VOLUME 8, ISSUE 32 | OCTOBER 9, 2012

Orthopedics This Week

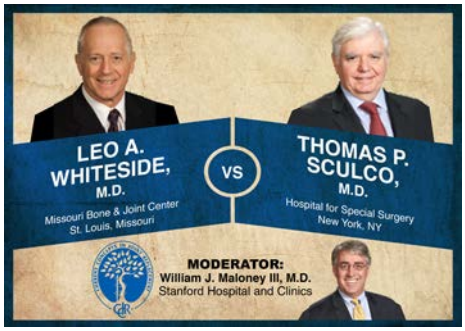
week in review

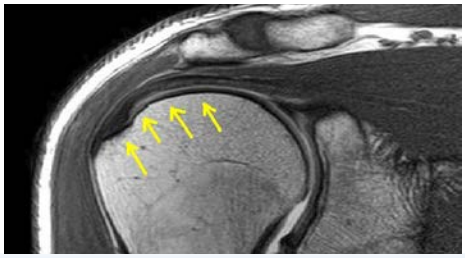
4 Medtronic Buys Access to 80% of China's Tier One Hospitals ♦ China is growing old before it grows rich. So, by government mandate, 80% of its hospitals are going to be rebuilt or expanded in the coming ten years. For $800 million Medtronic just bought access to most of them—the most valuable healthcare franchise in the world. It's a steal of historic proportions.

8 Exorcising the "Ghost of Pedicle Screw Past" ♦ The FDA gathered its orthopedic panel to advise the agency about an industry petition to classify cervical pedicle and lateral mass screws as Class II devices. One panel member said they could have done this in 45 minutes after every major medical society testified in favor of the classification. Why was a panel meeting needed? Call it the "Ghost of Pedicle Screw Past."

12 Whiteside and Sculco Debate Sequential Bilateral TKA ♦ Bilateral simultaneous TKA may be more cost effective for the hospital, and it's within the standard of care, but it's riskier, asserts Leo Whiteside. But this is a good operation in the fit, bilaterally affected patient, counters Tom Sculco.

16 Aging Stem Cells Affect Rotator Cuff Healing? Cole's New Cartilage, "X" that X-Ray, JBJS Gets New Editor and More…





breaking news

19 Time to **Stress Test PRP and Stem Cell Products**

NuVasive Hit by **Poachers** and **PODs**

Lobo Named **Stryker CEO/President**

TKAs UP 162% Among Medicare Enrollees

Bilateral Knee Patients: **Complication Rates Increasing**

Chronic Sleep Loss=Bone Loss?

Former Hospital for Special Surgery **CEO Arrested**

Supremes Reconsidering **Obamacare?**

Europe to "Reboot" **Device Oversight**

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Ninety percent of orthopedic company stocks increased in value last month (21 of 23). Average rate of increase was 4.47%. By comparison, S&P 500 rose 4.1%. NASDAQ composite inched up 2.2%. Buyers like orthopedic stocks. Elasticity of demand is low. Core demand rising inexorably. And it is, ultimately, affordable—however the payments are structured.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Globus Medical	30.06%	3.63%	FDA grants PMA for Globus's cervical artificial disc. Still the #1 ortho stock.
2	6	Medtronic	28.65	9.35	We like the Kanghui buy. MDT gets access to most of China's Tier One hospitals and 30% of the Tier Two hospitals.
3	4	ArthroCare	(0.80)	11.94	Zero debt, 6x current ratio and most analysts think earnings grew 20% in Q3.
4	3	Orthofix	16.23	5.86	Profitability rising. Most analysts expect OFIX to earn 10% more on 17% fewer sales for Q3.
5	2	Zimmer	26.37	6.84	At just 15.6x trailing earnings and delivering 26% operating margins, ZMH is certainly cheap.
6	5	Smith & Nephew	21.36	3.08	SNN's new TRIGEN bone screw ensures that surgeons won't "lose" the screw during surgery.
7	7	Symmetry Medical	5.63	4.04	SMA expected to post up some big sales and earnings growth rates this quarter—+24% sales and +275% earnings.
8	10	Exactech	7.68	10.42	September was one of EXAC's best months in a long time. Stock up 10%.
9	9	Stryker	23.68	3.18	New CEO. Promoted from within and with a strong supporting cast, Lobo can restore SYK's mojo.
10	NR	Conmed	10.39	4.44	Back on the Power Rankings, CNMD continues to grow via acquisition—the latest is Viking Systems.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$1.15	$109	71.93%
2	CryoLife	CRY	$6.31	$173	15.78%
3	RTI Biologics Inc	RTIX	$4.54	$254	13.78%
4	ArthroCare	ARTC	$33.19	$920	11.94%
5	Exactech	EXAC	$18.23	$242	10.42%
6	Medtronic	MDT	$44.67	$45,570	9.35%
7	Alphatec Holdings	ATEC	$1.79	$161	9.15%
8	Tornier N.V.	TRNX	$19.62	$779	7.57%
9	Zimmer Holdings	ZMH	$66.88	$11,684	6.84%
10	Orthofix	OFIX	$45.32	$860	5.86%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	NuVasive	NUVA	$14.57	$633	-31.01%
2	Bacterin Intl Holdings	BONE	$1.49	$63	-9.70%
3	MiMedx Group	MDXG	$2.75	$235	0.36%
4	Integra LifeSciences	IART	$40.61	$1,098	0.79%
5	Smith & Nephew	SNN	$54.86	$9,884	3.08%
6	Stryker	SYK	$54.81	$20,852	3.18%
7	Johnson & Johnson	JNJ	$69.65	$192,028	3.54%
8	Globus Medical	GMED	$16.55	$1,497	3.63%
9	Symmetry Medical	SMA	$9.78	$358	4.04%
10	Conmed	CNMD	$28.72	$816	4.44%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Zimmer Holdings	ZMH	$66.88	$11,684	13.22
2	Medtronic	MDT	$44.67	$45,570	13.26
3	Johnson & Johnson	JNJ	$69.65	$192,028	13.82
4	Stryker	SYK	$54.81	$20,852	14.09
5	Orthofix	OFIX	$45.32	$860	15.47

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$22.06	$874	84.85
2	Symmetry Medical	SMA	$9.78	$358	57.53
3	NuVasive	NUVA	$14.57	$633	44.15
4	RTI Biologics Inc	RTIX	$4.54	$254	25.22
5	Exactech	EXAC	$18.23	$242	22.51

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$45.32	$860	1.01
2	ArthroCare	ARTC	$33.19	$920	1.07
3	Globus Medical	GMED	$16.55	$1,497	1.21
4	Zimmer Holdings	ZMH	$66.88	$11,684	1.36
5	Stryker	SYK	$54.81	$20,852	1.42

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
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3	Symmetry Medical	SMA	$9.78	$358	4.79
4	Smith & Nephew	SNN	$54.86	$9,884	3.90
5	NuVasive	NUVA	$14.57	$633	3.90

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.79	$161	0.81
2	Symmetry Medical	SMA	$9.78	$358	1.00
3	Conmed	CNMD	$28.72	$816	1.13
4	NuVasive	NUVA	$14.57	$633	1.17
5	Exactech	EXAC	$18.23	$242	1.18

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.15	$109	95.24
2	MiMedx Group	MDXG	$2.75	$235	30.28
3	MAKO Surgical	MAKO	$16.63	$710	8.40
4	Globus Medical	GMED	$16.55	$1,497	4.52
5	TranS1	TSON	$2.71	$74	3.86

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

Medtronic Buys Access to 80% of China's Tier One Hospitals

By Robin Young

Courtesy of Hospital 301, Beijing, China

What's medical product distribution worth in China? Apparently about $250,000 per hospital (Tier One and Tier Two combined). Since its founding in 1997, China's Kanghui Holdings (KH) has built a distribution network in China that, according to their U.S. filings, reaches into 968 Tier One hospitals (80% of the total) and 2,001 Tier Two hospitals (30% of the total).

Last week Medtronic announced that it was going to pay $755 million ($816 million excluding cash acquired) for China's Kanghui Holdings and thereby purchase access to, effectively, 80% of China's Tier One hospitals and 30% of China's Tier Two hospitals.

How good was Medtronic's purchase? It was a steal.

KangWho?

Fifteen-year old Kanghui was founded to create a domestic Chinese orthopedic implant manufacturer and distributor. After a decade and a half, Kanghui had become the largest domestic China manufacturer and distributor of orthopedic products. This year KH will likely distribute roughly $65 million in trauma and spinal implants through a network of 335 domestic Chinese distributors.

Medtronic paid 12x sales for Kanghui. The average price-to-sales for an orthopedic manufacturer in the U.S. is a little under 3x.

Either Medtronic CEO Omar Ishrak has been Shanghaied by a fast talking Kanghui exec or there is more to Kanghui than meets the eye.

It's not manufacturing. The idea that Medtronic paid 4x the average price-to-sales ratio to get manufacturing capacity in China is improbable. Manufacturing capacity in China is cheap.

What we are witnessing, we think, is strategic wager on the rapidly evolving Chinese medical market.

It's all About Hospital Access in China

Twenty-five years ago the cable TV business in the United States was going through a period of explosive growth and the capital markets were throwing money at it. Investors had a short hand way of pricing cable companies in those days. It was number of houses wired and the number of houses passed. Each house had a dollar value. A wired house was worth $150 – $200. A passed house was worth $40 – $100. Cable company pricing was easy. Number of houses times either $150 or $40 or some blend of the two numbers.

Medicine in China is the same way. Except the measure is hospitals. Hospitals under contract. Kanghui has access to 80% of the largest and most sophisticated hospitals in China.

China is also a country embarking on a major expansion of per capita access to healthcare.

China Will Grow Old Before It Grows Rich

The Chinese government now believes that China will grow old before it grows rich and realizing this, has mandated increased access to healthcare in China.

Thirty-five years ago Deng Xiapeng set in motion the engine of economic reform that moved his country away from such Marxist ideas as equal access for equal need. China's economy grew at an average annual rate of 10% since 1978 and 500 million people moved out of poverty. A million millionaires form the top of China's economic strata. The middle kingdom is the world's second largest economy.

But this remarkable economy is also plagued with large income disparities. Since China's economic reforms took hold, access to health services, especially for the poor and elderly, declined.

From 1978 to 2000, funding fell for state-owned health facilities and in keeping with the overall theme of economic self-determination the government encouraged hospitals to be more autonomous, self-supporting and profit oriented.

Among the many benefits of that approach was an extraordinary leap in access to advanced, Western style medical technologies, physician training and treatment capabilities.

But cutting hospital's loose from the government mandated system also triggered soaring healthcare prices and sharply increasing in the number of days in the hospital. According to data from the Chinese Government's China Health and Retirement Longitudinal Study (CHARL) database, the proportion of China's population that could afford and get access to healthcare dropped significantly—particularly among China's rural and 204 million poor people.

Income and proximity to urban centers, therefore, became the two most important determinants of access to healthcare in China.

China's government wants to change that. Now.

Being Old in China

The old-age dependency ratio—defined as the ratio of those aged 65 and over to those between the ages of 15 and 64—will double in China over the next 20 years. At the same time the working-age population will start to decline after 2015. By 2050, 27% of China's population will be elderly. This change in the age profile of the population has a direct impact on demand for hip, knee, shoulder and spinal care.

And that demand will place new burdens on China's uneven health care system. So, as detailed in the CHARL database, rural seniors and females have significantly less access to hospitals or physicians but a higher need for physician visits.

The Government's Response – Universal Healthcare Coverage

To address both, the current level of healthcare utilization inequality and the aging of its population, in 2002 China's

government set in motion a series of programs to expand access to healthcare by expanding access to healthcare insurance.

Specifically China's Central Committee implemented two schemes to increase health insurance coverage for its rural, elderly, unemployed and poor. The two insurance programs were the New Cooperative Medical Scheme (NCMS) and the Resident Basic Medical Insurance (URBMI).

