrthoPro and Solana Surgical

Judge Approves $56 Million Biomet Metal Hip Settlement

A federal judge approved settlement of Biomet, Inc.'s metal-on-metal hip lawsuits on February 3, 2014. The company now joins Johnson & Johnson's (J&J) DePuy Synthes Companies and Stryker Corporation in announcing some settlements of consolidated lawsuits.

buzzle.com and RRY Publications LLC

M2a Magnum System

The cases in Biomet's litigation primarily involved alleged defects in Biomet's M2a Magnum system of hip implant products. Plaintiffs' claims focused upon the metal-on-metal design of the system and the alleged propensity of the devices to generate high levels of metal ions, causing metallosis in the surrounding tissue, and/or early failure.

Almost 900 cases had been filed in Indiana federal court against Biomet. According to a Scheduling Order issued on December 10, 2013, U.S. District Judge Robert Miller had directed parties to choose three cases as trial candidates by February 7, 2014.

$56 Million for Patients and Lawyers

Reuters reported that the company will pay at least $56 million in the settlement. That's far less than the $2.5 bil-

lion-plus settlement agreed to by J&J or the limited settlement of four Stryker cases in New Jersey at the beginning of December.

As part of the settlement, *Reuters* reports that Biomet will deposit $50 million into an escrow account and another $6 million into an attorney fee fund. The agreement extends to all pending cases, and any future lawsuit filed in a federal court on or before April 15, 2014.

Plaintiffs who have received a Biomet M2a 38 or M2a Magnum hip replacement system as part of an initial hip replacement that was rectified more than 180 days after it was implanted shall, reportedly, receive a base award of $200,000.

According to ***Reuters,*** Biomet maintains that the injuries, losses and damages were not due to its hip implants. The company issued a press release saying it is pleased to have reached this settlement: "Biomet appreciates the guidance provided by Judge Miller to bring this litigation to an expeditious and efficient resolution."

—*WE (February 4, 2014)*

Amedica Seeks $35 Million in IPO

Amedica Corporation plans to raise $35 million in the company's initial public offering (IPO).

According to *nasdaq.com*, the announcement was made on January 29, 2014. The Salt Lake City, Utah-based maker of medical devices using its silicon nitride technology platform plans to offer 3.2 million shares at a price range of $10 to $12. At $11 per share, Amedica would command a fully diluted market value of $143 million. The planned NASDAQ symbol is AMDA.

The company reportedly booked $23 million in sales for the 12 months ended September 30, 2013. The initial Securities Exchange Commission (SEC) filing was done confidentially on September 23, 2013 and filed publicly on November 8, 2013. It wasn't the first attempt to go public, as the company previously filed for an IPO in May 2007, before withdrawing the offering three months later based on market conditions. JPM Securities is reportedly the sole bookrunner on the deal.

The company's products are aimed at the orthopedic and spinal markets. The company makes interbody devices used in spinal fusion procedures; their semi-radiolucent silicon nitride material is designed to promote bone growth and help prevent infection.

Over the last few months, the company signed an agreement with Kyocera Industrial Ceramics Corporation for the commercial manufacturing of silicon nitride medical devices and a partnership with K2M, Inc. to expand the distribution of interbody spinal fusion devices in Europe.

Amedica is privately owned and was founded in 1996. The company operates an ISO 13485 certified manufacturing facility, and, its spine products are FDA cleared, CE marked, and are currently marketed in the U.S. and select markets in Europe and South America.

—*WE (February 3, 2014)*

Amedica Corporation

LEGAL

Record Number of Healthcare Fraud Prosecutions in 2013

The Justice Department's Medicare Fraud Strike Force set a record for numbers of healthcare prosecutions in 2013.

The strike force filed 137 cases, charged 345 individuals, secured 234 guilty pleas and succeeded in securing 46 jury trial convictions. The defendants charged and sentenced are facing an average of 52 months in prison.

The strike force is currently operating in nine cities: Baton Rouge, Louisiana; Brooklyn, New York; Chicago, Illinois; Dallas, Texas; Detroit, Michigan; Houston, Texas; Los Angeles, California; Miami and Tampa, Florida. Since its inception in March 2007, strike force prosecutors have charged more than 1,700 defendants who have collectively billed the Medicare program more than $5.5 billion.

