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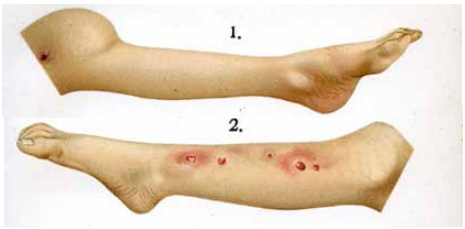
Orthopedics This Week

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: While orthopedic equity valuations ended 2013 up a champagne popping 33%, in 2014 investors, we think, will sit on their investments or take profits. No way orthopedic equity valuations rise in 2014 at the same torrid rate as 2013. Orthofix, Symmetry and Baxano, however, could well have strong rebound years in 2014.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	6	Orthofix	16.25%	10.42%	At 10.92x trailing earnings, OFIX's P/E is not only the lowest in ortho, it is also way below the general market's 15x.
2	1	Integra LifeSciences	11.77	2.57	If Wall Street's analysts are right, IART will post up 25–30% earnings gains on a $100 million more sales in 2014.
3	5	Conmed	10.37	7.61	CNMD has been attracting buyers for the last four months and the stock price reflects that. Still comparatively cheap at these P/E rates.
4	4	Symmetry Medical	6.50	6.00	SMA is paying off its mezzanine debt sooner than expected. Should have a major upside effect on earnings in 2014.
5	8	Zimmer	27.31	2.85	2014 will be the year of the knee—which plays to ZMH's strength. 2014 should be a record TKA unit shipment year.
6	9	Stryker	15.22	2.11	Like ZMH, SYK's knee business is trending upward and should stay strong well into and beyond 2015.
7	2	Exactech	10.00	1.96	As we expected, investors like their 35% gains in EXAC from 2013, but now want to take profits.
8	3	Globus Medical	28.53	2.03	Most analysts think GMED will report flat earnings for Q4. Yet they also forecast 12% sales growth. So declining margins?
9	7	NuVasive	6.30	0.34	Zacks just reiterated its "Strong Buy" for NUVA. But NUVA is acting like investors want to just sit on the stock.
10	10	Medtronic	28.84	2.45	MDT's new regional headquarters is in Shanghai. China has yet to move MDT's sales or earnings growth rates.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	$8.43	$872	24.70%
2	Bacterin Intl Holdings	BONE	$0.51	$27	20.76%
3	Aurora Spine	ASG	$3.60	$45	18.44%
4	RTI Biologics Inc.	RTIX	$3.45	$195	13.49%
5	TiGenix	TIG.BR	$0.71	$114	13.14%
6	Orthofix	OFIX	$23.11	$450	10.42%
7	Alphatec Holdings	ATEC	$2.07	$202	8.95%
8	Conmed	CNMD	$42.41	$1,171	7.61%
9	Tornier N.V.	TRNX	$18.64	$904	6.88%
10	Symmetry Medical	SMA	$9.90	$369	6.00%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Johnson & Johnson	JNJ	$91.85	$259,149	-1.90%
2	MAKO Surgical	MAKO	$29.99	$1,544	0.13%
3	NuVasive	NUVA	$32.49	$1,450	0.34%
4	Baxano Surgical Inc.	BAXS	$1.11	$50	1.83%
5	Exactech	EXAC	$24.44	$331	1.96%
6	Globus Medical	GMED	$19.59	$1,827	2.03%
7	Stryker	SYK	$74.84	$28,321	2.11%
8	Wright Medical	WMGI	$30.22	$1,423	2.30%
9	Medtronic	MDT	$58.34	$58,244	2.48%
10	Integra LifeSciences	IART	$47.81	$1,536	2.57%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$23.11	$450	9.28
2	Medtronic	MDT	$58.34	$58,244	15.69
3	Zimmer Holdings	ZMH	$92.64	$15,840	16.57
4	Johnson & Johnson	JNJ	$91.85	$259,149	17.13
5	Smith & Nephew	SNN	$71.12	$12,695	17.41

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$32.49	$1,450	85.50
2	Symmetry Medical	SMA	$9.90	$369	49.90
3	Integra LifeSciences	IART	$47.81	$1,536	30.51
4	CryoLife	CRY	$11.07	$306	28.58
5	ArthroCare	ARTC	$39.73	$1,127	25.44

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$19.59	$1,827	1.17
2	Orthofix	OFIX	$23.11	$450	1.33
3	Exactech	EXAC	$24.44	$331	1.63
4	Conmed	CNMD	$42.41	$1,171	1.66
5	Zimmer Holdings	ZMH	$92.64	$15,840	1.74

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	$11.07	$306	7.15
2	NuVasive	NUVA	$32.49	$1,450	6.95
3	Symmetry Medical	SMA	$9.90	$369	4.16
4	Integra LifeSciences	IART	$47.81	$1,536	4.08
5	Johnson & Johnson	JNJ	$91.85	$259,149	2.69

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	$0.51	$27	0.81
2	Symmetry Medical	SMA	$9.90	$369	0.90
3	Orthofix	OFIX	$23.11	$450	0.97
4	Alphatec Holdings	ATEC	$2.07	$202	1.03
5	RTI Biologics Inc.	RTIX	$3.45	$195	1.09

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	$8.43	$872	32.24
2	TiGenix	TIG.BR	$0.71	$114	27.80
3	MAKO Surgical	MAKO	$29.99	$1,544	15.03
4	Globus Medical	GMED	$19.59	$1,827	4.73
5	Johnson & Johnson	JNJ	$91.85	$259,149	3.86

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

Fearless Predictions for 2014

BY ROBIN YOUNG

Wikimedia Commons, RRY Publications and Prabhu Namgyel

One year from now, here is what we will be saying about the orthopedic industry:

- **2014 was the year of the knee.** Three factors converged in 2014 to push knee reconstruction surgery growth rates well above consensus forecasts. Those factors are reduced reimbursement for HA [hyaluronic acid] injections, new knee implant designs and greater numbers of patients courtesy of both Obamacare and an ever more arthritic baby boomer generation.
- **One of spine's young turks was acquired**. LDR, Globus and NuVasive started 2014 as the three fastest growing, most innovative spinal implant companies in orthopedics. By year's end one had been acquired.
- **Orthopedic equity valuations rose less than 10% on average in 2014.** While orthopedic equity valuations ended 2013 up a stellar 33%; in 2014 investors either sat on their profits (and dollar cost averaged) or took profits. Overall, orthopedic equity valuations rose less than 10% in 2014. Three companies (Orthofix, Symmetry and Baxano), however, rebounded smartly from their poor 2013 stock performances.
- **For the fourth year in a row, outpatient care was the fastest growing form of orthopedic care.**
- **Medical Device Tax was not repealed.** Despite a determined effort on the part of AdvaMed and major medical device companies, Congress chose to keep the added revenues. On the plus side, physician pay reform passed.
- **Overall, the number of orthopedic procedures rose 7.5% in 2014**. The combination of a steadily improving economy, Obamacare and key product and process innovations pushed the overall number of orthopedic procedures up 7.5%—exceeding even the most optimistic forecast.

Welcome to 2014

An increasingly arthritic baby boomer generation plus Obamacare means that the number of patients darkening the doors of clinics is expanding at an accelerated rate. It also means that everyone will be busy this year.

Where will these new patients go for treatment? Care delivery is going through its greatest period of change since maybe ever.

Implant technology remains stolidly rooted in the 510(k) innovation model.

The last two major innovations—two incision hips and MoM hips—well, we know how they turned out. But the Persona and Attune knees have excited surgeons for good reason—better fit implants with minimal learning curve.

Stem cells for knees—now that's interesting—but will the FDA make it yet another stillborn technology?

So, here are our fearless predictions for 2014.

2014 Will Be the Year of the Knee

Piper Jaffray analyst Matt Miksic noticed an interesting connection between the volumes of HA scrips and U.S. knee reconstruction procedures. Said Miksic his December 16, 2013 report, "During periods of rising (HA) scrip growth, we generally see U.S. knee growth slowing. Throughout 2H11 and 1H12, HA scrips growth slowed corresponding to gradual increases in U.S. knee growth during the same period. As HA scrips rose to record levels of growth in 2009 and 2010, we saw knee growth continue to decline through the end of the year, despite the typical seasonality."

Indeed, the chart accompanying Miksic's note showed a clear inverse correlation between HA scrips and U.S. knee recon growth rates. When HA scrips growth rates rose, knee recon fell. And vice versa.

HA reimbursement is tightening up and those injections will likely slow in 2014, we believe, setting the stage for an upward bias to knee procedure growth rates.

Adding to the tailwind are two new designs: Zimmer's Persona and DePuy's Attune which are generating genuine excitement and interest among surgeons. While both systems are off-the-shelf systems, they still offer a higher degree of personalization for the patient. In addition, both systems are natural evolution of knee implants and are not only more efficient in terms of instrumentation but offer better fit (and therefore outcome) to the patient.

Finally, a new forecast from CMS [Centers for Medicare and Medicaid Services] raised the expected growth rate of medical procedures in 2014 substantially. According to CMS, improving economic conditions, an aging population and the coverage expansion from the Affordable Care Act (ACA) will move national health spending growth from 3.8% in 2013 to 6.1% in 2014!

NuVasive, Globus or LDR – Who Gets Bought in 2014?

These three spine companies are the fastest growing spinal implant companies in the market and each one has

paced sales growth with a drumbeat of innovation. The odds that one of these three is purchased in 2014, we think, is about 50/50—which in the world of M&A are high odds.

Who might be buying? Biomet, Zimmer, Orthofix, Integra and Stryker are logical candidates.

For 2014, procedure growth should accelerate for many of the same reasons we mentioned for knee recon procedures—improving economy and coverage expansion. But pricing pressures remain tough forcing innovators to be more evolutionary than revolutionary. Sales growth for 2013 will probably come in 2-3%. Next year, procedure growth seems likely to reach 4-6% but continued difficult reimbursement will probably dampen overall spinal implant growth rates to levels that are only slightly better than 2013.

For the major spinal implant companies who are looking for double-digit spine growth, M&A will be the way to go.