Underlying the new medical insurance schemes is the government's decision to establish universal access to healthcare coverage and thereby diminish the role of income or wealth in determining that access. URBMI, which is a voluntary household-based insurance program extended healthcare coverage to the unemployed, students, children, and the elderly.

Quick reminder: China is ruled by a communist party. Socialism and improbably long agency names are in its DNA. The most recent mandate regarding access to healthcare in China came from, ready now, the Opinions of the Central Committee of the Communist Party of China and the State Council on Deepening Reform of Medical and Health Care System and the Implementation Plan for the Recent Priorities of the Health Care System Reform (2009-2011).

The new plan builds on the 2002 initiatives by increasing subsidies for the country's two largest health insurance programs—the Urban Residents Basic Medical Insurance Program and the New Rural Cooperative Medical Program—and increasing reimbursement caps for the social medical expense pools of China's three major government mandated medical insurance programs.

Long term, China is heading for universal healthcare coverage.

80% of China's Hospitals To Be Rebuilt, Expanded or Relocated in 10 Years

China today has 18,396 hospitals with 4.2 beds per thousand people. China has 22% of world's population but only 2% of world's total medical resources. As China's economy grows, that gap will close. In the next ten years, 80% of the Chinese hospitals will be rebuilt, expanded or relocated.

In the first half of 2011, China's government increased healthcare spending 61.4% to more than 245 billion RMP (source: Standing Committee of the National People's Congress). Despite the ramp up in spending, healthcare expenditure in China still remains modest in international comparison at 5.1% of GDP in 2009. The research firm Espicom Business Intelligence projects that health expenditure in China will rise from an estimated US$277.3 billion in 2011 to US$593.4 billion by 2016, with per capita spending more than doubling during this period from US$210 in 2011 to US$437 by 2016.

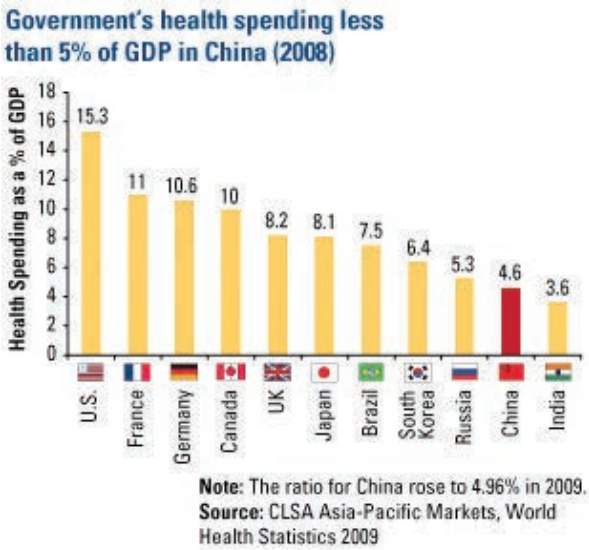
Per Capita

China's per capita health care spending is $210. The global average is $292. Europe is at $2,204. The U.S. per capita is $7,960. Where is China going? In ten years it will be half of Europe and growing. (So, quick…what's $1,000 times 1.5 billion?)

The percent of China's GDP dedicated to purchasing medical products and services (5.1%) could approach European levels in just a decade or two—due to these new government programs. Europe spends 9.3% of its GDP on healthcare. U.S. spends 17.6%.

A European level of healthcare spending would add up to $680 billion in China, today. In ten years it could be as high as $1 trillion.

Here's where China ranks in terms of key health statistics today.



Source: http://advisoranalyst.com/glablog/wp-content/uploads/HLIC/2e1053af789256d80caf906fff26ccd5.gif

KEY HEALTH STATISTICS	CHINA	UNITED STATES	EUROPEAN UNION	WORLDWIDE
Hospital Beds / 10,000 Population	**42**	**30**	**61**	**30**
Number of Physicians	1,905,436	749,566	2,942,286	8,652,107
Physicians / 10,000 Population	14.2	24.2	33.2	14.2
2000 Percent of GDP Spent on Healthcare	4.6%	13.4%	8.0%	5.8%
2009 Percent of GDP Spent on Healthcare	5.1%	17.6%	9.3%	6.6%
2000 Government Spending as % of Healthcare	38.3%	43.2%	73.9%	57.6%
2009 Government Spending as % of Healthcare	52.5%	47.7%	74.9%	61.0%
2000 Per Capita Healthcare Spending in US$	$43	$4,703	$937	$106
2009 Per Capita Healthcare Spending in US$	$191	$7,960	$2,204	$292
Gross National Income per Capita	$7,640	$47,360	$24,196	$6,965

Source: WHO Global Healthcare Statistics: 2012

What's Access to China's Hospitals Worth?

The average hospital in China triggers about $40 million in purchases. In ten years, that number should be more than $100 million per Tier One hospital.

Still, despite its size and dynamism, China presents a number of structural problems for Western medical products distributor. Two that stand out are, to put it bluntly:

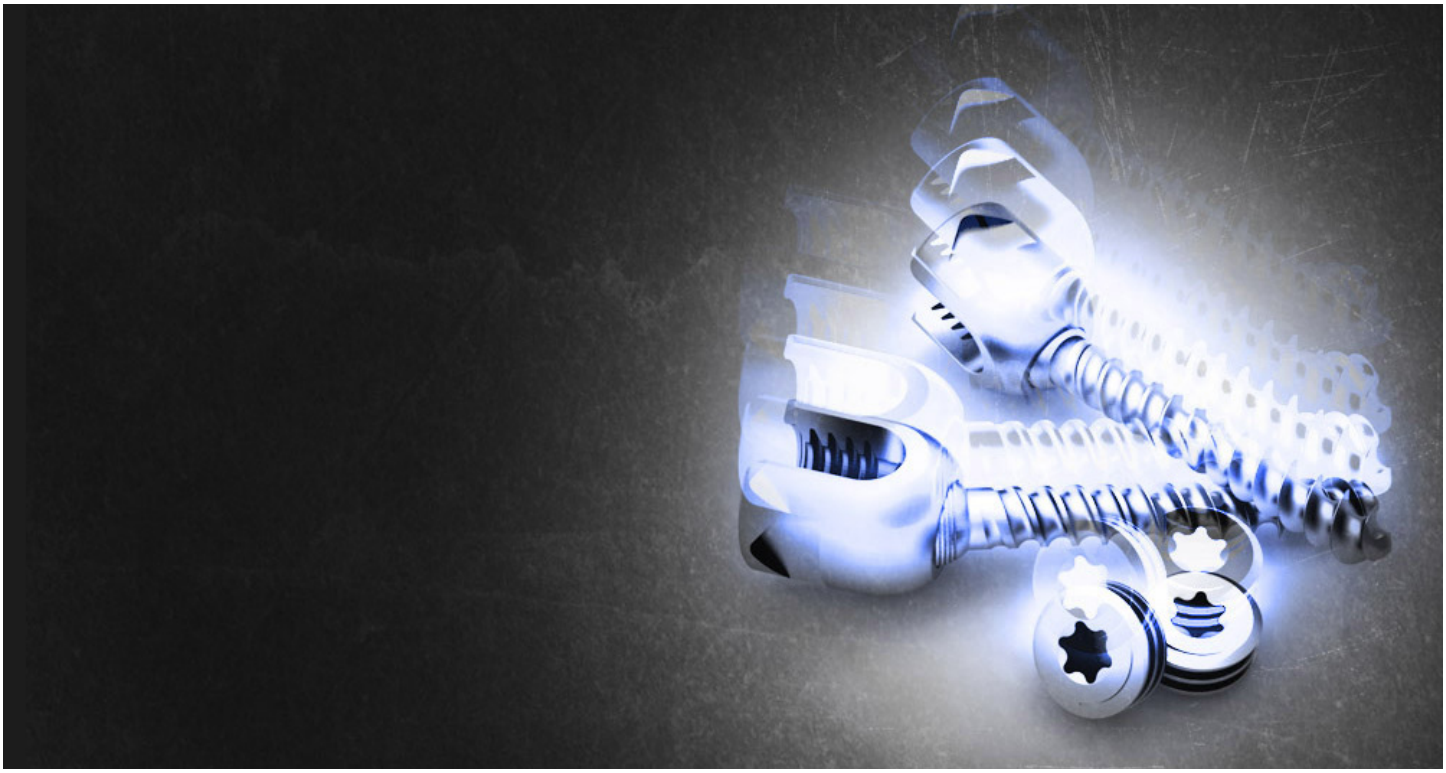
1. Too many cash transactions.
2. A government which actively tamps down rates of healthcare profitability.

This means, in China, Medtronic and any other orthopedic company will actually have to "make it up in volume."

But at least Medtronic is now officially in 80% of China's Tier One hospitals and 30% of its Tier Two hospitals. At just $250,000 per hospital, it's a steal. ♦

Exorcising the "Ghost of Pedicle Screw Past"

By Walter Eisner



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"We could have gotten this over with in 45 minutes."

That's what we overheard an unidentified panel member tell a colleague during the last break of the day at the FDA's orthopedic advisory panel held on September 21.

The panel had been called together by the FDA to offer the agency recommendations regarding the classification of posterior cervical screws, including pedicle and lateral mass screws.

Surgeon Support

The panel heard the same message all day long from the Scoliosis Research Society (SRS), the American Academy of Orthopaedic Surgeons (AAOS), the American Association of Neurological Surgeons (AANS), the North American Spine Society (NASS) and the Cervical Spine Research Society (CSRS). That message was that pedicle and lateral mass screws used in the cervical spine have been the gold standard for the last decade and it was time to finally classify the screws so that they could be used "on-label" and the proper procedures for use could be taught by surgeons.

Cervical pedicle and lateral mass screws are components of rigid, posterior spinal screw and rod systems generally intended as an adjunct to fusion for the treatment of degenerative disc disease (as defined by neck pain confirmed by radiographic studies), trauma, deformity, failed previous fusion, tumor, infection, and inflammatory.

Currently the screws for the cervical spine are not classified and their use for anything other than use in the lumbar spine is considered off-label. The result is that surgeons can only teach the standard of care one student at a time during their practice of medicine.

OSMA Petition

For the first time in recent memory the FDA convened the panel to consider a petition, not from a particular company, but from the industry as a group

through the Orthopedic Surgical Manufacturing Association (OSMA). The association had petitioned the FDA to classify the screws for the use in cervical as a Class II device.

The Panel had a jovial, yes, jovial time bantering over the value of screws over the previous standard of care, wires, hooks and cables. After the united medical society support of OSMA's petition and an FDA staff recommendation for classification with tight controls, there wasn't much science or clinical data to argue over.

"Ghost of Pedicle Screw Past"

After all that agreement and clear demonstration that the screws are the standard of care for certain procedures, it was a little baffling to figure out why the FDA even called this meeting.

Call it the "Ghost of Pedicle Screw Past"

Minneapolis attorney Bob Klepinski, a veteran of the pedicle screw lawsuits of the 90s said the agency was probably being particularly careful over any pedicle screw issue.

Over 3,000 lawsuits were filed over pedicle screws in the 90s. NASS was sued over 400 times in 42 states after the society had sponsored five continuing medical education (CME) activities that mentioned off-label uses of pedicle screws. AAOS and SRS were also sued.

Physicians, manufacturers, societies that mentioned pedicle screws in their CME courses, and the individual faculty who taught the courses that included pedicle screws were all sued. Some called it a witch hunt against the spine industry.

Every one of the cases against the surgeon societies was dismissed by 1999 for lack of evidence.

To read a more detailed history of the development of the pedicle screw, read our April 3, 2007 story by Robin Young titled: *When No Good Deed Went Unpunished: The First Decade.*

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FDA On the Hot Seat

In addition, the FDA has been through a lot of turmoil over the past few years, evidenced by the perplexing Regen Biologics actions that involved two panel meetings, political scandal reporting by the *Wall Street Journal,* the unprecedented revocation of the company's 510(k) clearance and the departure of long serving top administrators.

