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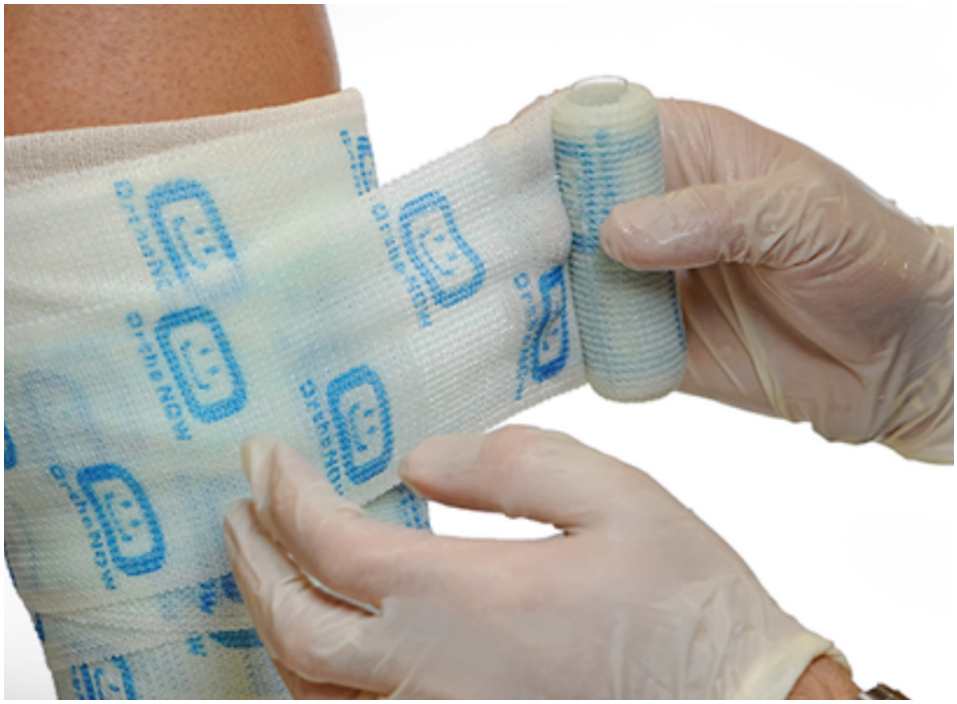
Orthopedics This Week

WEEK IN REVIEW



BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: The significance of the explosion in merger and acquisition activity among U.S. companies is that it signals the beginning of a corporate spending led boost for the overall economy. As the FED begins to tighten, where's the new source of capital? As debt gets more expensive, capital on the sidelines is starting to come into play. No wonder the DOW popped 186 points on Friday. This bodes very well for the next 12 months.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	4	Stryker	11.52%	(4.97%)	U.S. M&A activity is up 67%. In ortho, SYK leads the charge. Wall Street is unimpressed. But at these prices, we get to buy this expanding portfolio waaay cheap. New #1.
2	2	Integra LifeSciences	12.57	5.35	Co-leader in the cheap ortho stock department. Solid beat of Wall Street's forecast sales and earnings.
3	3	NuVasive	8.01	3.01	Still basking in the glow of a rocking, stellar quarter. Price remains at attractive valuations—whether PE, PSR or PEG.
4	6	Symmetry Medical	6.55	3.08	Top performer over the last 30 days. Major strategic changes in the works as SMA monetizes its core business.
5	1	Medtronic	28.84	(2.28)	Tax inversion is a loophole, not a business strategy and the government is trying to close it. Too clever.
6	5	Zimmer	29.12	(7.43)	Uff Da! Quarter sucked. Ok, there is the Biomet deal. Will patience be rewarded? Sure. Think 2015.
7	7	Orthofix	7.46	(8.37)	OFIX delays 10Q filing. Again, those %!*#! Restatements. Like Zombie blood suckers they rise again.
8	10	Exactech	10.26	(5.70)	The little ortho company that could. Sales up 6%. Most importantly, earnings up double that at 12%.
9	8	Johnson & Johnson	26.58	(4.68)	Still too expensive. For literally years JNJ was ortho's cheapest stock. So much so, that breaking up was a reasonable strategy to build S/H value.
10	9	MicroPort Scientific	36.16	(10.41)	Institutional shareholders still haven't got a handle on MicroPort. Start with the operating margin, then go to market positioning in China.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	CryoLife	CRY	$10.39	$290	19.43%
2	RTI Biologics Inc	RTIX	$4.87	$277	11.95%
3	LDR Holding Corp.	LDRH	$24.61	$639	6.21%
4	Integra LifeSciences	IART	$48.65	$1,586	5.35%
5	Symmetry Medical	SMA	$9.38	$352	3.08%
6	NuVasive	NUVA	$35.56	$1,670	3.01%
7	K2M Group Holdings	KTWO	$15.92	$591	1.92%
8	Alphatec Holdings	ATEC	$1.38	$135	-2.13%
9	Medtronic	MDT	$62.15	$61,913	-2.28%
10	MiMedx Group	MDXG	$6.52	$689	-4.40%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	$4.52	$25	-34.49%
2	Baxano Surgical Inc	BAXS	$0.41	$20	-24.17%
3	Aurora Spine	ASG	$1.95	$31	-20.45%
4	Globus Medical	GMED	$19.29	$1,820	-16.09%
5	ConMed	CNMD	$36.71	$1,004	-15.73%
6	TiGenix	TIG.BR	$0.67	$108	-13.79%
7	MicroPort Scientific	853	$0.59	$838	-10.41%
8	Orthofix	OFIX	$32.40	$597	-8.37%
9	Zimmer Holdings	ZMH	$96.08	$16,230	-7.43%
10	Tornier N.V.	TRNX	$21.73	$1,063	-6.30%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$62.15	$61,913	16.40
2	Zimmer Holdings	ZMH	$96.08	$16,230	17.09
3	Johnson & Johnson	JNJ	$101.08	$285,075	17.34
4	Stryker	SYK	$79.81	$30,215	18.94
5	Exactech	EXAC	$23.48	$323	19.37