ROI

According to a recent report by the Inspector General for the U.S. Department of Health and Human Services, for every dollar the Departments of Justice and Health and Human Services have spent fighting healthcare fraud, they have returned an average of nearly eight dollars to the U.S. Treasury, the Medicare Trust Fund and others.

U.S. Attorney General Eric Holder said, "By targeting our enforcement efforts to 'hot spots' in nine cities, the Medicare Fraud Strike Force is allowing us to fight back more effectively than ever before."

"Under the supervision of the Criminal Division and U.S. Attorney's Offices, the Medicare Fraud Strike Force is formed by coordinated teams of investigators and prosecutors—including personnel from the Justice Department, the U.S. Department of Health and Human Services and the FBI—who analyze Medicare claims data to target specific geographic areas showing unusually high levels of Medicare billing."

A January 27, 2014 statement from the Justice Department stated that "by focusing on the worst offenders engaged in current fraud schemes in the highest intensity regions, the strike force seeks to deter fraud in the target community and prevent it from spreading to other areas. "

"Nationwide Takedown"

An example of the investigations involved the May 2013 "nationwide takedown" by the strike force in eight cities that resulted in charges against 89 individuals, including doctors, nurses and other licensed medical professionals, for their alleged participation in Medicare fraud schemes involving approximately $223 million in false billings.

The defendants were charged of committing various health care fraud-related crimes, including conspiracy to commit health care fraud, violations of the anti-kickback statutes and money laundering. The charges were based on a variety of alleged fraud schemes involving various medical treatments and services, primarily home health care, but also mental health services, psychotherapy, physical and occupational therapy, durable medical equipment (DME) and ambulance services.

The defendants allegedly participated in schemes to submit claims to Medicare for treatments that were medically unnecessary and often never provided. In many cases patient recruiters, Medicare beneficiaries and other co-conspirators were paid cash kickbacks in return for supplying beneficiary information to providers, so that the providers could then submit fraudulent billings to Medicare. Collectively, the defendants were accused of conspiring to submit a total of approximately $223 million in fraudulent billing.

Overutilization and Physicians

As we reported recently, the government is taking a new direction in prosecuting providers not just for patently criminal conduct, but under the anti-kickback statute in the context of overutilization due to alleged physician conflicts of interests.

—*WE (January 29, 2014)*

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BIOLOGICS

Stem Cells Help Bridge Nerve Gap

A research team in Milan, Italy has used skin-derived stem cells (SDSCs) along with a collagen tube designed to successfully bridge gaps in injured nerves in rat models to rescue the peripheral nerves in the upper arms of a patient who, otherwise, would have had to undergo amputations. The researchers have followed up on the patient for three years using, among other tests, electrophysiological and MRI examinations.

"Our three-year follow up has witnessed nerve regeneration with suitable functional recovery in the patient and the salvage of upper arms from amputation," wrote the researchers. "This finding opens an alternative avenue for patients who are at-risk of amputation after the injury to important nerves." The study will be published in a future issue of *Cell Transplantation*.

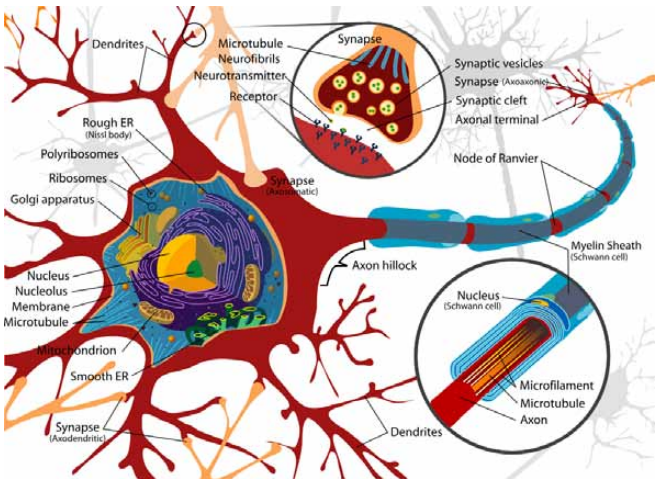
Yvan Torrente, M.D., of the Department of Pathophysiology and Transplantation at the University of Milan, acknowledged that peripheral nerve repair with satisfactory functional recovery is a great surgical challenge, especially for severe nerve injuries. "However," he said, "we hypothesized that the combination of autologous (self-donated) SDSCs placed in collagen tubes to bridge gaps in the damaged nerves would restore the continuity of injured nerves and save from amputation the upper arms of a patient with poly-injury to motor and sensory nerves."