This all happened while whistleblowing agency scientists went to Congress and the press and accused FDA political appointees of ignoring their scientific advice. They also accused the agency of retaliating because they exercised their right of free speech and assembly.

The agency, in turn, electronically bugged their own scientists by tracking their computer activities. The now former scientists and the agency are fighting each other in a whistleblower lawsuit.

fighting each other in a whistleblower lawsuit.

Then came data from overseas registries and surgeon societies that certain large head metal-on-metal hips cleared by the FDA were failing in unacceptable numbers.

Jeff Shuren, M.D., JD, the agency's current top device regulator, inherited a lot of FDA staff dysfunction. He's been battered by patient advocates who accuse him of kowtowing cow towing to industry and not protecting public health. And, he's been battered by industry and investors who accuse him of stifling innovation and failing to promote public health.

So the agency can be forgiven for the extra caution.

While support for bringing the screws under Class II of devices was universal, with some special controls, one patient advocacy group objected to the petition and urged to FDA to require manufacturers to go through the PMA (premarket approval) process for all devices implanted in humans.

Diana Zuckerman, Ph.D., president of the National Research Center for Women & Families testified that the FDA and OSMA reviews did not discuss a four-year study of 84 patients with 33 complications. She noted that the researchers found that 13% of patients had neurological damage after surgery, with palsy cited as the most common injury. Another 13% had implant failures. If 13% is considered low risk, then it has to be "looked at in terms of the benefits," she said. Patients who benefit have to be "counterbalanced by patients being harmed," she said.

When pressed for details of the study, she was unable to produce it.

Panel Deliberations

Panel member John Kirkpatrick, M.D., made it clear to industry that support


Raj Rao, M.D. /http://fcd.mcw.edu

John Kirkpatrick, M.D./ http://ufandshandsjax.org

for their petition was only for fixed stabilization and not for dynamic stabilization.

Raj Rao, M.D., from the Medical College of Wisconsin Milwaukee, agreed that all the screws and devices used in the posterior cervical spine are reasonably safe when used in the appropriate fashion for the appropriate indications, but cautioned that there should be a way to distinguish between pedicle screws C3 to C6 and lateral mass C3 to C6 for labeling due to the risks associated with the presence of vertebral arteries.

Another panel member, statistician Brent Blumenstein, Ph.D., who is fond of telling his colleagues that he worships at the altar of randomization, was disappointed that there was no comparative data comparing screws to hooks, wires and cables.

Equipoise

John Heller, M.D., one of OSMA's presenters, spoke of "equipoise" and noted that it is difficult to suggest to patients that entering a blind clinical trial offered equal opportunities for each treatment. He said he could not in good conscience offer that choice to his patients.

Recommendations

Ultimately, the panel offered the following observations to the FDA:

- Available scientific evidence supported a reasonable assurance of safety for the use of cervical screw fixation systems in treatment of the proposed, indicated population. The panel did express concerns in the future regarding training and collection of long term data.
- Available scientific evidence supported a reasonable assurance of effectiveness in the use of cervical screw fixation systems for treatment in the proposed, indicated population.
- Support of the FDA's proposed indications for use. Panel consensus supported inclusion of the specific screw trajectories presented by the FDA.
- Reasonable evidence to support use of posterior cervical screws as an adjunct to fusion in the pediatric population. The FDA recognizes that this determination is based on modest level of evidence and lack of long term clinical data. It was emphasized by the panel that size of the osseous elements is more critical than chronological patient age.
- Support of the non-fusion use of posterior cervical screws for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The panel emphasized that their discussions were limited to this narrow patient population and should not be extrapolated to other non-fusion applications or technology.
- Other than the risks associated with the presence of the vertebral arteries, the panel did not identify any other unique risks, as compared to other spinal implants, which may be present in the cervical spine.
- Confirmed the completeness of the FDA's identified risks to health. In addition, the risk of iatrogenic foraminal stenosis associated with implant-related changes in spinal alignment resulting in neurologic injury was also raised.
- Support of the adequacy of the proposed special controls. An additional recommendation was made with regards to the specific risks relating to C3-C6 pedicle screw placement.
- Support of the requirement of cross-sectional imaging as part of pre-operative planning for procedures which utilize posterior cervical screw fixation.

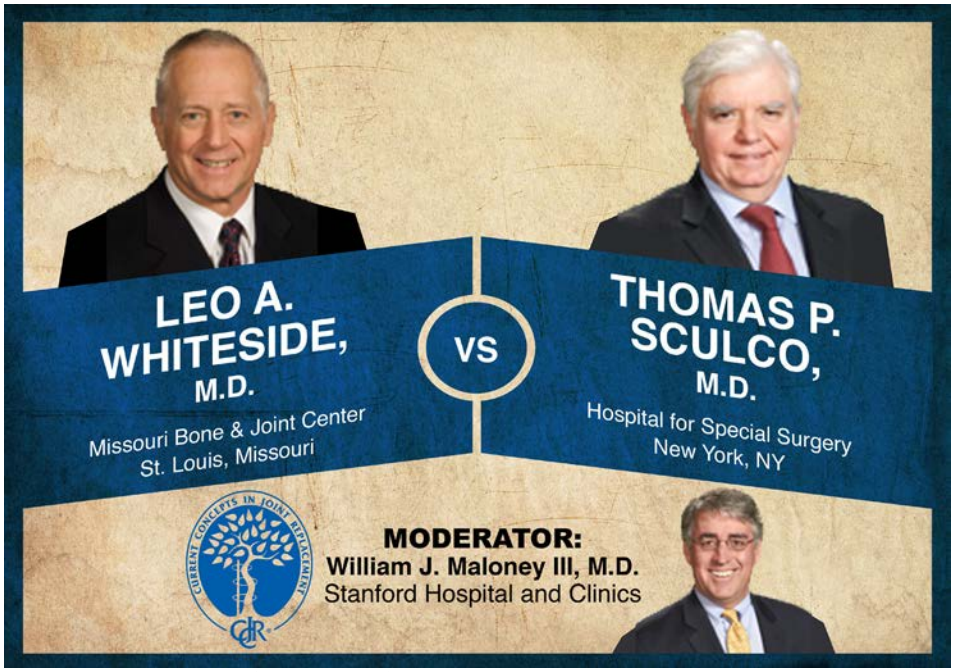
After all was said and done, it was clear this really wasn't about science. Perhaps the meeting served as a metaphor to exorcise the Ghosts of Pedicle Screw Past. Somewhere, Dr. Steffee must be smiling. ♦

Whiteside and Sculco Debate Sequential Bilateral TKA

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

Bilateral simultaneous total knee arthroplasty (TKA) may be more cost effective for the hospital, and it's within the standard of care, but it's riskier, asserts Leo Whiteside. But this is a good operation in the fit, bilaterally affected patient, counters Tom Sculco.

This week's Orthopaedic Crossfire® debate is "Sequential Bilateral TKA: Double Trouble." For the proposition was Leo A. Whiteside, M.D. from the Missouri Bone & Joint Center. Against the proposition was Thomas P. Sculco of Hospital for Special Surgery; moderating was William J. Maloney III, M.D. from Stanford Hospital and Clinics.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Whiteside: "I'm going to talk a lot about risk to benefit ratios. One of the major things we deal with in total knee replacement (TKA) is fat embolism. Fat embolism in bilateral total knee replacement was first identified by Larry Dorr as a significant issue. He found that in 12% of patients he had to see clinically he discovered fat embolization. In another study he had to cancel 5 out of 79 and found that clinical signs were unreliable and had to monitor bilateral knee replacements with a Swann-Ganz Catheter. It's more than double the risk when you double the operation."

"Part of the problem is the tourniquet; it releases all the emboli that occur at one time. Another issue is the intermedullary rod; it can be put in wrong, pressurizing the medullary canal and leading to embolization. Cement is a significant issue in putting implants in. As the implant is pressed in, cement can come to the surface; as it's driven in further, fat comes further to the surface, runs out, and you know where that fat is going. Berman pointed this out in relation to cement and most total TKA are done with cement. When the tourniquet is released the heart rate increases…you don't really know what is going on unless you consider what is going through the heart at this time."

"There is also selection bias here. A blinded, randomized controlled study is not possible because it's tougher on a patient to have bilateral TKA, and you select a healthier group. It should have a lower complication rate. The selection bias favors the stronger, healthier group. There are several studies showing that the results are about equal for staged bilateral versus simultaneous bilateral, but they are generally smaller studies and they don't include a large enough group to point out the differences. In Ritter's study, one of the best and biggest studies looking at Medicare data, he found that there was a three time greater death rate when you compared staged bilateral to simultaneous bilateral…and two times the number of ICU days. So it's not just twice as bad it's more than twice as bad."

"Another study which looked at the Swedish literature found that the 30 day mortality rate was 1.94 times higher when two knees were done simultaneously as opposed to staged out for about three months. In a large

meta-analysis Restrepo found that the chances of pulmonary embolism, cardiac complications and mortality were way higher when you did two together versus two separated by three months or more. How much less safe than unilateral total knee? Luscombe found wound complications: 6% versus 0.7%; deep infections: 3.5% versus 0.7%; cardiac complications: 3.5% versus 0.7%. Lane's study showed much higher complication rate than unilateral total knee and not just by a factor of two, but a factor of 17 in some cases."

"Thirty day mortality in a large Mayo Clinic study was related to cement fixation and to bilateral simultaneous total knee replacement. The results of treatment of infection in both knees after bilateral TKA (Wolf) significantly relates to the way the patient does postoperatively. I suggest that you minimize your risks. A low pressure, flat reamer decreases the pressure in the medullary canal and aspirates the medullary canal before you put in the medullary rod. Use intermedullary alignment, but do it carefully and discretely so that you don't embolize the patient as you go."

"Cementless tibial and femoral components embolize the patient much less. Bilateral simultaneous TKA may be more cost effective for the hospital, and it's within the standard of care, but it's riskier. You should share those numbers with the patient, let them know it's riskier, and do everything you can to minimize the risk—consider a Swann-Ganz Catheter and careful monitoring."

Dr. Sculco: "I recommend bilateral simultaneous TKA in selected patients; I do 40-50 a year. I do this operation because overwhelmingly patients prefer to have both knees done in one setting. There is less overall recovery time, it's one operative procedure, so the risk may be a little higher in terms of that procedure, but that patient is coming back for a second procedure and the risks are attendant to that second operation when they return. It's symmetrical recovery and it's less costly overall."

"Ideal patient: one who has significant bilateral flexion deformities because if you correct just one, inevitably the one you've done will return to the flex posture until you've corrected the second side. Cost savings have been demonstrated to be less overall—as high as 36% with one stage bilateral procedures."

"Leo has pointed out the disadvantages. However, in a paper we published looking at 501 consecutive simultaneous TKA at our hospital we had no deaths, strokes, or myocardial infarctions—mostly because of patient selection. These patients were monitored very carefully postoperatively and were kept in the ICU overnight; some spend

more than one night there. We looked at complications: major complications, we found cardiac was 5.6%, 2.1% pulmonary (2.7% but none went on to mortality)."

"You also see fat emboli in unilateral knees. In a study of transcranial Doppler monitoring where 60% of patients with unilateral TKA you could detect fat emboli during the initial procedure; it wasn't really any different in the bilateral group. Other major complications were gastrointestinal, confusion, and wound infection, none of which led to mortality or significant disability. As patients got older, probably because there was more comorbidity we saw a higher incidence of major complications. "

"Additionally, and this goes along with age for the most part, as the ASA Classification for those patients went up prior to surgery, we saw an increased risk of complications. Patient selection is key. This is not an operation for patients with significant comorbidity. The problem with most of the studies in the literature is that they are low volume. So we looked at a large database of over four million total knee replacements over 14 years. About 4% of those underwent bilateral TKA; we looked at complications after those series and found that comorbidities are less than the unilateral group or a revision group. When we looked at complications we saw that mortality was greater in the bilateral one stage group, as was pulmonary embolism."