Outpatient Care Will Be the Fastest Growing Care Sector

Orthopedic care is now provided in offices of the family practitioner, the internist, the orthopedist's ambulatory surgical center, the pain management clinic, the pharmacy, the physical medicine specialist, the rheumatologist, the sports medicine clinic and, of course, the chiropractor. Among established orthopedic programs at large hospital networks, the fastest growing practice sector is outpatient orthopedic care.

According to a 2013 survey of hospital executives, 69% are embracing outpatient care as their principal means for revenue growth. According to the HealthLeaders Media Industry Survey 2013, 69% of hospital leaders and 66% of health system leaders identify outpatient care expansion as their No. 1 strategy to grow in this era of ever tightening reimbursement rules and millions of newly insured patients coming into the system courtesy of the Affordable Care Act.

Finally, "outpatient" care is increasingly defined as a diversified approach to orthopedic care and encompasses everything from knee injections at the pharmacy to arthroscopic care at an ambulatory surgery center.

The Medical Device Tax Will not Be Repealed but Physician Pay Reform Will Pass

Physician pay in Medicare Part B (aka: Sustainable Growth Rate – SGR) has done more to generate physician ill will toward Medicare specifically and gov-

ernment intrusion generally than any other action since it was passed in 1997.

Key bipartisan committee leaders in the U.S. House and Senate have now agreed on legislation to permanently and totally repeal the SGR and replace it with a new and smart set of physician performance standards.

The cost of the repeal is estimated by the Congressional Budget Office at around $116 billion—well below the $350 billion estimate from just two to three years ago.

Which brings us to the Medical Device Tax. The good news is that a **non-binding** commitment to repeal the Medical Device Excise Tax (MDET) was in the just passed and soon-to-be-signed into law by Obama budget. The specific language, while non-binding, does create a political pathway for repeal. But, any repeal that does not include an alternative funding source will not be supported by Obama. Add in the new funding requirement to pay for the $116 billion repeal of the SGR and we think that MDET likely gets pushed off to 2015 or later. Not this year.

2014 Will Be a Year pf Accelerated Orthopedic Procedure Growth

Courtesy of Wells Fargo analyst Larry Biegelsen, we saw CMS' annual forecast for total U.S. health spending. This forecast was published in October 2013. CMS now expects that annual health spending will shift into a higher growth gear in 2014. In 2013, say CMS' analysts, health spending likely grew 3.8% year-over-year. But for 2014 health spending is going to ratchet up to 6.1%. This represents a whopping 230 basis point jump in a single year.

According to CMS, an improving economy plus coverage expansion in the Affordable Care Act and an aging population are the causes.

Interestingly enough, the largest reason for such a higher rate of spending growth is the ACA. CMS' analysts estimate that of the 2.3% jump in growth from 2013 to 2014, 1.6% of it comes from the ACA. Put another way…70% of the growth increase is coming from ACA's coverage expansion.

Expect a Busy and Successful Year

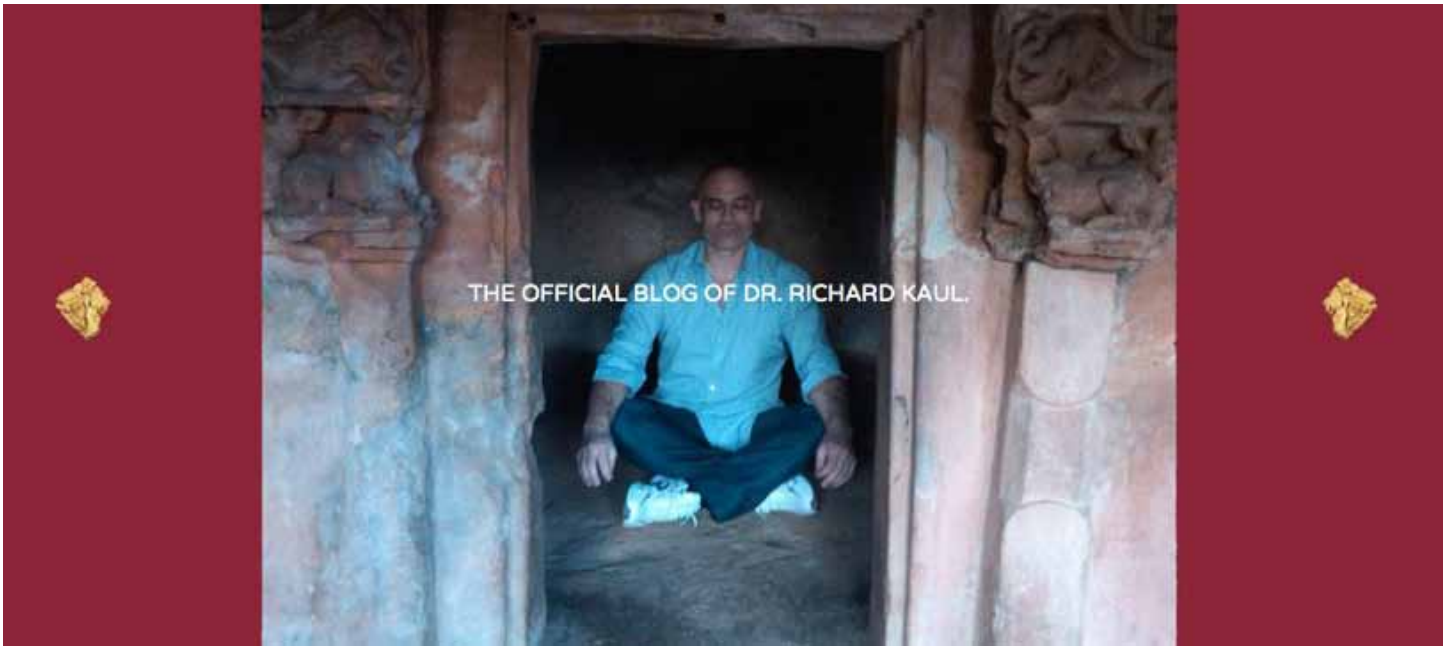
The New Year, it appears, will be particularly busy with more orthopedic procedures scheduled than in 2013, more points of care and expansion by several care providers to make room for millions of new patients.

The news out of Washington will be mixed. Large joint surgeons may well be the busiest guys in the hospital—followed by their techs, nurses and industry sales reps.

So, enjoy the football games on January 1st, eat hearty, sleep well—even if it's on the couch—because 2014 promises to be one of the best in a long while. ♦

What's Next for Spine's Most Notorious Rogue?

BY WALTER EISNER



Richard Kaul/drrichardkaul.com

On December 13, 2013 New Jersey Administrative Judge J. Howard Solomon issued a 105-page decision that Richard Kaul, M.D. should lose his medical license. Kaul was fortunate he wasn't remanded to nearby Rahway Federal Penitentiary.

The state, which accepted Kaul as an immigrant from England, has now called him a man "lacking good moral character" and a "danger to the public."

Kaul Unrepentant

Kaul has not gone gently into the good night, launching a massive public relations campaign (http://drrichardkaul.com/) to charge that the effort to take away his medical license is about constraint of trade, corrupt doctors and a scope of practice fight between traditional spine surgeons and upstart interventionalists.

Two weeks before the judge's decision, Kaul went online to fire one last volley at his critics.

"…The [previous] suspension of my license is a direct consequence of the vicious turf war between a small group of politically powerful and self-interested neurosurgeons and the larger but less organized minimally invasive pain physicians (MIPP)."

"The unanswered question is which neurosurgeon corrupted which physician on the medical board to bring about this 21st century equivalent of a lynching, an injustice that…was intended to intimidate other MIPPs from developing high quality cost effective spine care."

Kaul says his practice, New Jersey Spine and Rehabilitation, became widely known for its "outstanding clinical record" and he was performing increasingly more complex cases with "great success in a cost effective manner." He established a charity to provide free health care to the people in the Congo and donated a surgical center and his services to help provide free care to U.S. patients without health insurance.

"The philanthropic and business success garnered significant positive media attention and some not so positive attention from a small group of local neurosurgeons," wrote Kaul.

"Dr. X" and the Spine Blogger

In his posting, Kaul identified a "Dr. X (real identity withheld)," who he says practices with the Atlantic Neuroscience Institute and at the University of Medicine and Dentistry of New Jersey.

He claims "Dr. X" and his neurosurgical colleagues executed the plan to revoke

his medical license. "Dr. X" had a close friend and business associate on the state medical board who would "take care of the matter."

On another website posting, someone purporting to be Kaul alleged that "Dr. X," who was then identified by name, was the anonymous "Spine Blogger."

Kaul even tried to put the current science of spine care on trial by arguing to the judge that there were no standards in place governing minimally invasive surgery and, therefore, he could not have deviated from standards.

But Judge Solomon had none of it, writing that argument is "without merit."

Deviation From Standard of Care

Judge Solomon wrote that the standard of care for each allegation of deviation by Kaul can be broadly articulated as "the degree of care, knowledge and skill ordinarily possessed and exercised in similar situations by the average member of the profession practicing in his field."

Accordingly, added Solomon, "the argument that no standard governs the practice of minimally invasive spinal surgery is rejected. Instead, Dr. [Greg] Przybylski's testimony on the standard of care applicable to these allegations must be considered in its entirety and weighed against any contrary testimony from [Kaul] or his experts."

The judge afforded "little, if any" weight to Kaul or his experts' testimony.

The testimony offered by Kaul, wrote Solomon, "confirmed his lack of education and training in the performance of spinal surgery...Nothing in his testimony advanced his training and skills

Richard Kaul/drrichardkaul.com

over the compelling testimony offered by [the state's experts] to the contrary."

"Gross Negligence"

This wasn't about politics, scope of practice or restraint of trade. Solomon said this was about a doctor who operated on patients "without sufficient training, skills and competence."

"I, therefore, conclude that [Kaul] engaged in gross negligence, gross malpractice and gross incompetence, which damaged or endangered the life, health, welfare, safety or property of his patients," wrote the judge.

Then Solomon got specific about Kaul's "incompetencies," including:

- Education, training, internships, residencies and fellowships which were insufficient to prepare him for surgeries of the spine, whether minimally invasive or open.
- CME courses he took were insufficient to provide such education and training.
- Did not receive sufficient monitoring by a trained overseer.
- Patient consents presented were unsigned.
- Failed to carry medical malpractice insurance.
- Did not have hospital or alternative privileges.
- Misrepresented his qualifications, not only on his website, but also in discussions with his patients.