According to the researchers, autologous SDSCs have advantages over other stem cells as they are an accessible source of stem cells that are rapidly expandable in culture and are capable of survival and integration within host tissues.

The technique of using the collagen tubes had been previously tested saving the damaged sciatic nerves on rats, but this is the first trial to have been carried out on a human patient.

Camillo Ricordi, M.D., co-editor-in-chief of *Cell Transplantation*, said," This single case study provides the first step towards a proof-of-principle for a new treatment for peripheral nerve injury" Stacy Joy Goodman, Professor of Surgery and Director of the Cell Transplant Center at the University of Miami, pointed out that "Further studies will be necessary to determine whether the work in this report could be validated, introducing a novel therapeutic strategy for peripheral nerve injury".

—*BY (February 3, 2014)*



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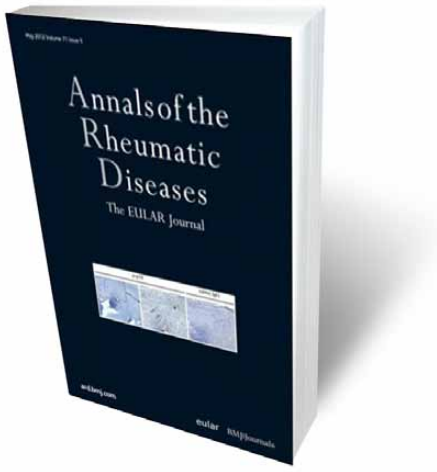
Hormone Replacement Therapy Cuts Revision Risk 40%

What does hormone replacement therapy (HRT) have to do with repeat surgery for a knee or hip replacement? Apparently a lot, according to the results of a large population-based study published online in the *Annals of the Rheumatic Diseases*. The study found that HRT, taken regularly for six months after a knee or hip replacement, seemed to cut the risk of repeat surgery by around 40%.



Courtesy of Annals of Rheumatic Diseases

The research team assessed the likelihood of repeat joint replacement surgery among women who required a first knee or hip replacement between 1986 and 2006. The details of their surgery had been entered into the primary care General Practice Research Database (GPRD), which holds millions of medical records for patients across the UK. The national data revealed that about 75% of the procedures had to be repeated because of osteolysis. Osteolysis occurs when particles from the implant seep into the surrounding tissue, prompting an inflammatory response which then destroys the bone around the implant.

More than 21,000 women eligible for the study had not used HRT, while more than 3,500 had done so for at least six months. The data provided matched samples of 2,700 HRT users and 8,100 women who had not used HRT. The researchers tracked the risk of repeat surgery in both sets of women for a minimum of three years.

Those who had taken HRT regularly for six months or more after their surgery were 38% less likely to require repeat surgery than were those who had not done so. Those who regularly took HRT for 12 months or more after their procedure were more than 50% less likely to need further surgery during the three year monitoring period.

Taking HRT before surgery made no difference to the risk of implant failure, the findings showed.

The authors of the study claim that this is the first study to show that HRT can help prevent repeat surgery in women who have undergone hip/knee replacements.

—BY (February 4, 2014)

LARGE JOINTS

VERASENSE Removes TKA Guesswork

A new device, made by OrthoSensor Inc. and called the VERASENSE, will do away with guesswork when a surgeon is quantifying soft tissue balance during a total knee arthroplasty (TKA), according to company officials. As described by James Snodgrass, writing for *European Plastics News*, the VERASENSE is a sterile, disposable plastic sensor that is placed between both plates of the replacement joint. The device uses sensor and accelerometer technologies to sense dynamic loads, the contact point of the femur through a full range of motion and verifies the alignment of limbs.

Snodgrass quotes Peter Walker, Ph.D. of New York University's Langone Medical Center, who said, "At the moment the surgeon relies on skill, experience and a lot of instrumentation to shape the bones so that they will accept the components very accurately. But one of the more difficult parts of the surgery is getting the knee to move very, very smoothly after the components are placed. It is a very, very difficult job because every patient is different.