"Also, inpatient mortality was somewhat higher in the bilateral group. But this dropped down. If you looked at every five year intervals you see that the complications were reduced from 1990 to 2004 due to better anesthetic management and better patient selection. Overall, you can reduce complications in this operation…I think it's a good operation in the fit, bilaterally affected patient. We have better intraoperative and postoperative monitoring, and you've got to do this surgery quickly."

Dr. Whiteside: "Tom is right. Selection is the key, as is being careful. You must think about fat embolization, tissue trauma, and be ready to abort the procedure if you see any changes. Tom, do you do a Swann-Ganz Catheter to monitor those patients? Do you ever do true bilateral simultaneous with one team on each side of the table working together?"

Dr. Sculco: "We used to use Swann-Ganz Catheters almost routinely in these patients, but we didn't find it that helpful…and there's some morbidity to putting a Swann-Ganz in. So we do it very infrequently now. Most patients are pretty fit, so the feeling of the anesthesiologist is that they don't need it to manage the patient. In terms of doing it simultaneously, I think that's not a good idea…not a good idea to have two tourniquets up at the same time. When you release the tourniquets they get a huge bolus of fat from both knees at the same time. So we stage them in the operating room."

Moderator Maloney: "Leo, is there any patient that you will do a bilateral TKA in?"

Dr. Whiteside: "Those who have a strong desire for bilateral TKA and who I think are healthy enough and they've been presented all of the risks…that's about one a year."

Moderator Maloney: "What about the patient with the bad deformity that Tom mentioned? Let's say a bilateral 30-40 degree flexion contracture with a 30 degree varus deformity. When would you do the second one?"

Dr. Whiteside: "Three months later. I especially don't like to do two very complex knee replacements at the same time."

Moderator Maloney: "How do you prevent the flexion deformity from reoccurring?"

Dr. Whiteside: "I haven't seen that to be a significant issue. They use a walker. If they can fully extend the knee they do, and they walk on the tip toes of the other side."

Moderator Maloney: "Tom?"

Dr. Sculco: "I've seen the opposite… on occasion where the patients are very sick and you've had to stage them, and I find that the first side that I've corrected

tends to go into the flex posture because it's almost impossible to walk with one flex knee and one straight knee. So they end up flexing the operative leg and you lose extension when you do the second side."

Moderator Maloney: "Patient indication: what are the red flags for not wanting to do a bilateral total knee replacement?"

Dr. Sculco: At our hospital we just had a conference between our anesthesiologists, internists, and knee surgeons. We're trying to develop some guidelines and benchmarks for who is the patient we should NOT do it on. Patients with significant cardiac risk, patients who have had CABG's (Cardiac Bypass Grafts), severe Type 1 diabetes, those over the age of 80, patients with severe pulmonary disease."

Moderator Maloney: "COPD tends to be a real risk factor for complication, as does congestive heart failure and bad valvular heart disease. What about the morbidly obese patient who is malnourished?"

Dr. Sculco: "We felt that a BMI of greater than 40 was a contraindication for doing both at the same time."

Moderator Maloney: "So that's the patient who's not maybe at risk for a general medical complication, but wound healing. So there's some consensus that there's a role for this operation in carefully selected patients."

Dr. Sculco: "We're looking at ways to modulate the pulmonary hit that the patient gets, and we're looking at enzymatic reactions. The lung produces desmosin and it seems that if you treat patients preoperatively with a low dose of cortisone you may be able to lessen that lung injury hit."

Moderator Maloney: "Every knee replacement has some embolization. You agree, Leo?"

Dr. Whiteside: "Yes."

Moderator Maloney: "Tom, comments on what Leo said about cementless fixation?"

Dr. Sculco: "We documented in the hip that the non-cemented are protected more from fat emboli, but also stem length is important. We use a prosthesis with a central peg but it's not very long. With all due respect, yours is longer and that would push more fat into the system, so it's somewhat of a tradeoff."

Moderator Maloney: "Thank you, gentlemen." ♦

Please visit www.CCJR.com to register for the 2012 CCJR Winter Meeting, December 12 - 15 in Orlando, Florida.

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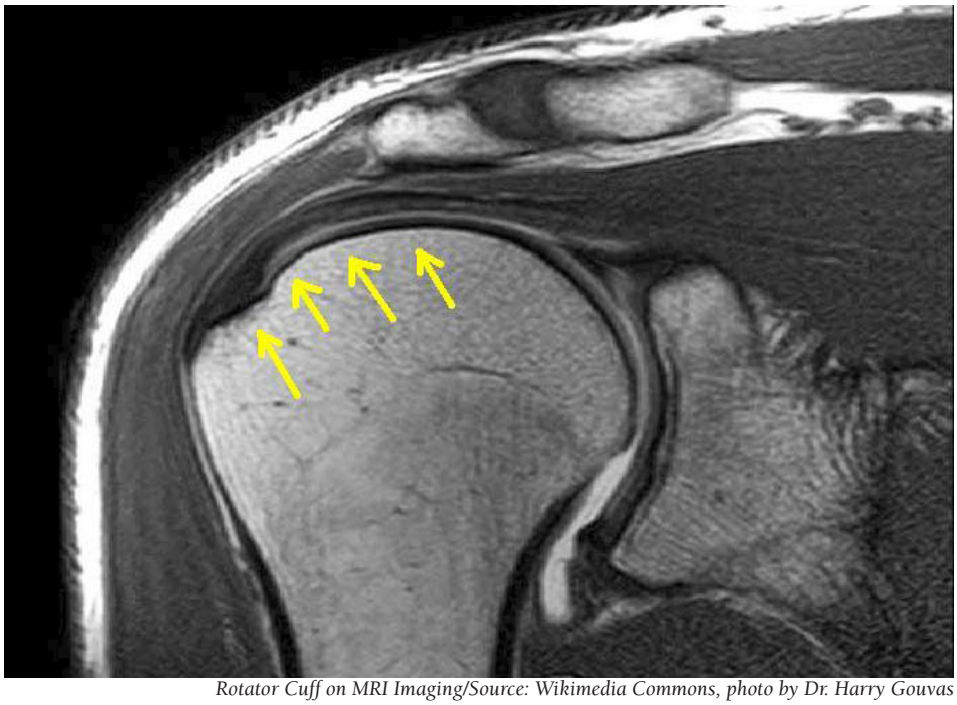
Aging Stem Cells Affect Rotator Cuff Healing? Cole's New Cartilage, "X" That X-Ray! and More…

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

"X" That X-Ray Sonia Chaudry, M.D. is a pediatric orthopedics fellow at Hospital for Sick Children in Toronto. She has recently published an article on the minimization of radiation exposure in orthopedics. Dr. Chaudry tells *OTW*, "Doctors are often quick to order studies such as CT scans and X-rays of limbs. There is often a medicolegal impetus to document anytime you touch or manipulate a patient in any way, and there used to be a dogma to do this radiographically with fractures even if they were stable. So for example if you adjust a cast you get a radiograph to make sure that the bone didn't move. Or let's say that you've put a cast on and the person comes back with an ulcer. Many would say, 'You should have taken X-rays to show that the cast was well applied.'"



Rotator Cuff on MRI Imaging/Source: Wikimedia Commons, photo by Dr. Harry Gouvas

"We looked at almost 250 people that had stable fractures, i.e., those that don't need to have the bone reset, but who were splinted while healing, and afterwards we found that none had moved. This gives physicians evidence based backing to forgo unnecessary X-rays without fear of medicolegal repercussions. This is rather groundbreaking, and I'm pleased to say that this has helped to change practice in my institution."

SIGN of a Global Take on Fracture Care? Recently, 150 surgeons, mostly from the developing world, attended the SIGN (Surgical Implant Generation Network) Fracture Care International Orthopaedic Surgical Implant Training Conference in Richland, Washington. Fifty of the surgeons attended the flap course and research course sponsored by the Institute for Global Orthopaedics and Traumatology at the University of California at San Francisco (UCSF). Lew Zirkle, M.D., founder of SIGN, told *OTW*, "We were so pleased to see an enthusiastic culture of collaboration amongst attendees. Attendees agreed upon the necessity of measuring results from the SIGN database by designing statistically significant clinical studies. We are, therefore, designing and implementing studies which examine stabilization in open fractures with the SIGN nail and by using silver dressings initially for open fractures. We are working with statisticians at the University of Washington and surgeons at UCSF. We expect more clinical studies will be designed."

"The series of SIGN nailings presented by these surgeons substantiate my impression that they are as good as any in the world; they have excellent results, especially when it comes to putting the SIGN nail into infected bones. To date, the SIGN network has performed 105,000 SIGN fracture surgeries worldwide. We are continuing to expand. We will visit our newest program in South Sudan where they have excellent surgeons but few implants and equipment.

Then, on a visit to Vietnam where SIGN started in 1999 will we knew many friendships. They helped in the early design and technique of SIGN surgery. In December we will travel to Haiti where the Haitian orthopedic residents are providing excellent results for the Haitian people."

Aging Stem Cells Affect Rotator Cuff Healing? Evan Flatow, M.D., Chair of Orthopaedics at the Mount Sinai Medical Center, tells *OTW,* "Herb Sun (Albert Einstein College of Medicine) and I were just awarded an R01 grant from the NIH [National Institutes of Health] to examine stem cells in tendon damage. The preliminary results show that stem cells in tendons age as we do. The challenge is to determine why rotator cuff tears do not heal well with surgeries in older people. One reason is that while these cells are regenerative, they also age and divide less. We studied gene transcription factors and found that some regulators of DNA transcription were able to undo that and make the cells young again. We are now looking at tendon healing in rats and mice, and trying to determine if we can help tendons heal by modulating stem cell activity."

"Nellie Andares, Ph.D., Assistant Professor of Orthopaedics at Mount Sinai, joined us last year. She has worked with me to look at how exercise affects tendon healing. Her own original research seeks to understand how fetal tissues heal without scar, and how we could use that information to improve adult healing. We are also trying to understand why tendons tear in the first place. We have used a model in which anesthetized rats undergo loading of their knee tendons in a special device. We have shown that small amounts of loading, such as exercise, can protect tendons against damaging loads."

"My clinical partner, Brad Parsons, M.D., and I have looked at rotator cuff healing in patients after arthroscopic repair. The traditional teaching was that these patients would get stiff if not moved vigorously, but we found that they heal better and still get good motion if protected in a sling for several weeks after repair before therapy begins. We will know more in a year."

Marc Swiontkowski, M.D. New Editor at *JBJS* The Journal of Bone & Joint Surgery, Inc., (JBJS, Inc.) has announced the appointment of Marc Swiontkowski, M.D. as editor of *JBJS Case Connector.* Dr. Swiontkowski is professor in the Department of Orthopaedic Surgery at the University of Minnesota and CEO of TRIA Orthopaedic Center in Bloomington, Minnesota. He received his medical degree from the University of Southern California and completed his orthopedic residency at University of Washington. He completed a Fellowship in orthopedic research at the Laboratory for Experimental Surgery in Davos, Switzerland. Dr. Swiontkowski has served on the Editorial Board of JBJS since 1995

HSS Teams Up With NFL Researchers at Hospital for Special Surgery will be giving their all when they begin using their new $100,000 grant from the National Football League (NFL) Charities. The team will be researching the use of platelet-rich plasma (PRP) and stem cells as treatments for tendon injury and degeneration. For years, PRP has been used to improve healing in various sports injuries, but there is little evidence of its efficacy. The hope is that this research would lead to the development of an effective therapeutic strategy for tendinopathy that may allow NFL players to return to competition more quickly. The researchers also say that it may lead to a decrease in complications related to tendinosis, such as tendon ruptures. The grant money will be used to investigate how degenerated tendons respond to PRP and bone marrow-derived stem cells as well as if these two treatments will be synergistic if they are combined. Researchers will test these treatments in a preclinical model of tendon injury and degeneration. Among the goals of the research are to examine the structural and mechanical properties of the treated tendon tissue and to see how it responds to PRP and stem cells.