He said Kaul performed spinal surgeries for which he was not adequately educated and trained. "His surgeries were done posteriorly through incision, implanting hardware, such as screws, rods, and purported structural support devices. This was far beyond his training as an anesthesiologist, who was allowed to perform needle-based procedures for pain management, such as epidural and facet injections for the alleviation of pain or discograms for the purpose of diagnostic testing."

Kaul admitted to the judge that first time he ever inserted a pedicle screw on a live patient was at an ambulatory surgical center when he was on his own.

"Dishonesty, Fraud and Deception"

The list of harmed patients was extensive and detailed. The judge noted one (among many) as an example of "gross negligence and incompetence."

T.Z. is a 40-year-old woman who was so traumatized by Kaul's surgery that she has been essentially relegated to a recliner. "In her instance, [Kaul] improperly inserted pedicle screws directly into her spinal canal, which not only caused her extreme pain and other maladies from which she still suffers, but also necessitated a revision surgery by an orthopedic surgeon to undo his neglect. This speaks volumes about [Kaul's] incompetency and lack of training."

In addition, Solomon concluded that Kaul "engaged in dishonesty, fraud,

deception, misrepresentation, false promise or false pretense," when another patient was told that she was getting a minimal procedure followed by a short recuperative period, and nothing more. "Instead, the surgery far exceeded her expectations, her understanding and the limitations she expressly stated."

Solomon also concluded that Kaul committed professional misconduct and failed to maintain good moral character due to his untruthful disclosures about his manslaughter conviction in England.

In one bizarre twist during the almost three-month long hearing, Kaul's attorney, Charles Shaw, asked to be relieved of his duties. He was ordered to continue.

Credibility of Witnesses

In arriving at his conclusions, Solomon said he had to rely on the credibility of witnesses and the medical records of the patients. In the end he simply found the state's witnesses credible and Kaul and his witnesses not credible.

The state produced several witnesses, starting with Greg Przybylski, M.D., a neurosurgeon and former president of the North American Spine Society. It was his opinion that Kaul did not have the requisite training to perform spinal surgeries, either open or minimally invasive.

He also testified that given Kaul's lack of training, he would not have been granted hospital privileges for either open or minimally invasive surgeries, particularly at JFK Hospital, where Dr. Przybylski sits on a credentialing subcommittee

Given Kaul's curriculum vitae, Dr. Przybylski opined that Kaul's performance of the surgeries in question, "constituted a gross deviation from medical standards."

Since complications could arise during open or minimally invasive surgeries, the surgeon must have hospital privileges in order to treat surgical complications or he would have to work with physicians who could provide the emergency care.

List of Deviations

The list of deviations cited by Dr. Przybylski and other state expert witnesses was long and repetitive:

- Performing discography inappropriately.
- Inappropriate performance of multiple surgeries in the same area, including multiple level fusions.
- The use of OptiMesh off-label for fusion.
- The history and physical examination undertaken by respondent was without any neurological examination.
- The consent forms were not signed.
- Inappropriate use of and improper placement of orthopedic hardware and intradiscal cages.
- Lack of clinical indications for fusion in a patient with normal discography and normal exam.
- A two-level microdiscectomy, when only one level was needed for a single level radiculopathy.
- Failure to have hospital privileges, or at least a signed agreement with other doctors with hospital privileges.
- Inappropriate use of epidural injections.
- Failure to diagnose post-op infections
- The improper screw positions, requiring hardware removal in a patient where fusion was not indicated.
- Lack of proper informed consent
- Malposition of orthopedic hardware resulting in an unstable construct and the need to revise the hardware in order to obtain fusion.
- Failure to recognize a post-op complication of foot drop.
- Inappropriate use of different hardware stabilization systems. The same system should have been used for interlocking purposes.

Kaul, Kamson and Remley Discredited

The judge dismissed the testimony of Kaul's expert witnesses, Solomon Kamson, M.D., and Kent Remley, M.D. Kamson is an anesthesiologist from State of Washington and a co-founder of a professional society called SASI (Society for Advanced Spinal Intervention), organized while Kaul was being tried in New Jersey. Remley is an interventional neuroradiologist from Indiana.

Each praised the work of Kaul, finding no deviations from the standard of care. Both acknowledged a business relationship with Kaul.

Remley did not know about several revision surgeries that took place to correct Kaul's surgeries. He told the judge that that had he known about them, he might have changed his opinions about deviations.

Then Solomon went into great detail on the suspension of Kamson's medical license by the State of Washington on allegations of negligence and misrepresenting himself to a patient. His license was placed on probation status for over five years for unprofessional conduct in causing injury to a patient.

"The suspensions and probations of Dr. Kamson's several medical licenses had a significant impact on his credibility," added Solomon.

In the end, the judge said the testimony of "each and every" witness produced by the state was deemed "extremely credible and compelling."

"Conversely, the testimony of Drs. Kamson and Remley…was deemed lacking in credibility.

Where the Dangerous Mr. Kaul Is Headed Next

According to Kaul's own statements, his next stop is the Democratic Republic of the Congo. Hopefully, they not only have stringent licensing requirements but more effective techniques for stopping Kaul's aptitude for malpractice and mayhem. ♦

Caption: Democratic Republic of the Congo/Wkimedia Commons and Connormah

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*Data is available on file.

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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 IMPLANT/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 IMPLANT/ 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 IMPLANT/OP-1 PUTTY in (1) pregnant women (2) patients with autoimmune disease or immune suppression (3) patients with renal impairment.

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OLYMPUS BIOTECH
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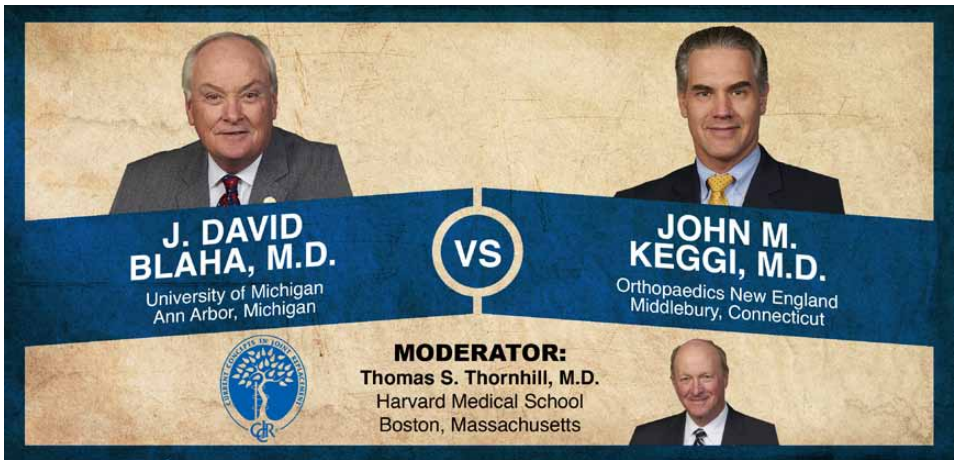
Blaha, Keggi Debate Femoral Neck Modularity

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

"I used to extoll the virtues of the modular neck," says David Blaha. "I've changed my mind because the risks have increased. The problem is corrosion." John Keggi retorts, "Let's not throw the baby out with the bath water. Modular stems do allow you to reconstruct femurs that you might not be able to reconstruct with a standard stem…and deformities that you definitely cannot reconstruct with a standard stem."



Current Concepts in Joint Replacement/RRY Photo Creation

This week's Orthopaedic Crossfire® debate is "Femoral Neck Modularity: A Bridge Too Far." For the proposition is J. David Blaha, M.D. of the University of Michigan in Ann Arbor; against the proposition is John M. Keggi, M.D. from the Orthopaedics New England in Middlebury, Connecticut. Moderating is Thomas S. Thornhill, M.D. from Harvard Medical School in Boston.

Dr. Blaha: "Tom will remember that I've stood up here and extolled the virtues of the modular neck, saying that it allows us to put the head where it's supposed to be relative to the musculature…so that each of the muscles finds the same lever arm that it would expect, thus providing a more functionally adequate result."

"I've also suggested that while fractures occurred, they only occurred in really heavy people with long modular necks. In the past, I believed that the short neck in a normal weight person was the reasonable thing to do. I've changed my mind because the risks have increased. The problem is corrosion…it eats away the material."

"Now we're looking at modularity in two sections, both at the top and at the bottom of the neck—which combines the worst of both worlds. Every orthopedic alloy corrodes the minute you expose it to air—it oxidizes. This 'passivates' the material, and if the passivation layer is left intact then very little further corrosion occurs. However, the modular neck is placed in a mechanically disadvantageous environment, and the loads can cause it to move relative to the pocket…and this can remove some of the passivation layer."

"The process continues at that layer, and in the process it produces titanium, hydrogen gas, and chloride ions, which decrease the thickness of the passivation layer. Hydrogen gas can form below the implant, and this whole mechanically assisted or accelerated crevice corrosion is the problem with modular junctions."

"We can change this by changing the material and structure of the neck and the stem, the length of the neck, size of the head, and the loads from the patient. The corrosion can make it difficult to remove the neck. We've had several cases where unexplained gas looked like infection. We aspirated the gas and it proved to be hydrogen gas. After we got to the point of removing the neck, applying the slap hammer to the neck led to a significant explosion in the OR…indicating that hydrogen gas had probably exploded."

"My first modular neck fracture had this gas and I didn't recognize that the gas from that corrosion was there. He felt a creaking and a snap. I thought it was because he was big and had a long modular neck."

"Problems of corrosion/fracture happen at all modular junctions. When modularity is absolutely necessary designs should have the best loading environment and maximum possible strength. Changing the material to cobalt might be a problem. It is stronger and it probably has less damage by corrosion. By changing the shape and the length of the titanium alloy neck some companies have suggested that they could make a modular neck that works better. The cobalt chromium in the beta alloy of titanium was suggested last year, but that has been withdrawn from the market."

"Modular necks allow you to uncouple the position of the stem from the head, you can find that 'sweet spot,' and you have clearance to do surgery through smaller portals. The disadvantages are corrosion, hydrogen embrittlement, pits in notch-sensitive titanium can lead to fracture, and hydrogen pneumarthrosis. A full 85% of modular necks I used were the same ones, so I only needed the modular necks in 15% of my cases."