"You are dealing with structures that have been arthritic, the joint surfaces have been arthritic, and you have to put the components in a very perfect alignment to restore what the knee was like when the knee was healthy. One of the things that can happen is a restricted range of motion. Everybody wants to get at least 120° if possible," he said.

The device's measurement of inter-compartmental loads and centre-of-load data provide a reference to determine the optimum placement of the tibia and femur and optimum balance of ligaments through a full range of motion. Thus, according to the company, the doctor can make evidence-based decisions regarding component position, soft tissue releases and limb alignment rather than relying on experience.

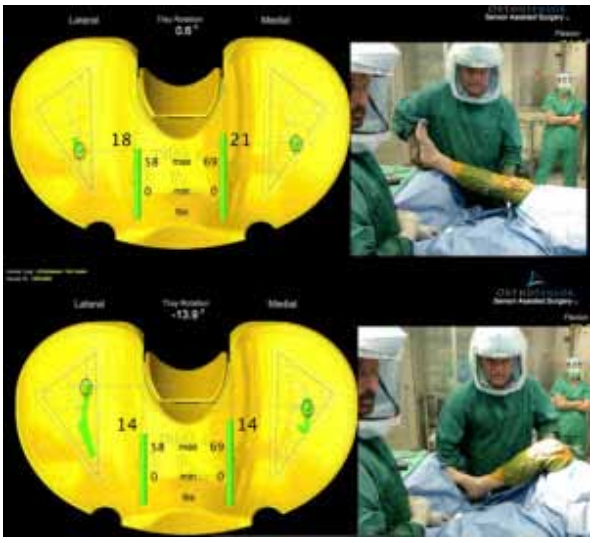
"The idea is to get the forces exactly equal on both sides of the knee, so the knee is perfectly balanced," said Walker, "so when you use it later on, in function, it will move very smoothly and be very stable."

The disposable device connects wirelessly to a transceiver and information is sent, via the transceiver, to control software on the surgeon's PC.

Because of its direct contact with exposed tissue, biocompatibility of the device was crucial. The case is injection molded in four sizes from Bayer MaterialScience's Makrolon Rx1851 polycarbonate. According to Snodgrass, the VERASENSE received U.S. Food and Drug Administration clearance for limb alignment in June 2013 and received European CE approval in October 2013. The company has now launched the product in the European market.

"We're pleased to have successfully achieved CE Mark for our VERASENSE technology," said Jay Pierce, OrthoSensor president and CEO. "This enables us to provide OrthoSensor's innovative technology to orthopaedic surgeons and patients in markets outside the US and creates significant growth opportunities for our business."

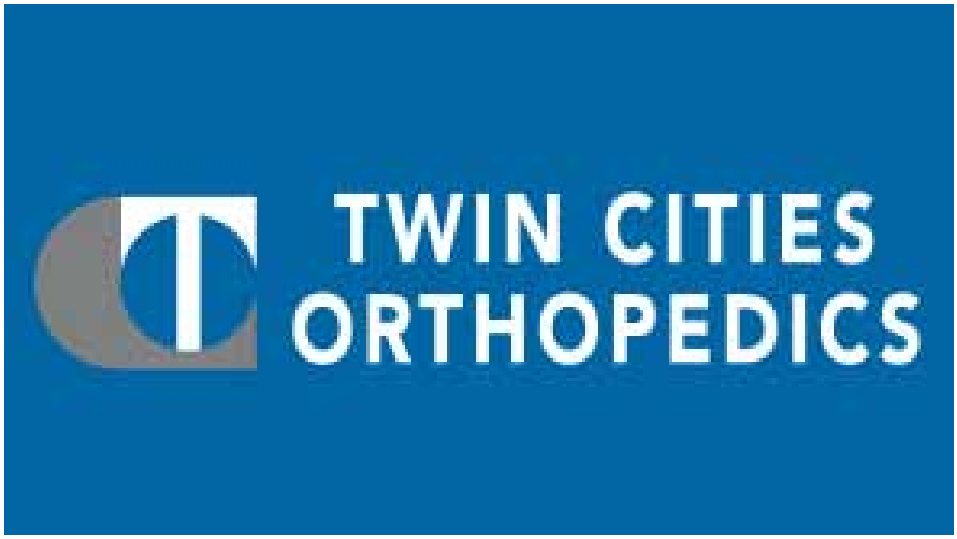
—BY (February 4, 2014)