Cole's New Cartilage Is a Single-Stage Knee Repair! Brian Cole, M.D., M.B.A. is a professor in the Department of Orthopedics at Rush University Medical Center and section head at the Cartilage Restoration Center at Rush. Dr. Cole has recently performed five surgeries using BioCartilage, a desiccated micronized cartilage extracellular matrix tissue provided by Arthrex. He tells *OTW*, "As a field we are in need of a single-stage cartilage repair procedure for chondral defects of the knee. To date, we have used microfracture, but that has shown mixed results. We have also used autologous chondrocyte implantation, a technique that requires two separate procedures and is relatively expensive. Other current options do not take advantage of readily available autologous biological sources of regeneration through the use of platelet-rich-plasma (PRP) and/or microfracture. BioCartilage is a unique new product containing micronized allogeneic cartilage; it is implanted with the addition of platelet rich plasma (PRP) in combination with atraumatically performed microfracture of the defect. The potentiation benefits come through access to the mesenchymal cells present in the subchondral bone in combination with a regeneration-friendly scaffold (BioCartilage) and the pro-anabolic and anti-catabolic effects of PRP."

Describing his experience with the surgery, Dr. Cole tells *OTW*, "In pursuing this procedure, we first needed to determine the best surgical technique. During the process, I learned that we should place the mixture of BioCartilage and PRP into the defect and then place the fibrin glue on top rather than at the base of the defect. Allowing the fibrin to set for 5 to 7 minutes leads to a stable scaffold that is very difficult to dislodge through range of motion. Also, the mixture is currently a 1:1 ratio of collagen scaffold and PRP and if it dries out a bit, the handling properties can be improved by adding a small amount of additional PRP."

"My colleagues and I are actively applying for grant support to perform a prospective clinical trial of patients receiving BioCartilage for the treatment of International Cartilage Repair Society (ICRS) grade 3 articular cartilage defects of the femoral condyle, trochlear groove, patella or tibia that measure between 1-5 cm^2. While eventually this study will be a prospective, longitudinal, non-randomized study of up to 40 human subjects, at present we are adding to the in vivo literature by performing a pivotal equine study beginning October 1, 2012 in collaboration with Dr. Lisa Fortier from Cornell Veterinary School and Jimi Cook, D.V.M., Ph.D. from University of Missouri Veterinary School. We will create two defects in five to six horses and compare this to microfracture alone. This will also be performed entirely arthroscopically."

"As for the multicenter clinical study, we will be using marrow stimulation as a historical control. The protocol is written and we have applied for a grant to support this initiative. We need to move slowly to assure that we are making a difference for our patients and continue to perform sound post-market research with clinical follow up." ♦

company

NuVasive Hit by Poachers and PODs

You have to admire Alex Lukianov. After company executives at NuVasive, Inc. saw that third quarter sales were going to be disappointing, Lukianov, the company's chairman and CEO, wasted no time in calling a hastily arranged conference call with Wall Street analysts on October 3 to give them the bad news.

The bad news was that sales came in at only $147 million instead of the $154 million, the company had told analysts to expect. While this was still a reported 11% growth over the previous year's third quarter, it was a decline by about $7 million from this year's second quarter. The subsequent pummeling in investor notes written by the analysts was followed by the company losing a third of its market value. Shares in the company fell 33% to $15.22.

"Poachers and PODs"

Company Chairman and CEO Alex Lukianov was clear. The results were directly and equally tied to poachers and PODs.

"We experienced an unexpected sequential decline in the third quarter due to unusually high account churn related primarily to the growth of surgeon participation in physician-owned distributorships [PODs] and to increasingly aggressive competitive tactics. As well, we heard from many surgeon customers of increased delays and denials from insurance payers. "

"We believe our ability to take market share with innovative procedural solutions and services remains strong. We are focused on addressing the new challenges," said Lukianov.

Pricing Pressure

In citing PODs and poachers as the reason for the sales results, Lukianov is describing what some are calling the "Era of the Big Price Squeeze." Hospitals are demanding price cuts. PODs, which Lukianov estimates have risen to 15% of the market, are giving it to them. He estimates NuVasive has lost around $15 million to $25 million in annualized sales as customers defected to PODs and sales reps defected to competitors.

Lukianov said the company can handle the poaching, noting that there are only so many $800,000 checks out there to poach sales people. He said smaller competitors were offering as high as $1 million to lure away reps and distributors. But PODs, he says, will require government action.

The one hour-plus conference call with analysts was unique in that there were few, if any questions about the spine market. The bulk of analyst's questions were about the PODs and poachers and how the sales shortfall was impacted by each.

Increasing Insurance Push-Back

Not to be lost in Lukianov's comments about sales numbers was his warning

Alex Lukianov, Chairman and CEO - NuVasive

that surgeons are, anecdotally, experiencing increasing payment denials by insurers. He said surgeons who used to tell him that insurer push-back wasn't hurting them, are now telling him new pressures are hitting them.

Lukianov said NuVasive was at the forefront in the last couple of years of helping surgeons deal with added payer barriers. Now, he says it seems the payers have figured out how to respond to surgeons' responses. He did not attribute any of the company's third quarter shortfall to insurer push-back. He added that increased reimbursement pressures could fuel more PODs, "as surgeons look for new sources of revenue."

Revenue Catalysts

The message from analysts wasn't all negative. Some agreed that the sales force will be stabilized and expect the PCM disc and the company's Japanese expansion to drive better revenue growth in 2013.

The company specifically noted these catalysts for growth:

- Continued expansion internationally including entry into the Japan market;
- Potential approval of PCM, the company's cervical TDR (total disc replacement) device for motion preservation;
- New launches and product highlights planned for the upcoming North American Spine Society (NASS) annual meeting; and
- Continued successful rollouts of its latest lumbar systems: Precept and MAS PLIF

Other companies will soon be releasing their third quarter results and the North American Spine Society is having its annual meeting in Dallas at the end of the month. We'll see who else is losing business to PODs and if the DePuy/Synthes merger is sparking new competition for sales reps and distributors.

—WE (October 5, 2012)

Lobo Named Stryker CEO/President

Kevin Lobo has been named president and CEO of Stryker Corporation.

The surprise announcement was made October 1.

Kevin Lobo/Stryker Corporation

Lobo joined Stryker in April 2011 when he was appointed as a group president to lead the company's newly formed Neurotechnology and Spine Group. Before he could measure drapes to his new office, he was named group president, Orthopaedics the following month. He replaced Mike Mogul, who left to head up DJO Global, Inc. Orthopaedics includes the company's Reconstructive, Osteosynthesis, Joint Preservation, Orthobiologics and Performance Solutions businesses.

Curt Hartman, Stryker's CFO and interim CEO since the February 2012 departure of the former hairman, President and CEO Stephen MacMillan, has decided to "pursue opportunities outside of Stryker," according to a company statement. Hartman has agreed to stay on as an advisor to Lobo to assure a smooth transition as the company conducts a search for a permanent CFO.

"After a very thorough search process involving external and internal candidates, we are pleased to name Kevin Lobo as Stryker's President and Chief Executive Officer," said William Parfet, the company's non-executive chairman of the board. "He is a talented executive with a broad range of global experience and he knows our company and industry extremely well. Since joining Stryker in 2011 he has proven to be a highly effective leader for our Orthopaedics Group, and he has won the confidence of employees, customers and the Board. We are excited about Stryker's future under Kevin and believe our shareholders and all stakeholders will benefit from his leadership."

Lobo said that Stryker is a company with a proud history and a bright future. "Since joining the company last year, I have witnessed firsthand the commitment of our talented people as they work to enhance the lives of patients. It's a privilege to have the opportunity to lead this great company, and I look forward to working with the Board and our people throughout the organization to maximize our strengths, build on our leadership position and create value for shareholders."

With his short tenure at the company, it's hard to predict what changes, if any, he will bring to the company. His predecessor was known for pursuing a "big footprint" strategy and building the company's value through lots of "singles and doubles," instead of home runs. The company did swing for the fences last year when it acquired Boston Scientific's neurovascular business and

Orthovita. The company also sold its OP-1 business.

Kevin Lobo Resume

Lobo has a broad and diverse 25-year business career that includes executive positions in general management and finance. After holding finance positions with KPMG and Unilever Canada, he joined Kraft Canada in 1992. He subsequently held executive positions at Rhone-Poulenc, including roles based in Europe as worldwide corporate controller of the chemical spin-out, Rhodia, and general manager of Specialty Phosphates EMEA. In 2003 he joined Johnson & Johnson at McNeil Consumer Healthcare as CFO. In 2004 he took on additional responsibilities as CFO of Ortho Women's Health and Urology and general manager of McNeil Canada. In 2005 he was named president of Johnson & Johnson's Medical Products Canada and in 2006 he became president of Ethicon Endo-Surgery, Inc., a $4 billion business.

Wells Fargo analyst, Larry Biegelsen said the news did not come as a complete surprise to his analyst team as they had heard recently that the Board was impressed with him and was considering him for the vacant CEO position. "Specifically, we heard that Mr. Lobo possesses good leadership skills and is well-liked and respected within Stryker. In addition, we heard the Board was interested in his international experience (Canada and Europe) because Stryker has historically not performed as well outside the U.S. as it has in the U.S."

Now that he can't be promoted any higher, this time Lobo should be able to measure and keep his drapes.

—WE (October 7, 2012)

legal

Former Hospital for Special Surgery CEO Arrested

The former head of the oldest and frequently top orthopedic hospital in the United States has been arrested.

John R. Reynolds, the former CEO of New York's Hospital for Special Surgery (HSS) was arrested on September 26 at his home in Massachusetts in connection with a decade-long kickback scheme involving $1.4 million in payments that Reynolds allegedly extorted or solicited from hospital vendors, a hospital employee, and a United Kingdom-based healthcare organization.

According to a press release from the U.S. Attorney's Office for the Southern District of New York, Reynolds is also charged with making false statements to law enforcement.

Manhattan U.S. Attorney Preet Bharara said: "By allegedly exploiting his position at the helm of a world renowned hospital for his own personal gain, John Reynolds tarnished the hospital's reputation and did a disservice to its employees. This office has zero tolerance for corruption, and we will aggressively prosecute anyone who engages in such conduct."

According to allegations unsealed on the 26 in Manhattan federal court, Reynolds was the CFO of HSS from 1986 until 1997. In 1997 he was made CEO and stayed in that position until October 2006 and served as a contract employee through December 2008.

"In violation of both the law and his duty to provide honest services to the

John Reynolds, former CEO of the Hospital for Special Surgery in Manhattan, in a 2005 handout photo.

Hospital," state the allegations, Reynolds engaged in three separate kickback schemes from 1996 through 2007 in which he solicited or extorted approximately $1.4 million in illegal kickbacks. Between 1996 and November 2002, he allegedly solicited and received approximately $420,000 in kickbacks from at least two different hospital vendors, in return for using his position at HSS to help them secure contracts and future business.

Between 2000 and 2005, the government claims Reynolds extorted and received approximately $298,500 in kickbacks from a subordinate employee of HSS in exchange for negotiating payment of that employee's annual bonus. And between 2005 and 2007, he allegedly solicited and received approximately $670,000 in kickbacks from a U.K.-based healthcare organization, in exchange for using his position at the hospital to approve a clinical partnership between the hospital and the organization.

During these time periods, Reynolds also, according to the government, repeatedly made false statements to, and withheld information from, hospital's board of directors about his

outside consulting arrangements, and other conflicts of interest that would or might prevent him from acting in the best interests of the hospital.