"Failure of the modular neck causes damage to the pocket. The only sure way to remove the problem is to remove the well-fixed stem, but that is a significant problem for the patient. In conclusion, 66-year-old orthopedists should leave experimentation that requires long-term follow-up to the young surgeons."

Dr. Keggi: "The blood is in the water on modularity and the sharks are circling. Now we certainly can recognize that there are modular failures. Dr. Josh Jacobs's group recently reported on their Rejuvenate experience and Dr. Padgett commented that it is the BIO in biomechanics that is at work in some of these modular failures."

"But there are also modular successes. And modular stems do in fact allow you to reconstruct femurs that you might not be able to reconstruct with a standard stem…or deformities that you definitely cannot reconstruct with a standard stem. Human anatomy follows a bell curve and standard stems do not."

"Other local factors can play a role. Femoral tilt—the angle of degree you put the stem in the femur—can change anteversion dramatically. Even 10 degrees of femoral tilt in the saggital plane can change the anteversion 5 or more degrees. That has the effect of decreasing the impingement free range of motion of the hip by more than 50%."

"Also, by reducing offset, function and pain are affected. In a 2012 study Cassidy et al. found that when they reduced offset by more than 5mm patients had more pain and less function. Dislocation rate is positively affected by modularity. In our 2006 study of 2,248 modular THAs [total hip arthroplasty] the dislocation rate was less than 1% across multiple centers, surgeons, and approaches."

"Our modular neck experience with one particular brand showed that two-thirds of patients received an angled neck…and that provided the optimum

range of motion and stability for the hip. But not all modular junctions are created equal. Some demonstrate dramatically higher rates of fretting, and neck stresses can change with subtle changes in varus/valgus positioning or design."

"There is a difference in modular stems based on their length and design. Also, how they bind in the well varies; some bind on the flat side and some bind on the curves, with the latter being more effective and stable. How much of the neck you preserve is important. Neck preservation also has the benefit of decreasing stresses in the prosthetic neck by 35%. So if you retain the femoral neck you reduce stresses. Assembly technique is critical—you must impact these forcefully and well."

"Revision is a concern, but my experience in removing 15 consecutive modular stems required no ETOs (extended trochanteric osteotomies) at all. In fact, if you use a neck-sparing stem then revision is easy. The neck-sparing stem has most of its fixation proximally. You can then perform a standard primary total hip osteotomy. That leaves very little fixation remaining, which can be easily addressed with the pencil burr. Then you can change that to a primary stem. So early revision is not a concern."

"We've looked at cobalt and chromium levels in 25 of our patients with a cobalt-chrome neck modular junction, and found the levels to be acceptable. And the U.S. experience with this stem has resulted in seven explanted stems and no evidence of corrosion or adverse local tissue reaction. So let's not throw the baby out with the bath water. We have modular necks, hip resurfacing, ceramics, uncemented knees, all of which have had their trials and tribulations in the past. But the current modular necks may be guilt by association."

"The ideal system is one that allows a monoblock option for the most common sizes, but also lets you go modular when you need it. You need a sturdy taper and a neck-sparing stem (to reduce stress at the modular junction), and you must assemble it well. And it must be well tested."

Moderator Thornhill: "If we're talking about the modularity that involves the morse taper between the ball and the stem…do you use that or pure monoblock?"

Dr. Blaha: "I prefer monoblock, but I can't get that anymore, so I use modularity at the head/neck junction. And a 12/14 taper is the one that comes out most of the time."

Moderator Thornhill: "How about the type of modularity that changes the anteversion/retroversion, i.e., in the body of it?"

Dr. Blaha: "There has been some corrosion at that junction as well. It's not as mechanically disadvantaged, so the mechanically accelerated crevice corrosion probably isn't as bad. I haven't used that, but I have no reason to say that it's not a good thing to do."

Moderator Thornhill: "What modularity would you not use…other than the implant that's been removed?"

Dr. Keggi: "I would not hesitate to use it in order to achieve the restoration of the hip. I would use proximal modularity (head on the neck) or the neck on the stem."

Moderator Thornhill: "So if you have someone who has DDH…60 degrees of anteversion of the femoral component, how do you deal with that?"

Dr. Blaha: "I'd use a Wagner type conus stem in which I can choose the position in the medullary canal and not have to use modularity."

Moderator Thornhill: "In the Australian registry the incidence of dislocation was actually higher in the modular necks than non-modular necks. I don't remember if it was late or early. Late could be due to corrosive wear and loosening of soft tissues."

Dr. Keggi: "It could. Certainly with the soft tissue damage late dislocation can be a sign of that. But that may be device-dependent. So it may be one of these same designs that turns out to have a high corrosion rate, flexible metal, or binding at different points in the well that aren't as stable as others."

Moderator Thornhill: "Impaction is interesting because we all do it differently. Should we be more concerned about our impaction technique?"

Dr. Keggi: "We should impact it as tightly as possible in the modular junction. When it comes to impacting a ceramic head that's a whole separate issue."

Dr. Blaha: "At Wright they looked at this and hand-assembled modular necks in a corrosion environment and they go to corrosion right away. Well assembled ones had very little corrosion. When we put this in, if we're using a modular neck and the head isn't directly on with the taper, the standard was to put the head on and then put the taper in and hit that three times. We may not have been driving along the axis of the modular neck, and we may have been galling instead of setting the taper. It may be that the taper junction isn't as prone to corrosion as we thought…if we set it correctly."

Dr. Keggi: "Sometimes people are concerned about the implant being a splitting wedge in the proximal femur, and maybe backed off their impaction of the femoral neck into the stem. If you're really concerned about it you could prophylactically wire the proximal femur before impaction."

Dr. Blaha: "That might mean we should assemble it before putting it in the patient, which means it becomes a fixed neck stem."

Moderator Thornhill: "Thank you both." ♦

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

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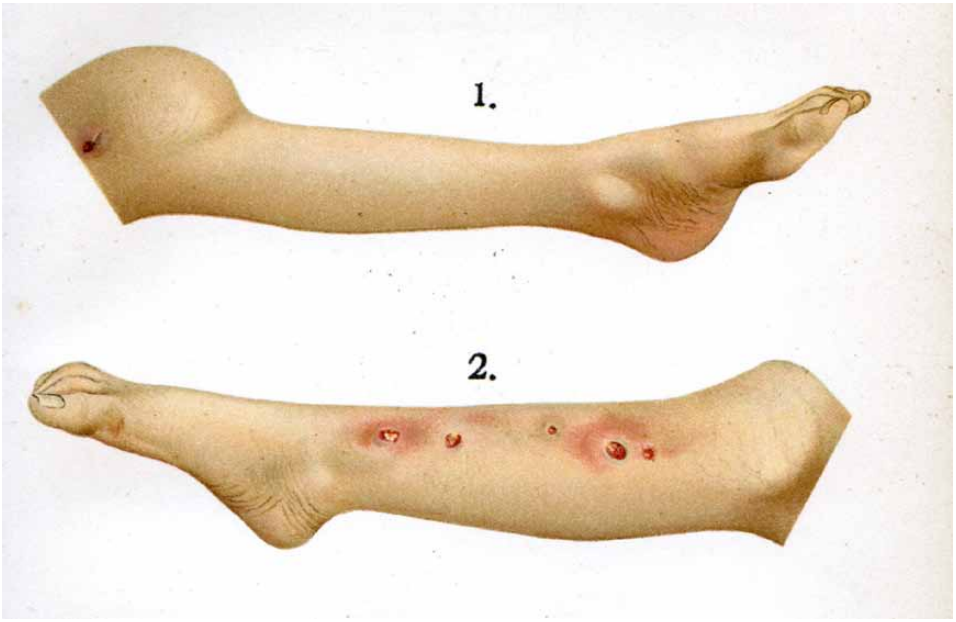
Uproar Over NEJM Partial Meniscectomy Study // Leslie J. Bisson, M.D. Installed as Mindell Professor, Chair at University of Buffalo // 10,000 Neutrophil Count – The Number to Remember for TKA Infection

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

Uproar Erupts Over NEJM Partial Meniscectomy Study Neal S. ElAttrache, M.D. is a sports medicine specialist with the Kerlan-Jobe Orthopaedic Clinic in Los Angeles, California. Dr. ElAttrache, the team physician for the LA Dodgers, tells *OTW*, "In the December edition of the *New England Journal of Medicine* there was an article implying that partial meniscectomy is not effective. I commend authors of studies such as this that focus on the efficacy of treatment especially in the current health care economic environment. However, I would advise caution in making sweeping general statements—in this case implying that partial meniscectomy is not effective—based on studies that have potential significant unaddressed flaws. There may be significant selection bias in this study. The study sample seems very small compared to the volume of meniscus operations that the contributing authors have been reported to perform. Is this due to applying indications in the clinical setting which are different from what were used for inclusion in the study? Did a very large number of patients refuse to be included in the study, instead opting for surgery? These are some material questions that need to be addressed."

"Additionally, there are also difficulties that can arise when using a study sample from one homogeneous socioeconomic and national population and attempting to make sweeping efficacy and value of treatment statements which are applied to a very different population. Again, I applaud the authors for conducting an important study such as this. The importance of the implications of the results and conclusions however, requires that the design, methods, data and conduct of the study are clearly understood and have a chance to be debated."



Pictures 1 and 2, Infection of the knee joint/Wikimedia Commons

Leslie J. Bisson, M.D. Installed as Mindell Professor, Chair of Orthopaedics Leslie J. Bisson, M.D. has been installed as the inaugural June A. and Eugene R. Mindell, MD Professor and Chair of the Department of Orthopaedics at the University of Buffalo (UB). Dr. Bisson's research, education and clinical interests include studying anterior cruciate ligament injuries, maximizing the strength of soft tissue repairs and exploring techniques to optimize rotator cuff healing. Dr. Bisson joined the department in 2007.

Dr. Bisson holds a number of roles, including director of UB's orthopaedic sports medicine fellowship; medical director and team orthopedic surgeon for the Buffalo Sabres; and team physician and orthopedic consultant for the Buffalo Bills.

John P. Kelly, M.D. Named Top Orthopedic Surgeon John P. Kelly, M.D., a physician at Orange County Orthopedic Specialists, has been named one of the top orthopedic surgeons in Orange County, according to *Orange Coast Magazine*'s January 2014 "Top Doctors" issue.