Courtesy of Martin W. Roche, M.D., Chief of Orthopedics and Director of the Holy Cross Orthopedic Institute, Fort Lauderdale, Florida

EXTREMITIES

$24k for Hip, $21k for Knee



Courtesy of Twin Cities Orthopedics

Twin Cities Orthopedics (TCO), of Golden Valley, Minnesota, which *OTW* reported in 2012 was providing one-bill knee replacements, is now offering the same program for hip, shoulder and ankle procedures. The program bills patients once for all aspects of the procedure, from medications to the surgery to physical therapy during recovery. Patients recover in suites resembling spas, managed and professionally staffed by Twin Cities Orthopedics instead of in hospitals.

Only one Twin Cities insurance company, Medica, is currently covering the cost for the one-bill joint replacement procedures. Twin Cities Orthopedics has performed approximately 50 of the one-bill knee replacement surgeries since inaugurating the system two years ago. CEO Troy Simonson says that a hip replacement procedure at TCO, under the one-bill system, costs about $24,000 and a knee joint replacement is $21,000.

—*BY (February 7, 2014)*

TRAUMA

Home Plate – Baseball's Danger Zone

It is the collisions at home plate, when a runner is almost home, that causes the most injuries. Professional baseball players are much more apt to be injured there than in any other type of base-running plays, according to a study led by Daryl Rosenbsaum, M.D., a sports medicine physician at Wake Forest Baptist Medical Center, Illinois.

Major League Baseball owners recognize that this is a serious problem and have proposed a rule change—still not acted upon—that would reduce the risk of injury when catchers try to block runners heading for home plate.

Researchers looked at data from the 2002 to 2011 baseball seasons and found that plays at home plate resulted in 4.3 times more injuries than other base-running plays. The injuries were severe enough that an average of three players per season had to be placed on the 15-day disabled list.

The injuries also cost teams an average of about $2.3 million a season according to the study, which was published in the *International Journal of Sports Medicine*. "That's just the financial impact. More difficult to quantify but also worth considering are the players' health and the effect of their absences on their teams' performance," said Rosenbaum, in a Wake Forest news release.

"I don't think fans go to Major League baseball games to see collisions, and I don't think if you remove them it would change the inherent nature of the game," he added. "Why are collisions allowed in this one scenario when they're not really part of the game?" A collegiate rule already prohibits catchers and other defensive players from blocking home plate and other bases.

—BY (February 7, 2014)

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Girls' Soccer Concussions Go Untreated

Many middle school girl soccer players experience concussions and most continue to play with their symptoms. That is the result of a study conducted by John W. O'Kane, M.D., of the University of Washington Sports Medicine Clinic, Seattle, and his colleagues, and reported by The JAMA Network. Unfortunately, although

Wikimedia Commons and albertherring

50,000 soccer-related concussions take place among high school players every year, injury-tracking systems for younger players are lacking. As a result, their experience is largely unstudied, according to O'Kane.

The study authors evaluated the frequency and duration of concussions in 351 female soccer players, ages 11 to 14 years, as well as whether the injuries resulted in stopping play and seeking medical attention. The girls played in soccer clubs in the Puget Sound region of Washington.

Among the 351 players, there were 59 concussions that resulted from 43,742 athletic exposure hours. Cumulative concussion incidence was 13% per sea-

son with an incidence of 1.2 per 1,000 athletic exposure hours. Symptoms lasted for a median of four days with the average of 9.4 days (concussion symptoms can include memory loss, dizziness, drowsiness, headache and nausea). Heading the ball accounted for 30.5% of the concussions. Most players, 58.6%, continued to play with symptoms, while almost half, 44.1%, sought medical attention, according to the results.

The authors note that the rate of 1.3 concussions per 1,000 athletic exposure hours was higher than what has been reported in other studies of girls' soccer at the high school and college levels.

"Future studies are needed to develop education strategies to ensure players understand and report concussion symptoms and that parents and coaches ensure appropriate medical evaluation and clearance before returning to play," the authors conclude. "Future studies should also compare short- and long-term outcomes for those who seek medical care and return to play according to recommended guidelines vs. those who do not seek medical care and/or return to play prematurely."