Reynolds, 63, of Cataumet, Massachusetts, is charged with one count of racketeering, which carries a maximum sentence of 20 years in prison, and one count of making false statements to the federal government, which carries a maximum sentence of 5 years in prison.

The New York Times reported on September 26 that Reynolds' lawyer, Michael J. Grudberg, said that his client had appeared before a federal magistrate judge in Boston, and was released pending further proceedings in Manhattan.

"The government's allegations are without basis in fact or law," Grudberg told the *Times*. "Mr. Reynolds served HSS faithfully and diligently for two decades, and looks forward to making his case in court."

Kickback charges that led to the federal indictment and arrest of Reynolds were not, according to *Crain's New York Business.com*, news to the hospital. But their scope and severity was "a shock," said Deborah Sale, the hospital's executive vice president for external affairs.

It's not the first time an allegation has been made that Reynolds was involved in kickbacks.

According to *Crain's*, he was named in a $10 million lawsuit brought by Healthwave Inc. in 2009 that alleged he took kickbacks from a Long Island supplier in return for steering roughly $150,000 a year in contracts its way."

—*WE (October 2, 2012)*

Supremes Reconsidering Obamacare?

The Supreme Court ruled the Affordable Care Act (ACA) constitutional in June. But Jerry Falwell's Liberty University is still trying to drive a stake through its heart.

Joyce Frieden of *MedPage Today* reports on October 1 that the Supreme Court, now in a new term, has given the Obama administration and Liberty University 30 days to file responses in a case previously dismissed by the Fourth Circuit Court of Appeals and refused to be heard by the Court after ruling the law constitutional.

Just in time for Halloween.

Liberty University and two women assert that the penalty under the mandate is really a tax and Congress can only impose taxes on actual purchases. They argue that the Supreme Court's upholding of the ACA did not address that specific question and want another chance to make their case.

The two women also contend that the individual mandate exceeds Congress's authority under the Commerce Clause of the Constitution. This, according to Frieden, is the position that the Supreme Court also took when it said that the ACA's individual mandate was not constitutional under the Commerce Clause but was constitutional under Congress' power to levy a tax.

The plaintiffs all are asking that the ACA not be enforced and that the Court declare it unconstitutional. The U.S. District Court for the Western District of Virginia dismissed the case in November 2010, ruling that the ACA is valid under the Commerce Clause.
"The plaintiffs," wrote Frieden, "then appealed the case to the U.S. Court of Appeals for the Fourth Circuit, which also dismissed the case in September 2011 but for a different reason—it said that under the Anti-Injunction Act (AIA), which says that a person cannot file suit over a particular tax until that tax has actually been levied, the suit was premature and couldn't be filed yet. (The Supreme Court rejected a similar AIA argument when it decided its case in June.)"

The plaintiffs have now asked the Supreme Court to reconsider its previous decision not to hear their case.

—*WE (October 2, 2012)*

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Stryker Recalls Neptune System After Fatality

Stryker Corp. issued an "Urgent" worldwide Class 1 Medical Device Recall of the Neptune Rover Waste Management System through a Product Bulletin on September 25.

The company said the recall was initiated on June 5, 2012 after receiving two reports of serious injury as a result of tissue damage associated with the use of the Neptune 2, including an event in which one customer connected the Neptune 2 System to a passive chest drainage tube post operatively, resulting in a fatality.

Customers were notified in June that the current IFU (instruction for use) did not specifically warn against connecting the Neptune Rover, which is a high vacuum/high flow device, to a passive drainage tube. Customers were instructed to review the revised IFU, distribute to affected departments, and educate users of the Neptune on this warning. Customers had to confirm with Stryker via business reply form that they have completed these actions.

Customers who have the Neptune 1 Gold, Neptune 1 Gold International or Neptune 1 Bronze will receive a follow-up mailing in October containing warning labels for the device and instructions detailing how to apply them. Customers may continue to use the Neptune 1 Gold, Neptune 1 Gold International, and the Neptune 1 Bronze. Users must be aware of the warning that was added to each device.

No FDA 510(k) Clearance

On September 18, 2012, Stryker notified customers via overnight delivery that it had expanded the recall on the Neptune 1 Silver, Neptune 2 Ultra (120V) and Neptune 2 Ultra (230V) because FDA has advised them that these devices require, but do not currently have, 510(k) clearance. FDA is therefore unable to determine whether these devices are as safe and effective as their legally marketed predicate, the Neptune 1 (Gold) Waste Management System (510(k) K012992). As such, Stryker has ceased distribution of the Neptune Silver, Neptune 2 Ultra (120V) and Neptune 2 Ultra (230V) devices until FDA clears these devices.

The company bulletin also said that the FDA does not consider the Neptune Silver, the Neptune 2 Ultra (120V) or the Neptune 2 Ultra (230V) to be legally marketed devices because their safety and effectiveness have not yet been determined. As such, FDA advises that the devices not be used.

However, customers who do not have an alternative device to use should weigh the risks and benefits associated with continued use of these devices. If customers choose to continue use of the Neptune Silver, Neptune 2 Ultra (120V) or Neptune 2 (230V), they must complete a Certificate of Medical Necessity and return it to Stryker by October 12, 2012.

Customers who submit their signed Certificate of Medical Necessity to Stryker will receive a follow-up mailing containing warning labels for the device and instructions detailing how to apply them.

Directors of orthopedics were included in the recall notification.

Customers who have questions about this recall should contact Stryker Instruments' Recall Coordinator, Angela Ragainis, Monday – Friday, 8am – 5pm ET, at 269-389-2316 or strykerinstrumentsrecalls@stryker.com

Attached is a revised recall notification.

http://www.stryker.com/stellent/groups/public/documents/adacct/147939.pdf


stryker
Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
269-323-7700
www.stryker.com
URGENT MEDICAL DEVICE RECALL NOTIFICATION (Revised)
RE: STRYKER NEPTUNE 1 (SILVER) & NEPTUNE 2 WASTE MANAGEMENT
ATTENTION: RISK MANAGER, OR DIRECTOR, DIRECTOR OF SURGERY
And the following areas:
DIRECTOR OF SURGICAL SERVICES
DIRECTOR OF ANESTHESIA
DIRECTOR OF OR NURSING
DIRECTOR OF ORTHOPEDICS
DIRECTOR OF MATERIALS MANAGEMENT
OFFICE MANAGER
Part Numbers: 0700-003-000 Neptune 1 Rover Silver (120V)
0702-001-000 Neptune 2 Rover Ultra (120V)
September 19, 2012
notify you of a Class I recall of the Neptune 1 Silver Waste
2 Ultra Waste Management System (Neptune 2).
struments has received two reports of
Neptune 2 device, including an
drainage tube post-

Neptune Recall Notification/Stryker Corp.

—WE (October 7, 2012)

Europe to "Reboot" Device Oversight

Europe wants to reboot its medical device regulations.

On September 26, 2012, the European Commission released a proposal for future regulation of medical devices. Within the package, according to an analysis from the BSI Group, the current three Directives on active implantable medical devices (AIMD), medical devices (MDD) as well as in vitro diagnostic medical devices (IVDD) are replaced by two Regulations, one covering all medical devices, the other covering IVDDs.

European Union/Wikimedia Commons

Uniformity, Predictability and Transparency

These new rules, states the BSI analysis, are proposed for a number of reasons, including the need to bring legislation in line with the pace of technological and scientific progress over the last 20 years. In addition the proposed changes bring uniformity as current Directives lead to different interpretation and implementation in the various EU (European Union) member states and consequently to different levels of patient and public health protection in the EU. The new Regulations also aim to improve traceability, and transparency.

The revision was initiated in 2008 before the recent silicone breast implant scandal and problems uncovered in registries about certain metal-on-metal hip joint replacements. "Lessons learned have been used to strengthen the system, and ensure it is ready to face the future," said the BSI statement.

The proposal includes more detail on medical devices and on IVDDs, it also encompasses the possibility of short-term further revision by referring to amending and implementing acts that can be added in the future.

Stronger Supervision

Independent assessment agencies will be given greater powers to monitor device manufacturers, including unannounced factory inspections and regular product testing, while EU governments will be obliged to improve their supervision of the agencies.

Better product traceability systems will also be introduced so that people can be alerted more rapidly to safety concerns surrounding a particular device.

The European market for medical devices is estimated at $123 billion in 2009.

The legislation must be jointly approved by EU governments and lawmakers. That could take up to two years.

Unhappy Manufacturers and Patient Advocates

Eucomed, which represents about 22,500 medical technology companies in Europe, reportedly said it was unhappy with the proposal for the new scrutiny panel procedure, which it said would "hamper innovation" whilst providing no extra safety nets for patients.

Equally unhappy was the European Consumer Organisation (BEUC), which reportedly argued that the plans fall short of increasing quality and safety standards and said medical device regulations should be beefed up to levels similar to those required for pharmaceuticals.

Below, courtesy of the BSI Group, are the main changes proposed for medical devices:

- *The MDD will become a Regulation rather than a Directive*
- *Wider and clearer scope of EU legislation, extended to include implants for aesthetic purposes, and human tissue derived devices*
- *Stronger supervision of notified bodies by national authorities*
- *More powers for notified bodies vis-à-vis the manufacturers, to ensure thorough testing and regular checks, including unannounced factory inspections at manufacturing sites*
- *Clearer rights and responsibilities for manufacturers, authorised representatives, importers and distrib-*

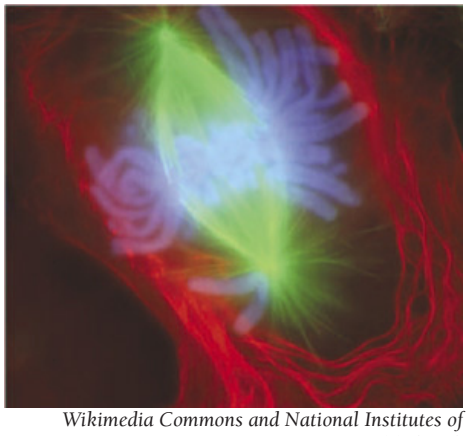
utors, including in the case of diagnostic services and internet sales
- *Extended database on medical devices (Eudamed), providing comprehensive and public information on products available on the EU market*
- *Better traceability of devices throughout the supply chain, enabling a swift and effective response to safety concerns (e.g. recalls)*
- *Reinforced rules for clinical investigations on devices and the required clinical data for the pre-market and the continuous post-market assessment of medical devices, including in vitro diagnostic medical devices*
- *Adaptation of the general health and safety requirements, including labelling provisions, to the technological and scientific progress*
- *A limited number of reclassifications (orthopaedic implant, aphaeresis equipment)*
- *Creation of a Medical Device Coordination Group (MDCG) composed of members representing national competent authorities in the field of medical devices to ensure better coordination between Member States, with the Commission providing the necessary scientific, technical and logistic support*
- *The Notified Body will have to inform the MDCG of all new high risk applications and submit a summary of safety and performance, the MDCG can request additional information within 15 days and additional information within 90 days, this does not apply to changes to existing products*
- *Each manufacturer and authorised representative will require a Qualified Person with five years of Medical Device regulatory experience to be responsible for the conformity of batches to be released, maintenance for the technical documentation and declaration of conformity plus vigilance reporting*

—WE (September 27, 2012)

biologics

Time to Stress Test PRP and Stem Cell Products

For years platelet-rich plasma (PRP) has been used to treat tendons for injury and degeneration—with more anecdotal evidence than high level scientific study based evidence. The same has been true of the use of stem cells. Recently researchers at Hospital for Special Surgery (HSS) have been awarded a $100,000 grant from the National Football League (NFL) Charities to research the use of PRP and stem cells as treatments for tendon injury. NFL players and other athletes suffer from tendon overuse injuries and they need new treatments.