Dr. Kelly specializes in sports medicine, minimally invasive joint replacement surgery, fractures, pediatric orthopedics, hand surgery, spinal disorders, and foot and ankle problems. He has traveled extensively to developing countries throughout Asia and Africa on volunteer surgical missions for the poor and for injured children. He has been recognized and given awards for his volunteer work. Dr. Kelly has published academic papers and has presented at national academic orthopedic meetings.

10,000 Neutrophil Count – The Number to Remember for TKA Infection When it comes to infection and total knee replacement, things are different in the early postop period. Craig Della Valle, M.D. is an orthopedic surgeon at Midwest Orthopaedics at Rush and Professor at Rush University Medical Center in Chicago. He tells *OTW*, "We just published a multicenter retrospective study in the *Journal of Bone and Joint Surgery* where we evaluated nearly 600 patients who presented within the first two years after primary total knee arthroplasty (TKA) who underwent knee aspiration as part of an evaluation for periprosthetic joint infection. We looked at the progression of the synovial fluid white blood count (WBC), polymorphonuclear cells (PMN) percentage, and total neutrophil count over time and our data suggests that these are excellent indications for the presence of infection but the optimal threshold for the diagnosis of infection changes over time. We have done earlier work on diagnosis of infection in the first six weeks however this most recent work really finishes the story by showing us what happens to these values over the first two years. We assumed that these values decreased but really didn't have parameters for diagnosing infection after six weeks."

"Not unexpectedly we found that these parameters do change over time and the appropriate thresholds for diagnosing infection thus change as well. The synovial fluid WBC and differential both decreased the most in the first 90 days post-operatively which is not surprising. What was unexpected, however was that the synovial fluid WBC count and differential changed at different rates over time; the synovial fluid WBC count showing a much more rapid decrease and the PMN percentage demonstrating a more linear change. Hence, we wound up finding that the total neutrophil count (determined by multiplying the synovial fluid WBC count by the percentage of PMN) may provide a better method to identify patients with a periprosthetic joint infection as it combines the two values.

Once again, this work really goes hand in hand with prior work we have done on the diagnosis of infection in the early postoperative period showing that if standard cut-off values for diagnosis of infection are utilized, false positive results occur which can lead to operative management when it is not necessary which is a big deal for both surgeons and patients alike. Based on our earlier work and this most recent paper, what we recommend for the diagnosis of infection in the first six weeks is a cut off value for the synovial fluid WBC count of about 12,000 WBC/uL and a differential showing 90% PMN which works out to a total neutrophil count of about 10,000 which while an oversimplification of something pretty complex, is an easy number for folks to remember."

Michael Greller, M.D. Honored With Patients' Choice Award Michael Greller, M.D., president of New Jersey-based Advanced Orthopedic and Sports Medicine Institutes, has been honored with the 2013 Patients' Choice Award. This is an online process that gives patients a chance to rate their physicians on their patient care and expertise.

Dr. Greller, assistant director of the Cartilage Restoration Center of New Jersey, has recently been appointed Team Physician for the NY/NJ Comets, a National Pro Fastpitch women's softball team and was a team physician for Saint John Vianney High School Football in 2013. He has served as a physician for the U.S. Open Tennis Tournament, Philadelphia High School football, Freehold Borough High School Football and several professional dance companies in New York City. His vast and diverse experience both in the office and on the field allows him to provide the best care to all of his patients.

Dr. Greller specializes in advanced, minimally invasive shoulder, knee, hip, and ankle arthroscopic procedures, including ACL, rotator cuff and meniscus surgery. He also performs minimally-invasive hip, knee, and shoulder replacements.

Pierre Guyot Named to Board of SpineGuard Pierre Guyot has been appointed to the Board of Directors at the France-based company, SpineGuard. Guyot has served as chief executive officer and board director of Mölnlycke Healthcare since 2007, leading the very successful development of this Swedish corporation both in terms of growth and profitability. Guyot has previously held executive management positions at Becton Dickinson, Johnson & Johnson, and Boston Scientific. ♦

COMPANY

SI-BONE Reaches 10,000 iFuse Procedures

SI-BONE, Inc. is announcing that it has reached the 10,000 procedure mark with its iFuse Implant System, incorporating over 29,000 iFuse implants. The system is available in the U.S. and over a dozen European countries and is now being used by over 700 surgeons worldwide.

As indicated by the company, iFuse has a unique triangular-shape and porous titanium plasma spray (TPS) coating, and is the clear market leader. In addition, the iFuse Implant System is the only MIS treatment option for which there is published peer-reviewed clinical data that supports safety and effectiveness.

SI-BONE points to two recently published papers highlighting the safety and effectiveness of iFuse. The first is a retrospective comparison study authored by Dr. Arnold Graham Smith, a surgeon with significant experience with both open SI (sacroiliac) joint fusion as well as the iFuse MIS procedure. Results of this study, which evaluated 263 patients, demonstrate a clear advantage of the iFuse compared to open fusion in both perioperative outcomes as well as pain relief at both 12 and 24 months. The second paper is an early analysis of the SIFI study, which is SI-BONE's prospective, single-arm, multicenter clinical trial with iFuse. Early results on 32 subjects showed a mean 49 point improvement in VAS and 15.8 point decrease in ODI at 6 months.

Jeffrey Dunn, president and CEO of SI-BONE, told *OTW*, "10,000 procedures is truly a significant milestone for us to achieve and it is very gratifying to know that our technology has helped so many people. However, in spite of this significant achievement, we believe there are potentially hundreds of thousands of additional patients suffering from SI joint issues and we will continue to accelerate our leadership efforts to educate patients, health care professionals and the insurers on the benefits of iFuse as the treatment of choice for these patients."

—EH (January 6, 2014)

SI-BONE, Inc.

Stryker Invests $120 Million to Remember the Sponge

Stryker Corporation's Tim Scannell's New Year's Eve resolution is to stop leaving sponges in patients after surgery. So his division is paying $120 million for a system used at grocery checkout counters and intended to prevent objects being left in patients after surgery.

The company announced it was acquiring Patient Safety Technologies, Inc. (PST) for $2.22 per share on the last day of the year. Happy New Year PST shareholders.

PST's proprietary Safety-Sponge System and SurgiCount 360 compliance software help prevent retained foreign objects (RFOs) in the operating room. The system includes bar-coded surgical sponges and towels, an integrated bar-code scanner, and compliance tracking software. The company reported $14.9 million in revenue for the first three quarters of 2013.

Leaving "stuff" behind in patients is expensive and the most common operating room "Never Event" in the U.S, according to the Stryker announcement. Sponges are the most common retained object, with approximately 2,300 incidents reported annually at an average cost per incident of over $400,000.

Leah Binder, a contributing writer to *Forbes*, wrote that the acquisition represents a significant sign of change ahead for the health care industry and a market breakthrough because the idea of preventing leftovers in patients is profitable.

"It costs a whopping $10 per surgery for [PST] to embed bar codes in surgical sponges...Yet 85% of the hospitals that find the money for robotics, CT scanners, lasers, pianos in the main lobby, valet parking, billboards and other dazzlements just can't find a few bucks to address one of the most appalling and nauseating problems any of us can imagine happening to us."

Binder says the market won't accept that patient safety hasn't been part of a business model, and Stryker's move is a major sign. "Business leaders are increasingly demanding transparency and insisting on results—and they are not waiting for Congress to make sure they get what they need from their health benefits investment. They are also moving toward high-deductible health plans, which give employees skin in the game in demanding the best value. Perhaps $10 isn't such a big investment after all, if you preserve your reputation in a new marketplace, where patients and employers insist their needs should come first."

Wikimedia Commons and Ali Amiani/Surgical Sponge

Over 300 hospitals have become customers of the system since introduced in 2006. The system will become part of Stryker's instruments division, run by Scannell, group president, MedSurg and Neurotechnology. "This acquisition aligns with Stryker's focus on offering products and services that have demonstrated cost effectiveness and clinical outcomes," said Scannell.

—WE (January 2, 2014)

Flower Orthopedics Adds Cannulated Screw, Foot Plates

Flower Orthopedics, innovator of the FlowerCube and Ready-for-Surgery bone fixation concept, is pleased to announce the addition of the Cannulated Screw and Foot Plate FlowerCubes to their product portfolio.

Flower offers now a comprehensive forefoot and midfoot plating portfolio. Incorporating 2.7mm and 3.0mm screw diameters, the low-profile plates supply anatomy-based solutions for the myriad of forefoot and midfoot injuries.

Additionally, the Cannulated Screw portfolio offers a range of lengths and diameters in fully threaded and partially threaded options for fractures, osteotomies and joint fusions. Tailored to specific surgical indications, the Cannulated Screw FlowerCubes contain all of the requisite implants and instruments for a procedure including: Cannulated Screws, Guide Wire Kits, Cannulated Drill Bits, Washers and Countersinks.

Oliver Burckhardt, president and CEO of Flower Orthopedics, told *OTW*, "We are excited to add these important products to our FlowerCube portfolio. We continue to execute on our strategy to have a Cube portfolio available that covers the majority of bone fixation surgeries and that stays true to our strategic approach to have all you need for surgery housed in the Cube."

The Flower Orthopedics iPad Application offers a virtual look inside of the FlowerCube showing the cube contents and layout prior to ordering. Product specialists are able to configure custom FlowerCubes, as well as order standard pre-built cubes.

An exclusive distribution partner, McKesson Medical-Surgical Inc., based in Richmond, Virginia is now offering Hand, Wrist, First Ray, Forearm, Cannulated Screw and Midfoot FlowerCubes to surgery center customers.

—*EH (December 19, 2013)*

Flower Orthopedics

Another First for HSS!

For the fifth year in a row Hospital for Special Surgery (HSS) has an infection rate that is significantly lower than the New York State average for hip replacement or revision surgeries, according to a report released by the State Department of Health. It is the only New York hospital to have achieved this result.

Courtesy of Hospital for Special Surgery

Surgeons at Hospital for Special Surgery performed more than 4,300 hip replacement surgeries during the year which was the most in New York State. Among the 165 hospitals included in the report, HSS had a statistically lower surgical site infection rate of 0.46% compared with the state average of 1% for total hip replacement or revision hip procedures.