—BY (February 4, 2014)

REIMBURSEMENT

Hospitals Cut Ortho Costs, Grow Earnings

While hospitals expect to cut costs for orthopedic devices, they expect their earnings to grow in 2014.

Hospital purchasing managers expect a slight improvement in procedure growth and mixed pricing trends in 2014. In addition hospital cost-reduction efforts will continue to be most focused on orthopedics.

Those are the findings of a survey of 106 hospital purchasing managers conducted by Needham & Company and reported by their analyst, Mike Matson, on February 6, 2014. The survey was sent to approximately 2,100 U.S. hospital purchasing managers and received responses from 106 participants, which results in a response rate of about 5%.

Cost Reductions Focused on Hips and Knees

Matson reported that most respondents indicated that they were most focused on reducing costs of hip and knee implants, followed by spinal implants, pacemakers, implantable cardiovert-

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er defibrillators (ICDs), drug-eluting stents (DES), vascular access products, endoscopic/energy products, urology products and hernia products.

This result, said Matson, is consistent with his belief that hospitals are more focused on reducing their spending on the higher-cost physician-preference items, such as hip and knee implants, than they are on lower-cost items, such as urinary catheters.

Not surprisingly, said Matson, the findings correlate with procedural profitability. "On average all procedures we asked about are profitable. But the degree of profitability varied with hip and knee procedures being the least profitable (profitable at 53% of respondents' hospitals) followed by spine fusion procedures (56%), ICD procedures (66%), DES procedures (84%), and pacemaker procedures (85%)."

Decreased Selling Prices

Respondents expect reconstructive average selling prices (ASPs) to decrease by 2.7% in the next 12 months (NTM) after decreasing by 2.7% in the last 12 months (LTM). "Respondents expect spine ASPs to decrease by 3.3% in the NTM after increasing by 1.0% in the LTM. Recon procedure growth is expected to increase to 1.8% in the NTM from 1.4% in the LTM and spine procedure growth is expected to increase to 1.1% in the NTM from 0.9% in the LTM."

Procedure Growth

Respondents expect spine procedure growth to improve by 0.2% to 1.1% from 0.9%, in the next 12 months while hip and knee replacement procedure growth to improve by 0.4% to 1.8% from 1.4 % in the next 12 months.

"In the NTM, Johnson & Johnson (JNJ) looks likely to gain the most U.S. recon share while Biomet, Inc. looks likely to lose the most. And JNJ looks likely to gain the most U.S. spine share while Medtronic, Inc. looks likely to lose the most," added Matson.

Hospital Earning Growth

In a separate, but related, news item, HCA Holdings, the largest hospital operator in the U.S., said its net income grew 35% in the fourth quarter, crediting the Affordable Care Act (ACA). The company said adjusted earnings could grow as much as 4% in 2014, with 1 to 2% of that attributed to the ACA. The hospital system didn't mention cutting payments for orthopedic devices.

—WE (February 9, 2014)

PEOPLE

Amedica Names Jeff White to Board

The directors of Amedica Corporation, a biomaterials company based in Salt Lake City, Utah, has named Jeff White to its board of directors. White is presently head of MedTech Advisory Group, LLC, a firm that advises mid-stage medical technology firms. Prior to founding MedTech, White served as global director of Business Development for Synthes, a multi-billion dollar global orthopedic firm that Johnson & Johnson acquired in 2013.

White also co-founded two medical device companies including Applied

Jeff White/Amedica

Spine Technologies, Inc. where he led efforts to develop innovative spinal devices for patients suffering from spinal injuries or degeneration. He has held various positions with US Surgical Corporation and Richard Allan Medical Industries, Inc.

"We are fortunate to welcome Jeff as the newest addition to our board of directors," said Eric Olson, president and chief executive officer of Amedica Corporation. "His extensive background and experience in bringing novel technology solutions to market will help Amedica position itself for success as we look to enter new markets with our Silicon Nitride technology platform."

Amedica is a privately owned company founded in 1996 that markets spinal fusion products and is developing other products for use in total hip and knee joint replacements.

—BY (February 7, 2014)

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