Wikimedia Commons and National Institutes of Health (NIH)

"We don't have a treatment that works 100 percent of the time, so there is room for improvement," said Scott Rodeo, M.D., co-chief of the Sports Medicine and Shoulder Service for Hospital for Special Surgery in New York City. "Many people are weekend warriors and they suffer from tendon overuse injuries. Hopefully, our study will be able to help a lot of these people." Rodeo, who will be heading up the research, has been

associate team physician for the New York Football Giants since 2000.

Researchers hope that their work will lead to the development of an effective therapeutic strategy for tendinopathy that will allow NFL players to return to competition more quickly. It may also lead to a decrease in complications related to tendinosis, such as tendon ruptures. Tendinosis is caused by repetitive microtears in the connective tissue in and around the tendon along with a failure of the body to mount a full healing response. Over time tendinosis leads to pain, reduced tensile strength and the chance of tendon rupture.

The grant money will be used to investigate how degenerated tendons respond to PRP and bone marrow-derived stem cells as well as if these two treatments will be synergistic if they are combined. Among the goals of the research are to examine the structural and mechanical properties of the treated tendon tissue to see how it responds to PRP and stem cells.

In recent years, physicians have found that some, but not all, patients with tendon disorders respond to treatment with PRP. PRP contains cells and growth factors that may stimulate healing of bone and soft tissue. Researchers surmise the mixed results may be caused by variations in preparation, timing, dosage and delivery of platelets, or differences in bioactivity.

Different PRP preparations contain different amounts of cell and growth factors. The researchers speculate that the studies that had negative results may have used PRP preparations with low bioactivity. To test this theory, researchers will test the bioactivity levels of the preparations used. Further, the researchers hope to be able to address the question of whether PRP treatments actually help heal the tendon structure or just ameliorate the pain.

"We don't really understand how PRP affects tendon structure after we place it into patients. Some individuals get pain relief while others do not. The reported clinical results are mixed, "said Richard Ma, M.D., an orthopedic surgery fellow in the Sports Medicine and Shoulder Service at Hospital for Special Surgery and co-principal investigator for the study. "The advantage of a preclinical research model is we can not only evaluate the effects of PRP on tendon architecture after injury, but we can also evaluate how it might improve the structural strength of these tendons."

Similar to PRP, studies using stem cells to treat tendon disorders have also yielded conflicting results. HSS researchers hope their experiments can tease out how this treatment impacts tendons. "Cell therapies such as bone marrow stem cells are attractive because it may provide the necessary stimulus to overcome the unfavorable biologic microenvironment in chronic tendon degeneration," said Ma. Stem cells have the capability of differentiating into diverse specialized cell types.

"We hope the results of our study will identify the important parameters that might improve the efficacy of PRP and stem cell treatments," said Ma. "Despite both treatments being readily clinically used, there is still a great deal we do not understand about PRP, stem cells, and how to optimize the composition to improve its efficacy for all patients. With our research proposal, we are hoping to address some of these questions that we have not been able to answer with human clinical studies."

—BY (September 30, 2012)

large joints

Chronic Sleep Loss=Bone Loss?

Scientists at the Medical College of Wisconsin, led by Carol Everson, Ph.D., professor of neurology, cell biology, neurobiology and anatomy, have discovered abnormalities in bone and bone marrow in rats undergoing chronic lack of sleep. They found abnormalities in serum markers of bone metabolism in sleep-deprived rats, which led them to conduct direct measurements of bone parameters; this time in rats experiencing recurrent sleep restriction during a large portion of their young adulthood.

Wikimedia Commons and Bertil Videt

The team found a dramatic imbalance between bone apposition and reabsorption, marked by an arrest in bone formation without reduced absorption. Furthermore, fat in the red marrow is greatly diminished and platelet-generating cells are doubled in number, indicating changes to marrow plasticity. "If the same processes are evoked in humans," said Dr. Everson in the September 18, 2012 news release, "the potential medical implications are far-reaching and may include poor repair of microdamage from activities of daily living, introduction of osteoporotic processes, and changes to progenitor cells that may affect disease predisposition and disease resistance."

The researchers observed changes in intramembranous ossification and marrow hypercellularity resulting from chronic sleep loss. "Marrow fat was greatly diminished and reflected increased blood cell production and differentiation. Our findings of increased megakaryocyte numbers, for example, suggest that there is an increased demand for cell delivery to the circulation consistent with an inflammatory response, and conceivably the promotion of thrombocytosis," said Dr. Everson.

Dr. Steven R. Goodman, Editor-in-Chief of *Experimental Biology and Medicine* said, "With increased life stress due to work-related, financial and other issues a large percentage of us are experiencing difficulties in sleeping. While we know that chronic sleep loss can affect our health little specific information has been available on how it may impact bone formation or loss. Drs. Everson and Toth, together with Anne Folley present exciting results indicating that sleep deprivation in rats arrests new bone formation, decreases fat within the red marrow and increases platelet levels. If true in humans, and I expect that it may be, this work will have great impact on our understanding of the impact of sleep deprivation on osteoporosis and inability to repair bone damage as we age."

Dr. Everson told *OTW*, "I was surprised to learn that sleep loss would arrest bone apposition and change the cellular make-up of the bone marrow. If these changes occur in sleep deficient humans, key aspects of development, repair, and recuperation would be affected. The findings on chronic sleep loss point to specific alterations in cellular and structural mechanisms that affect growth and repair. Orthopedic surgeons should be aware that sleep deficiency may be an important risk factor for abnormal bone health that could affect healing."

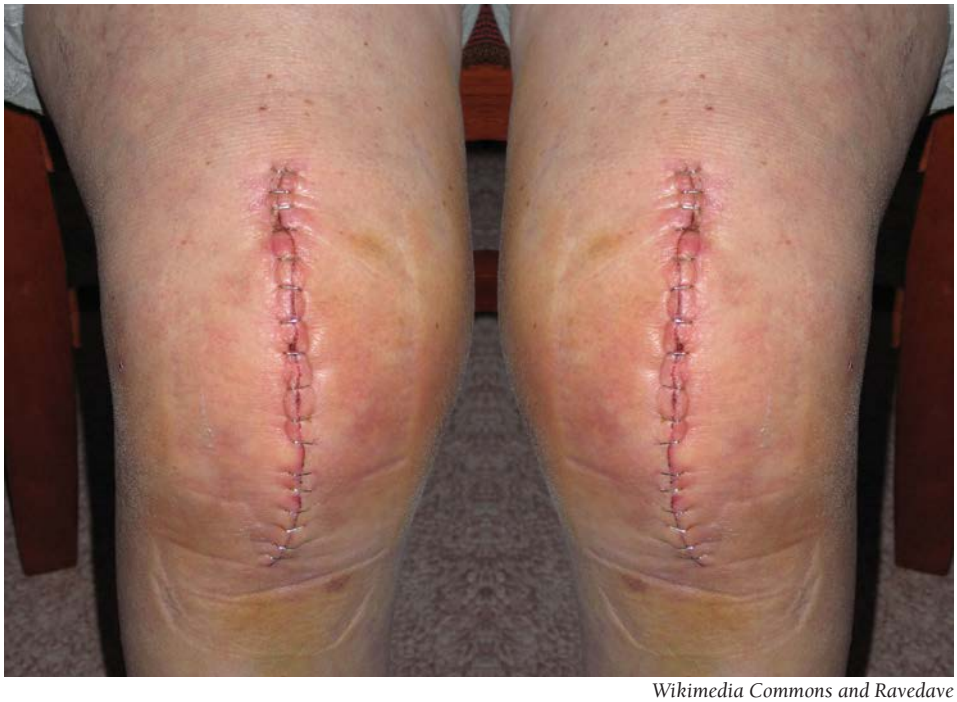
—EH (October 4, 2012)

Bilateral Knee Patients: Complication Rates Increasing

Due to the inherent risks, doctors in recent years have been selecting younger and healthier patients for bilateral total knee replacements. Now researchers from Hospital for Special Surgery (HSS) have found that although patients are younger and healthier than those undergoing only one-sided surgery, they are becoming sicker and some complication rates have risen.

The team says that an increase in obesity appears to be driving the complication rates, as well as the increase in total knee replacements. Researchers identified 258,524 bilateral total knee replacements performed between 1999 and 2008. The number of annual bilateral procedures increased by 75%. Over the time period studied, the researchers identified a 3% increase in pneumonia, a 6% increase in pulmonary embolism, and a 3% increase in nonmyocardial infarction cardiac complications.

Stavros Memtsoudis, M.D., Ph.D., director of Critical Care Services at Hospital for Special Surgery, was asked how workups can be done more thoroughly/appropriately. He told *OTW*, "This was at the heart of the recent Consensus Conference on Bilateral Total Knee Arthroplasty, organized by Hospital for Special Surgery, at which experts from around the country came together to address this kind of question. In brief, appropriate selection of patients and workup were deemed of utmost importance in order to achieve the best possible outcomes. While a number of specific comorbidities and patient



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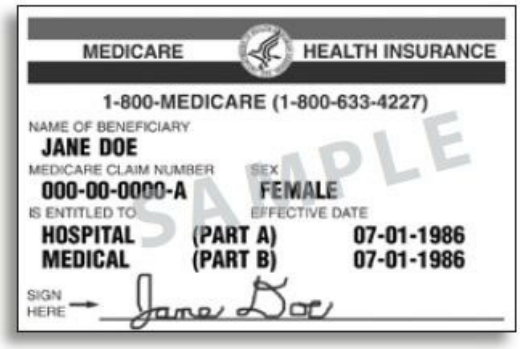
characteristics were identified as exclusion criteria, the overarching theme was that patients with significant cardiac, pulmonary, renal and cerebrovascular disease as well as poorly controlled diabetes and excessive weight should not be considered to be adequate candidates. Workup for bilateral procedures should be performed with the notion that these interventions are higher risk, thus requiring more thorough testing, to unveil difficult to diagnose problems like pulmonary hypertension which occurs more frequently in patients with sleep apnea and COPD, for example. Further, co-management with a medical service was recommended, as was more intensive monitoring perioperatively."

Dr. Memtsoudis added, "The most surprising finding was the recognition that many complications did not decrease over time and that some of them even increased. Also, the fact that the bilateral population of patients was getting sicker over time was interesting. While we expected to see these trends among the general orthopedic patient population, we thought that temporal changes in bilateral knee arthroplasty candidates would somehow behave differently. Before the study we speculated that the desire of clinicians to select healthier patients given the heightened awareness of increased risk when dealing with these patients would have led to a very different epidemiologic picture. However, it seems that although still younger and healthier then unilateral knee arthroplasty patients, trends towards increasing comorbidity burden persist even in the bilateral group and may represent the underlying reason for our findings regarding complication rates."

—EH (October 2, 2012)

TKAs UP 162% Among Medicare Enrollees



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New knees are becoming old hat. For every 10,000 Medicare enrollees, 62.1 have received a total knee arthroplasty (TKA) procedure. The number of procedures jumped 162%—to 243,802—from 1991 to 2010 and the per capita rate rose 99%. This is according to an analysis of fee-for-service Medicare records by Peter Cram, M.D., MBA, of the University of Iowa in Iowa City and reported by Crystal Phend of *MedPage Today*.

While patients stayed for shorter and shorter periods of time in the hospital, that cost saving was offset by rising readmissions and complications in revision procedures, particularly those related to wound infections, Cram and his associates reported in their article in the September 26 issue of the *Journal of the American Medical Association*.

"This growth is likely driven by a combination of factors including an expansion in the types of patients considered likely to benefit from a TKA, an aging population, and an increasing prevalence of certain conditions that predispose patients to osteoarthritis, most notably obesity," they wrote.