"At Hospital for Special Surgery, we perform almost four times more total hip replacement surgeries than any other hospital in New York State, and the most in the world," said Surgeon-in-Chief Thomas P. Sculco, M.D. "We are highly committed to employing the most advanced techniques to prevent this devastating complication. We are also committed to research in finding new ways to prevent infection."

The HSS anesthesiologists are leaders in using regional anesthesia for joint replacement, which limits anesthesia only to the surgical region and reduces bleeding and surgical time. During surgery, a patient's exposure to contaminants is minimized, because the individual is isolated from the environment by a specially designed Plexiglas enclosure, which helps to improve air flow and to restrict excess personnel at the surgical field. "We utilize less invasive surgical procedures, which reduce operating time, lessen blood loss and lead to rapid recovery. More rapid surgery is another important factor in reducing infection," said Sculco.

According to the press release, the Hospital for Special Surgery is a world leader in orthopedics, rheumatology and rehabilitation. The hospital is nationally ranked No. 1 in orthopedics, No. 4 in rheumatology and No. 5 in geriatrics by *U.S. News & World Report* (2013-14), and is the first hospital in New York State to receive Magnet Recognition for Excellence in Nursing Service from the American Nurses Credentialing Center three consecutive times.

—BY (December 23, 2013)

LEGAL

Whistleblowers Collect Big in 2013 - Orthopedics Top "Stark" Judgment

The year 2013 was another banner year for healthcare whistleblowers. The year also included the largest judgment in the history of the Stark Law with Tuomey Healthcare System, Inc. ordered to cough up $237 million.

According to the Department of Justice (DOJ), the government paid out more than $345 million to "courageous" individuals who exposed fraud and false claims by filing a qui tam complaint. The government recovered a total of $2.6 billion from those lawsuits.

It was the fourth straight year that DOJ recovered more than $2 billion in cases involving healthcare fraud.

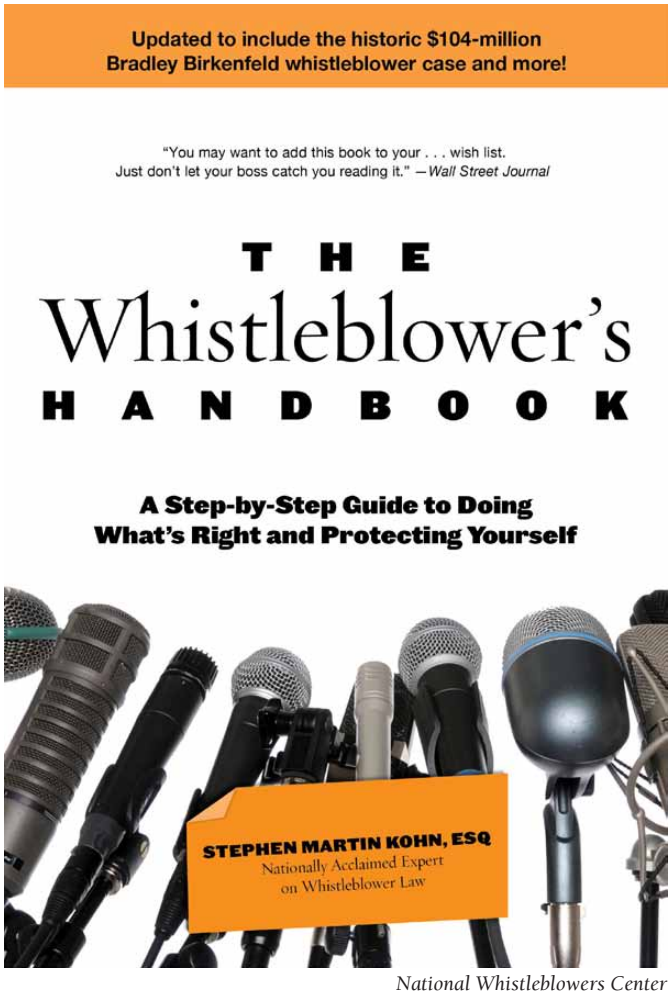
Of the total $2.6 billion recovered, $1.8 billion was from alleged false claims for drugs and medical devices under federally insured health programs that, in addition to Medicare and Medicaid, include TRICARE, which provides benefits for military personnel and their families, veterans' health care programs and the Federal Employees Health Benefits Program. The department recovered an additional $443 million for state Medicaid programs.

Orthopedics: Biggest Stark Judgment in History

The $237 million judgment against South Carolina-based Tuomey Healthcare System, Inc. came after a four-week trial. Tuomey's appeal of the $237 million judgment is pending. If the judgment is affirmed on appeal, this will be the largest judgment in the history of the Stark Law.

The hospital system was ordered to pay up after a jury found that the hospital entered into agreements with part-time orthopedic surgeons working in the hospital's outpatient surgery center. The government accused the hospital of hiring the surgeons with the intention they would refer patients from their practices to the center.

The department also recovered $26.3 million in a settlement with Steven J. Wasserman M.D., a dermatologist practicing in Florida, to resolve allegations that he entered into an illegal kickback arrangement with Tampa Pathology Laboratory that resulted in increased claims to Medicare. That settlement is



National Whistleblowers Center

one of the largest with an individual in the history of the False Claims Act.

Drugs: Off-Label Marketing

Many of the settlements involved allegations of off-label marketing of drugs. For example, Abbott Laboratories Inc. paid $1.5 billion to resolve allegations that it illegally promoted the drug Depakote to treat agitation and aggression in elderly dementia patients and schizophrenia when neither of these uses was approved as safe and effective by the FDA. The landmark settlement included $575 million in federal civil recoveries, $225 million in state civil recoveries and nearly $700 million in criminal fines and forfeitures.

In another drug case, Amgen Inc. paid $762 million, including $598.5 million in False Claims Act recoveries, to settle allegations that included its illegal promotion of Aranesp, a drug used to treat anemia, in doses not approved by the FDA and for off-label use to treat non-anemia-related conditions.

$1.98 Billion for Whistleblowers Since 2009

Whistleblower lawsuits were in the range of 300-400 per year from 2000 to 2009, when they began their climb from 433 lawsuits in fiscal year 2009 to 752 lawsuits in fiscal year 2013. Qui tam recoveries exceeded $2 billion for the first time in fiscal year 2010 and have continued to exceed that amount every year since. Qui tam recoveries this past fiscal year bring the department's totals since January 2009 to $13.4 billion. During the same period, the department paid out $1.98 billion in whistleblower awards.

—WE (January 3, 2014)

BIOLOGICS

BioPen Deposits Stem Cells Like Writing

They call it a BioPen. Its inventors use it to deposit regenerative stem cells onto damaged bone and cartilage in a process very much like 3D printing. The BioPen co-developer, Peter Choony, M.D., a professor of surgery at University of Melbourne and Director of Orthopaedics at St. Vincent's Hospital, Melbourne, explains that the device extrudes cell material in a biopolymer, such as seaweed extract, that is combined in the nozzle with a second layer of protective gel. This allows the surgeon to fill in areas where bone or cartilage is missing by drawing across the surface.

Technologists in the laboratory with the impossibly long name of Australian Research Council Centre of Excellence for Electromaterials Science (ACES) at the University of Wollongong, in New South Wales, combined the principles of 3D printing with stem cell research to develop the BioPen. The BioPen deposits its material in layers. Each layer is exposed to ultraviolet light from a source attached to the pen, hardening the gel so further layers can be added, eventually building a three-dimensional framework.

The protective gel gradually degrades as the cells it contains begin to multiply and grow into new tissue to repair the damaged area. Choony says that an additional polymer layer can be added to increase the structural strength of the material within the wound, while drugs that stimulate cellular growth or aid recovery can also be added to the cell-loaded material.

The key benefit of the handheld technique over the current process of injecting stem cells into the injury site is that surgeons have more control over where to deposit the cell-loaded material and can create customized implants as they work. This should reduce the amount of time the patient spends in surgery.

"This type of treatment may be suitable for repairing acutely damaged bone and cartilage, for example from sporting or motor vehicle injuries," said Choong. "The research team brings together the science of stem cells and polymer chemistry to help surgeons design and personalize solutions for reconstructing bone and joint defects in real time."

The developers say that all of the components in the implantable material are non toxic and are designed to degrade as cells populate and remodel the damaged bone area. The device is small and so is easily portable. Choony plans to begin optimizing the cell material so it can be used and tested in clinical trials.

—BY (December 31, 2013)

Courtesy of University of Wollongong

LARGE JOINTS

Death Rate Double in Certain RA Patients

New research from the University of Pittsburgh indicates that mortality rates are two times higher in postmenopausal women with rheumatoid arthritis (RA) and anti-cyclic citrullinated peptide (anti-CCP) antibodies. These higher mortality rates persisted after adjusting for age, positive rheumatoid factor, positive antinuclear antibodies (ANA) and disease modifying antirheumatic drug (DMARD) use.

For the present study researchers from the University of Pittsburgh, led by Lewis Kuller, M.D., Dr.P.H. and Larry Moreland, M.D., measured anti-CCP, rheumatoid factor and ANA in close to 10,000 women who self-reported RA as part of the Women's Health Initiative (WHI)—clinical trials and observational study of postmenopausal women, conducted by the National Institutes of Health (NIH). Participants included in the present research had a mean age of 64 years with 65% Caucasian, 25% African-American and 10% Hispanic.

The team found that anti-CCP was prevalent in 8.1% of the group, of whom 58% reported DMARD use during follow-up. Only 7.3% of the remaining 9,179 women with self-report RA, but negative anti-CCP, were using DMARDs. During the 10-year study period, 13% of women died—14% who self-reported RA at the start of the study and follow-up; 16% who reported RA at baseline; and 11% who reported RA at follow-up.

Further analysis determined that cardiovascular disease, including coronary heart disease and stroke, and cancer were the main cause of death among women with RA. Women with positive anti-CCP had a substantially higher mortality risk that was independent of DMARD use, including methotrexate, and modifiable risk factors (obesity, smoking) associated with mortality.