According to Phend, Cram's group analyzed the records of 3.3 million Medicare Part A beneficiaries ages 65 and older who had a primary knee replacement and 318,563 who had a revision procedure. They found that the trends in utilization from 1991 to 2010 showed a 162% increase in the total volume of primary procedures from 93,230 to 243,802; a 106% rise in revision TKA volume, from 9,650 to 19,871; and a 99% increase in the per capita rate of primary knee replacement from 31.2 to 62.1 per 10,000 Medicare enrollees. Finally, there was a 59% increase in per capita revision procedures, from 3.2 to 5.1 per 10,000 Medicare enrollees.

The researchers questioned whether the growth in TKAs reflected the fact that it was an "appropriate use of a highly effective procedure or overuse of a highly reimbursed procedure for which indications still depend on clinical judgment." In other words—was

the procedure urged on the patient by the doctors? "It is likely that both factors are at play," they wrote.

Patients' hospital length of stay fell from an average of 8 days for a primary knee replacement in the 1991-1994 time period to 4 days in 2007-2010 and from 9 days to 5 for revision procedures over the same time period. The authors speculated that the shortening length of stay reflected changes in the payment system that provided a powerful incentive for hospitals to speedily discharge patients to their homes or skilled nursing facilities.

Phend reported that revision procedures were associated with a more than doubling in readmission rates for wound infection from 1% to 3% and more than a 100% increase in readmissions for hemorrhage, sepsis, and heart attack. Patients who returned to the hospital soon after their procedure tended to be older, male, black and sicker with comorbidities.

The researchers discovered that centers that did more knee replacements were associated with lower readmission rates for both primary and revision procedures. Surprisingly, a significant percentage of TKAs were performed by surgeons doing fewer than 12 cases a year.

Reflecting this fact, the researchers wrote, "Careful consideration should be given to whether the majority of these cases should be shifted toward high-volume centers, which often have the infrastructure and the experience needed to develop the highly coordinated care pathways necessary to optimize the quality outcomes and efficiency of the episode of care for complex patients."

—BY (October 2, 2012)

spine

Spinal Elements Introduces Hero Allograft, Honors Donors

Product release with a purpose…Spinal Elements, Inc. has announced its intention to improve the image of tissue donation when it launches its Hero Allograft human tissue product at the upcoming meeting of the North American Spine Society (NASS) later this month. Hero consists of various configurations of human allograft tissue including demineralized bone matrix (DBM) in paste or putty form, compressible cancellous blocks and strips, and structural grafts.

Spinal Elements chose to name its first-ever allograft tissue product "Hero" to honor those whose donation made the tissue possible. The company will donate its net proceeds from the sale of Hero Allograft to charities that benefit children with life-threatening medical conditions.

Spinal Elements launches Hero on the heels of the release of the book *The Dark Side of Tissue Donation* by Chris Truitt. Truitt comments in the October 1, 2012 news release, "What Spinal Elements is doing by donating the net proceeds from the sale of Hero Allograft to charities that benefit children is unprecedented and extraordinary. It honors the altruistic and noble gift that families give."

Todd Andres, CEO and co-founder of Spinal Elements, added, "We feel that the best way to pay respect to the donation of human tissue is to donate our efforts to get it to the patients who need it and to extend that gift to ailing children. We refer to that as honoring the gift and paying it forward."

Jason Blain, president and co-founder of Spinal Elements, told *OTW*, "Spinal

Spinal Elements

Elements has never been a company that does something because of the status quo. When we develop a product or introduce a technology, we do it because it's the right thing to do and because we can offer something no one else addresses. If you look at allograft as a product, it is a commodity…and that's how the spine and orthopedics market sees it. To me that is shame. Allograft is the physical embodiment of a human life and deserves that level of respect. It is a gift."

Regarding the product background, Blain told *OTW*, "As our company grows, we are continually able to support a broadening range of spinal fusion procedures due to our expanding product offering. We have offered a synthetic graft material for some time, but until now we have not offered allograft in any form. We needed a solution for our distributors and surgeons who wanted just one sales representative in the room during a procedure. Therefore, we knew that we needed to offer allograft products based on the needs of our customers."

"Our decision to donate our proceeds is an easy decision…it's the only possible route for us. The decision at its core defines the culture of our company. By donating the proceeds to the Make-A-Wish Foundation and St. Jude Children's Research Hospital we're furthering the donor's gift to those who can't help themselves. I feel that Hero is more than about a product. It's about a statement of what we want to be and how we feel allograft should be treated."

—EH (October 4, 2012)

Silicon Nitride vs. Titanium or PEEK

Move over titanium (TI) and poly-ether-ether-ketone (PEEK)—there is a new challenger on the block. Salt Lake City, Utah, based Amedica Corporation announced on September 13 enhanced biomaterial claims based on newly published data for the company's proprietary competing silicon nitride biomaterial.

Traditional treatment for the 65 million Americans who suffer from lower back pain includes implanting metal or plastic spacers between the vertebrae .While these spacers provide bone support and reduce pain; they do not actively participate in the bone fusion process and lack anti-infective characteristics. This is where silicon nitrides comes in.

Amedica's new claims for silicon nitrides are based on peer-reviewed reports that silicon nitride's hydrophilic surface demonstrates superior new bone growth and bacterial-resistant properties—greatly reducing the risk of infection—when compared to traditional treatments using titanium (Ti) or poly-ether-ether-ketone (PEEK.)

According to Amedica officials, researchers writing in the *International Journal of Nanomedicine* found that silicon nitrides is far less vulnerable to bacterial colonization (S. epidermidis, S. aureus, P. aeruginosa, E. coli and Enterococcus) than are PEEK and titanium. Because of the positive surface charge, nanostructure and hydrophilic

Wikimedia Commons and PD-USGOV-DOE.

nature of silicon nitride, there was also rapid adherence of fibronectin, vitronectin and laminin proteins which can decrease susceptibility to bacteria and increase osteointegration.

Researchers writing in the journal *Acta Biomaterialia* (2012) reported that the amount of regenerated bone associated with the silicon nitride implants was essentially two- to three-times that of the other two implant materials at three months post-surgery. After 14 days, silicon nitride demonstrated significantly greater new bone formation at both the surgical site and the implant interface.

Thomas J. Webster, Ph.D., lead investigator, chair and professor of the Department of Chemical Engineering at Northeastern University, said, "Selectively engineering the biomaterial or surface structure of the implant can decrease bacterial adhesion, therefore lessening the risk potential for infection. Our study examined the innate biomaterial characteristics of silicon nitride, PEEK and titanium, and it was evident that silicon nitride holds the greatest potential for decreased risk of bacterial infection."

"The expansion of these biomaterial claims to our silicon nitride interbody fusion devices demonstrates the clear superiority of our technology in comparison to PEEK and titanium," said Eric K. Olson, president and CEO, Amedica. "The company is prepared to take advantage of these enhanced claims, to dramatically increase sale of our silicon nitride products and grow company revenue. Ultimately, we believe, this technology will become the new standard of care."

Amedica officials report that silicon nitride has been used in interbody fusion devices for more than four years with a proven record of safety and effectiveness. They say that surgeons at leading hospitals are utilizing silicon nitride interbody fusion devices to help minimize patient exposure to infection risk while increasing the potential for fusion.

"Patients undergoing spinal fusion surgery typically experience pain and decreased range of motion, which can vastly diminish their quality of life. My goal is to treat these patients and get them back to activities of daily living as soon as possible," said Grant Skidmore, M.D., of Neurosurgical Specialists, Inc., in Norfolk, Virginia." In my experience, silicon nitride interbody fusion devices exceed the capabilities of PEEK and titanium, resulting in less risk of infection and faster fusion rates. This means better results for my patients."

—BY (October 1, 2012)

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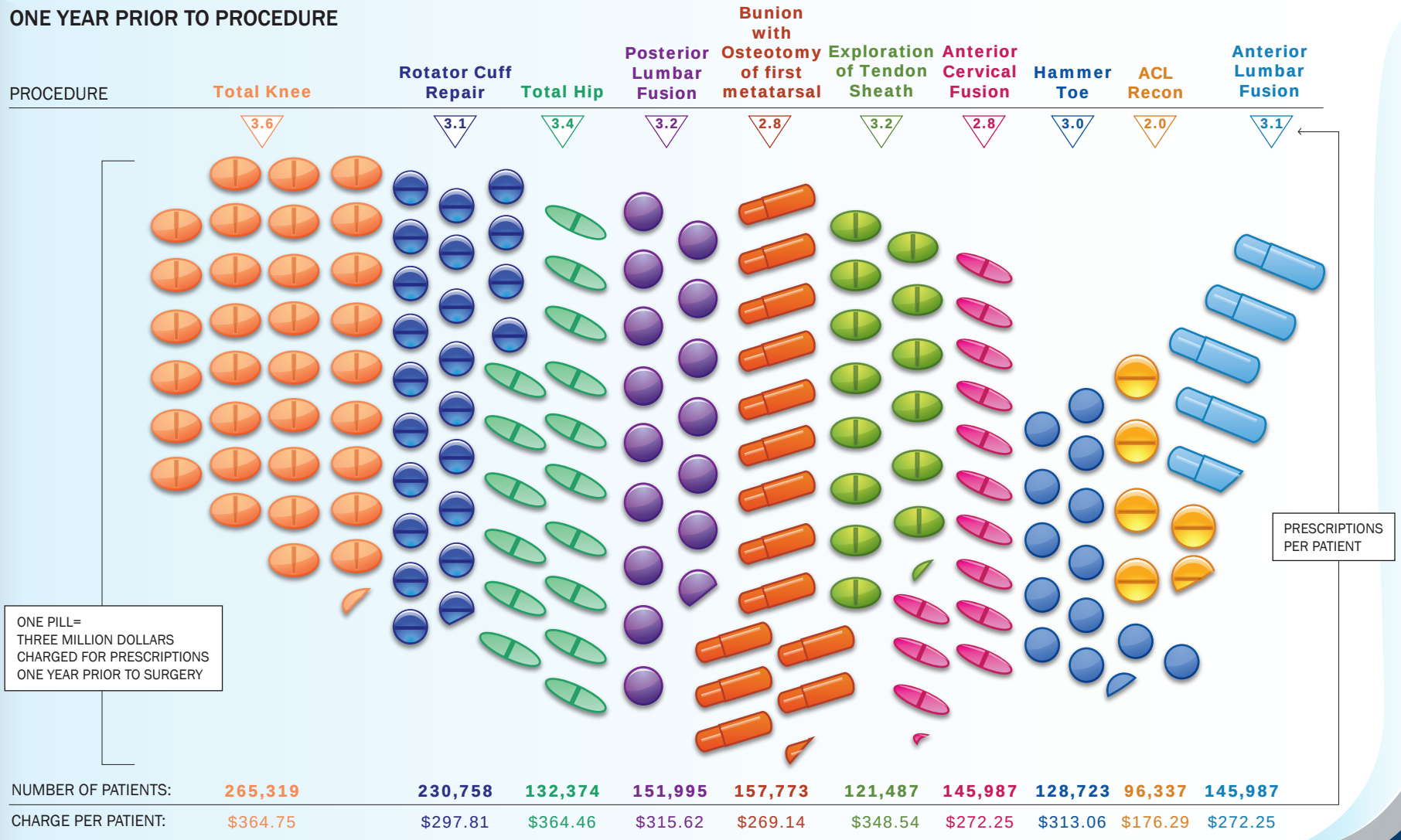

	Total Knee	Rotator Cuff Repair	Total Hip	Posterior Lumbar Fusion	Bunion with Osteotomy of first metatarsal	Exploration of Tendon Sheath	Anterior Cervical Fusion	Hammer Toe	ACL Recon	Anterior Lumbar Fusion
NUMBER OF PATIENTS:	265,319	230,758	132,374	151,995	157,773	121,487	145,987	128,723	96,337	145,987
CHARGE PER PATIENT:	$364.75	$297.81	$364.46	$315.62	$269.14	$348.54	$272.25	$313.06	$176.29	$272.25

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