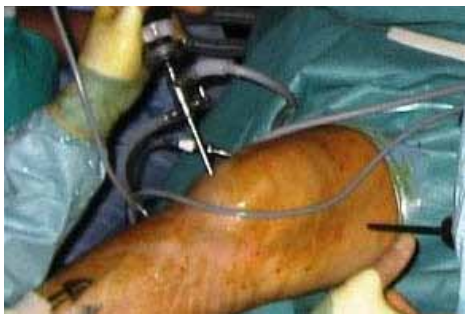
"Our study is the first large longitudinal study to evaluate anti-CCP, RF, risk factors and mortality," said Dr. Kuller in the December 23, 2013 news release. "Further investigation to determine specific causes of excess mortality, particularly among RA patients with positive anti-CCP, are needed."

—EH (January 2, 2014)

Morguefile and Schick

Sham Surgery as Good as Partial Meniscectomy

Sham surgery is just as effective as an arthroscopic partial meniscectomy in diminishing knee pain.



FXRX Orthopaedics & Bracing/knee scope

That's the result of a trial from the University of Helsinki, Finland involving 146 patients reported in the December 16, 2013 issue of the *New England Journal of Medicine* (*NEJM*). None of the patients had knee osteoarthritis but had symptoms of a degenerative medial meniscus tear. The outcomes after arthroscopic partial meniscectomy were no better than those after a sham surgical procedure.

The experiment involved volunteers whose knee pain appeared to be caused by wear and tear of the meniscus. After 12 months, the average improvement among the people who received real surgery and those who got the sham surgery was essentially the same, reported the research team, and led by Teppo Jarvinen, M.D., Ph.D.

There was no significant improvement in knee pain after exercise and no sizable improvement in the likelihood that a patient would require subsequent knee surgery.

However, according to Craig Bennett, M.D., chief of sports medicine at the

University of Maryland Medical Center, the findings should not be over-generalized. One problem, he told *Reuters Health* in a telephone interview, is that sham surgery is, in fact, a surgical procedure with potential benefit.

People with knee pain who seem to be candidates for meniscal repair may be suffering because of debris in a swollen knee joint. "If you scope the knee (without touching the cushion), that will often help even if you don't completely address the torn meniscus issue," he said.

The researchers conducted a multicenter, randomized, double-blind, sham-controlled trial in the patients 35 to 65 years of age who had knee symptoms consistent with a degenerative medial meniscus tear and no knee osteoarthritis. Patients were randomly assigned to arthroscopic partial meniscectomy or sham surgery.

The primary outcomes were changes in the Lysholm and Western Ontario Meniscal Evaluation Tool (WOMET) scores (each ranging from 0 to 100, with lower scores indicating more severe symptoms) and in knee pain after exercise (rated on a scale from 0 to 10, with 0 denoting no pain) at 12 months after the procedure.

In the intention-to-treat analysis, according to the *NEJM* article, there were no significant between-group differences in the change from baseline to 12 months in any primary outcome. The mean changes (improvements) in the primary outcome measures were as follows:

- Lysholm score, 21.7 points in the partial-meniscectomy group as compared with 23.3 points in the sham-surgery group (between-group difference, –1.6 points; 95% confidence interval [CI], –7.2 to 4.0);
- WOMET score, 24.6 and 27.1 points, respectively (between-group difference, –2.5 points; 95% CI, –9.2 to 4.1); and score for knee pain after exercise, 3.1 and 3.3 points, respectively (between-group difference, –0.1; 95% CI, –0.9 to 0.7).

There were no significant differences between groups in the number of patients who required subsequent knee surgery (two in the partial-meniscectomy group and five in the sham-surgery group) or serious adverse events (one and zero, respectively).

Because about 700,000 such surgeries are done in the U.S. each year at a cost of $4 billion, the new findings "will not be welcomed with open arms," Dr. Jarvinen predicted in a phone interview reported by Reuters.

—*WE (December 26, 2013)*

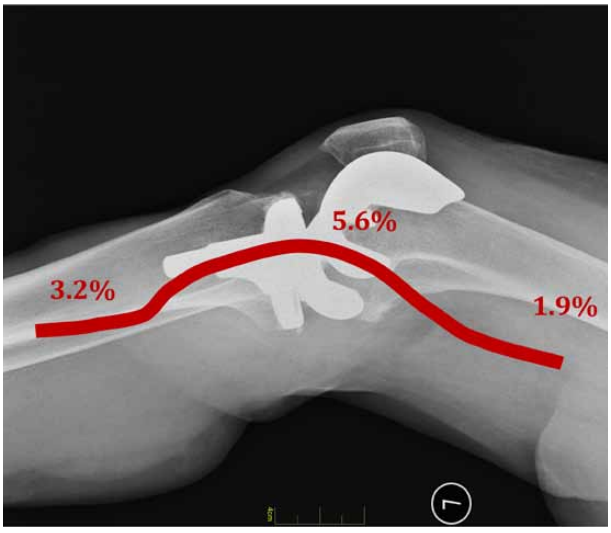
New Report: Global TKA Growth Rate Down to 1.9%

Market Research Reports, Inc. make good reading when they deal with the world-wide knee replacement market. The market value of knee replacement is expected to increase over the next few years from $6.544 billion in 2012 to $7.459 billion by 2019 which represents a compound annual growth rate of 1.9%.

The United States had the largest market share in 2012 at 63%, followed by France, Germany, Italy, Spain, the UK, Japan, Brazil, China and India. According to analysts, "The knee replacement market represents the largest joint reconstruction market in the world. Although it has continued to grow at a steady rate in procedure volume, profit margins have been negatively affected by health executives scrutinizing purchases and using multiple channels to procure orthopedic devices at highly competitive prices."

The driver of the expected growth is the rising prevalence of symptomatic arthritis. Researchers believe that emerging markets, such as India and China, will see a higher growth level in knee replacement and will provide the key for players to gain additional market share.

One analyst wrote, "As the knee replacement procedure volume rises over the next decade, it will become increasingly important to improve surgical accuracy and reduce revision rates to a specific level. Future competition among vendors will thus be more likely to center on the instrumentation and ancillary equipment, such as patient-specific



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instruments, navigation systems, and robotic systems."

Another researcher noted that current economic conditions are forcing patients to reconsider hip and knee replacements due to the costs involved. Knee replacement is more likely to be deferred by patients than is hip replacement, he said, because medical treatments, such as viscosupplementation, can, at least for a time, ease the pain in knees.

—BY (December 23, 2013)

EXTREMITIES

Auxilium Doses First Patient in CCH/Frozen Shoulder Study

Auxilium Pharmaceuticals, Inc. has announced that the first patient was dosed in its Phase 2b study of collagenase clostridium histolyticum (CCH) for the treatment of adult patients with adhesive capsulitis, commonly known as frozen shoulder syndrome (FSS).

CCH is a biologic approved in the U.S., EU, Canada and Australia under the trade name XIAFLEX for the treatment of adult Dupuytren's contracture (DC) patients with a palpable cord and in the U.S. as the first FDA approved non-surgical treatment of adult men with Peyronie's disease (PD) with a palpable plaque. XIAFLEX consists of a combination of two subtypes of collagenase, derived from Clostridium histolyticum. Together, the collagenase sub-types are thought to work synergistically to break the bonds of the triple helix collagen structure. XIAFLEX has been granted Orphan Drug Designation in the U.S. by the FDA for DC and PD.

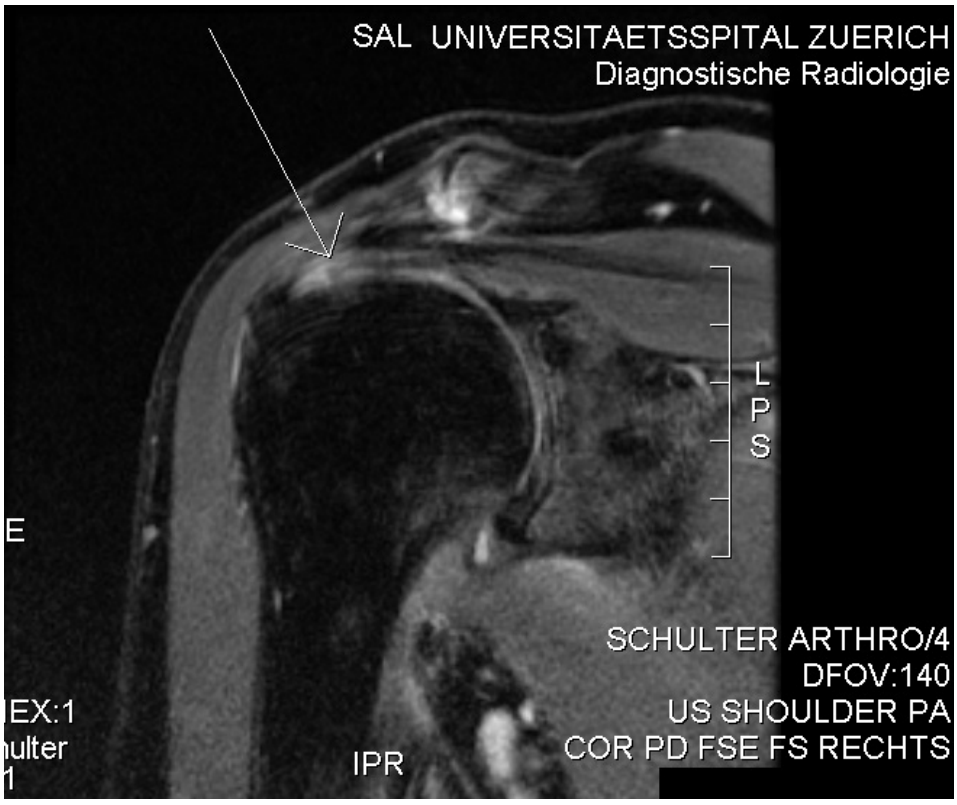
"The initiation of our Phase 2b Frozen Shoulder syndrome study represents another development milestone for Auxilium as we further evolve our pipeline and advance a fourth potential indication for CCH," explained Adrian Adams, chief executive officer and president of Auxilium. "We believe that our continued measured investments in research and development, together with the upcoming product launches of XIAFLEX in Peyronie's disease and STENDRATM in erectile dysfunction, position the company well for growth and shareholder value creation."

The Phase 2b study is a double-blind, placebo-controlled study of the safety and efficacy of CCH for the treatment of Stage 2 unilateral idiopathic FSS. The study will enroll approximately 300 adult men and women at approximately 35 sites in the U.S. and Australia. Subjects will be randomized 3:1 to receive CCH or placebo and will receive up to three ultrasound-guided injections of study drug.

"We are very excited to be moving into this next phase of development for CCH in the potential treatment of frozen shoulder," said Dr. James Tursi, chief medical officer of Auxilium. "FSS is a condition with no approved therapies and limited treatment options. Innovative treatment approaches such as CCH, if approved by the FDA, may allow patients quicker relief from limits in range of motion and associated pain."

Adrian Adams told *OTW*, "While we haven't provided a specific timeline for the resulting data announcement, these type of Phase 2 trials typically take 12-24 months to complete. We'll be sharing more details as we near trial completion."

—EH (December 26, 2013)



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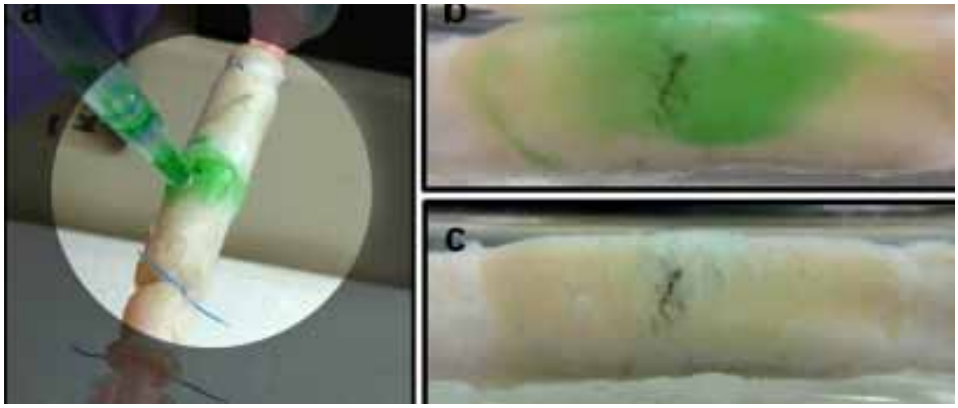
TRAUMA

Hydrogel Seals Wounds Then Releases



Courtesy of Boston University and Mark Grinstaff

Everyone of a certain age remembers the pain of a doctor's stripping off adhesive tape from a wound. Now a chemist, Professor Mark Grinstaff, Ph.D., his students and Harvard Medical School Assistant Professors of Orthopedic Surgery Edward K. Rodriguez, M.D. and Ara Nazarian, Dr.Sc. have developed a hydrogel that not only seals wounds but can then be dissolved and gently removed from the site of the injury.

As explained by writer Mark Dwortzan in BU Biomedical Engineering, the gel is intended for use with wounds that must be quickly closed to stem blood loss and prevent infection, but then later reopened for additional treatment. The developers of the gel say that their wound closure system is the first that will not only stop bleeding for several hours, adhere to the wound site, be easy to apply and also be simple to remove when other procedures are called for.

"Today's trauma wound closure materials, once applied, must later be cut out," said Grinstaff. "We've introduced a mild process for removing a hydrogel sealant from a wound where there's no cutting or scraping involved."

The idea for a wound-sealing reversible hydrogel emerged from a meeting Grinstaff had with Rodriguez and Nazarian. Grinstaff had long been interested in hydrogels and wanted to explore how the doctors treated wounds and how that treatment could be improved. He put his postdoctoral fellow Cynthia Ghobril and graduate student Kristie Charoen, along with two colleagues, to work on the problem. With support from the National Institutes of Health the group designed the hydrogel and tested it to ensure that it was safe and non-toxic.

According to Dwortzan, the hydrogel is applied from a double-barreled syringe. Each barrel contains a different compound. When the two compounds meet they combine within seconds to form a honeycomb-like network of cross-linked chemical bonds. The product absorbs fluid on the surface, has the consistency of gelatin and sticks like an adhesive, remaining intact for several days. To remove it, doctors add a solution of cysteine methyl ester, which is a derivative of a natural amino acid, to the hydrogel which causes its cross-linked bonds to break apart. The gel dissolves within 30 minutes.

Dwortzen writes that, over the next six months, with funding from the Wallace H. Coulter Foundation, the team plans to evaluate the hydrogel for the treatment of burns.

—BY (December 31, 2013)

REIMBURSEMENT

Glaxo Goes Cold Turkey on Doc Payments

One of the world's largest drug makers is going cold turkey and cutting off payments to physicians for hawking their drugs.

GlaxoSmithKline (GSK), Britain's biggest pharmaceutical company announced on December 17, 2013, that it will stop paying physicians for promoting its drugs and scrap prescription targets for its marketing staff. The entire industry has been under heavy scrutiny and pressure to clean up questionable marketing practices. Regulators have been particularly heavy handed in China where industry executives have been threatened with jail time after being accused of bribing physicians with up to $494 million payments through travel agencies to boost its drug sales.

The company said the action was not directly related to its Chinese problems and were rather part of a broad effort to improve transparency. No other company has yet followed suit.

Disruption Now or Later

Giving up payments to physicians and ditching marketing targets is a kind of unilateral disarmament that the company must think will lessen future business disruption from government officials. Zimmer Holdings Inc.'s CEO Dave Dvorak went further than competitors in cancelling and restructuring surgeon contracts with the company after then U.S. Attorney Christopher Christie's purge of 2008. At the time, Dvorak argued the disruption of surgeon-industry relationships will come sooner or later and he'd rather get it over with right away.

"Where GSK leads we must hope that other companies will follow," Fiona Godlee, editor of the *British Medical Journal* and an influential campaigner against undue industry influence in medical practice, told Reuters.

"But there is a long way to go if we are to truly extricate medicine from commercial influence. Doctors and their societies have been too ready to compromise themselves."

$3 Billion U.S. Settlement

In the U.S., the industry's biggest market by far, many companies have run into conflicts over improper sales tactics and GSK reached a record $3 billion settlement with the Justice Department last year over charges that it provided misleading information on certain drugs. A number of other firms have taken some steps to clean up their marketing practices and companies are being forced to disclose payments to doctors under U.S. healthcare law.
The decision to stop payments to doctors for speaking about medicines during meetings with other prescribers is a big change for an industry that has always relied heavily on experts to influence their peers.

GSK will still pay fees to doctors carrying out company-sponsored clinical research, advisory activities and market research, which it said were essential in providing insights on specific diseases.

Andrew Huth and RRY/Wikimedia Commons

Pro/Con

PBS interviewed Harvard University's Dr. Jerry Avorn and Dr. Thomas Stossel about the business and ethical issues surrounding GSK's decision and whether doctors should be paid by pharmaceutical companies to promote their drugs.

They had different opinions about GSK's decision. "I do think they're setting a good example," Dr. Avorn said. "I wonder whether some of the other companies are going to hang back and see what is this doing to their sales, because you can probably sell more drugs when you can totally control the flow of information than if you just pay a hospital or a medical school to do whatever kind of education it wants."

Dr. Stossel said that a one-size fits all approach is not the best for healthcare education. He worried that if companies, which don't have "the Glaxo profile," restricted the cutting-edge information given to doctors, the real victim would be patients.

Andrew Witty, GSK's CEO said in a statement that his company's actions were designed to ensure that patients' interests always came first.

"We recognize that we have an important role to play in providing doctors with information about our medicines, but this must be done clearly, transparently and without any perception of conflict of interest," he said.

—*WE (December 23, 2013)*

Doc Fix and Device Tax Legislation Passed by Congress

A federal budget bill including a 3-month SGR (sustainable growth rate) "patch" and a non-binding repeal of the 2.3% medical device tax was passed by the U.S. Senate on December 18, 2013. The House of Representatives passed the bill a few days earlier. When the bill gets to the President, he has reportedly agreed to sign the measure. More on the device tax below.

Doc Fix

The budget legislation delays a 24% cut to physicians' Medicare payments scheduled to take effect January 1, 2014. Physicians will get a 0.5% raise for the first three months of 2014. However, the bill both preserves an annual 2% reduction to Medicare rates called for by the across-the-board budget cuts called sequestration and extends it two years beyond its original expiration date of 2021.

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SGR Replacement Proposal

The SGR "patch" gives politicians time to try to work out a deal to scrap the SGR altogether. Two similar bipartisan bills have been introduced in the Senate and the House to repeal the SGR.

David Pittman, Washington Correspondent for *MedPage Today* reported on December 18, 2013, that both measures would shift compensation from fee-for-service to pay-for-performance and consolidate three Medicare incentive programs, including meaningful use of electronic health records, into a single program.

The Senate Finance Committee and the House Ways and Means Committee each approved its version of SGR repeal last week. Pittman reports that The American Medical Association (AMA) and other medical societies prefer the House bill because it gives physicians an annual Medicare update, or raise, of 0.5% from 2014 through 2016. In contrast, the Senate bill freezes Medicare rates at their current levels for 10 years.

A Medicare rate increase makes any SGR repeal bill more costly. Pittman wrote that the Congressional Budget Office (CBO) recently put the cost of repealing the SGR formula and freezing rates for 10 years at $116.5 billion. The price tag would increase by additional $19.6 billion if physicians received an annual 0.5% raise for 10 years, according to the CBO. So over the course of three years, an annual 0.5% raise would send the cost to easily more than $120 billion.

Possible Device Tax Repeal

Stewart Eisenhart of the Emergo Group told *OTW* that the legislation passed by the Senate is the exact same bill passed by the House and includes the language to repeal the device tax. The President has reportedly said he intends to sign the bipartisan budget bill.

The budget deal includes language from a non-binding Senate vote to repeal the medical device tax that removes a hurdle to rolling back the tax.

AdvaMed President & CEO Stephen Ubl said AdvaMed is "encouraged that the budget deal preserves language from the Senate Budget Resolution calling for repeal of the medical device tax. We look forward to working with lawmakers on both sides of the aisle moving forward to achieve repeal of this tax."

J.C. Scott, AdvaMed's senior executive vice president for government affairs told *MassDevice.com* that the move makes it easier to find ways to replace the revenue that would be lost if the 2.3% levy on U.S. medical device sales is lifted.

"The practical effect is that Senate rules say if you repeal a tax you have to replace it with new tax revenues. This means they could look to other areas besides new taxes [to replace those revenues]," Scott explained. "There continues to be bipartisan support for repealing the tax."

—*WE (January 5, 2014)*

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