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$32.40	$597	270.29
2	NuVasive	NUVA	$35.56	$1,670	67.99
3	MicroPort Scientific	853	$0.59	$838	32.93
4	Symmetry Medical	SMA	$9.38	$352	31.80
5	CryoLife	CRY	$10.39	$290	31.21

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	$10.39	$290	1.04
2	Exactech	EXAC	$23.48	$323	1.08
3	Globus Medical	GMED	$19.29	$1,820	1.29
4	ConMed	CNMD	$36.71	$1,004	1.60
5	Zimmer Holdings	ZMH	$96.08	$16,230	2.07

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$32.40	$597	14.69
2	NuVasive	NUVA	$35.56	$1,670	5.56
3	Smith & Nephew	SNN	$82.91	$14,824	2.81
4	Symmetry Medical	SMA	$9.38	$352	2.65
5	Medtronic	MDT	$62.15	$61,913	2.46

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.38	$135	0.66
2	Bacterin Intl Holdings	BONE	$4.52	$25	0.75
3	Symmetry Medical	SMA	$9.38	$352	0.88
4	Baxano Surgical Inc	BAXS	$0.41	$20	0.98
5	RTI Biologics Inc	RTIX	$4.87	$277	1.14

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.67	$108	18.84
2	MiMedx Group	MDXG	$6.52	$689	8.69
3	LDR Holding Corp.	LDRH	$24.61	$639	5.73
4	Wright Medical	WMGI	$29.86	$1,506	5.60
5	MicroPort Scientific	85300.0%	$0.59	$838	5.49

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

Franchising Orthopedics-on-Demand

BY WALTER EISNER

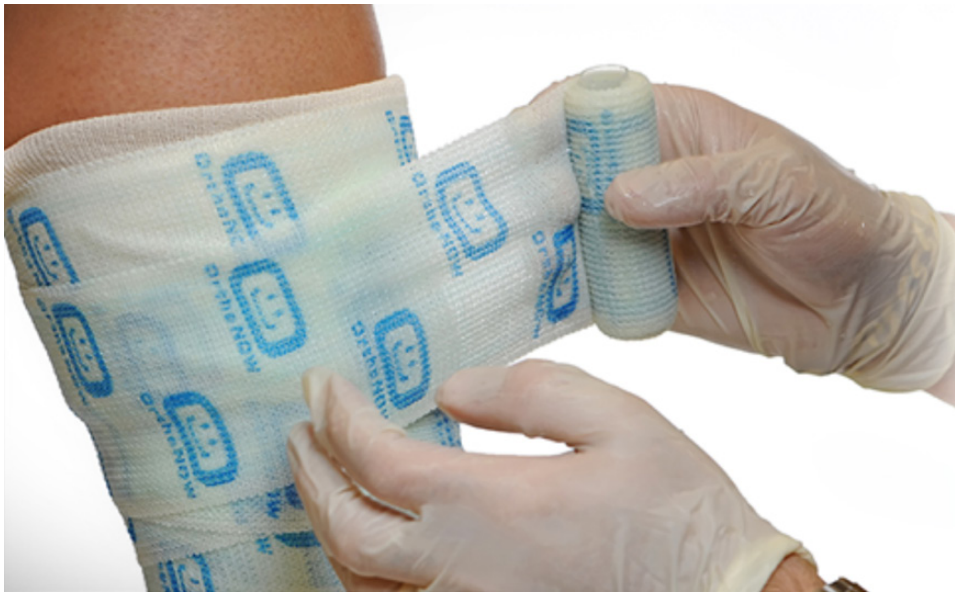
Alejandro Badia, M.D. thought there had to be a better way.

The Miami hand surgeon was seeing workers comp patients too late. Had he seen them earlier he could have gotten them back to work faster. Instead, they went to the hospital emergency room. In one wrist pain analysis he figured he'd have saved the system over $10,000 per patient and had that patient back to work three months sooner.

Alejandro Badia, M.D./OrthoNOW, LLC

So he decided to get into the orthopedic urgent care business. Cheaper, faster, better and, most of all, independent from hospitals.

At first, he decided to purchase a general urgent care franchise hoping it would attract patients with orthopedic injuries and function as a feeder for his existing surgery center. That model had a problem however. "The franchise's branding didn't send the message that I wanted to communicate, which was a focus on acute injuries and orthopedic issues," said Badia in an interview with *CareCloud* in July 2012. "It didn't attract the population I was looking for."



OrthoNOW, LLC

So Badia went his own way and brought in a couple of orthopedic business pros, Tom Ferro and Mike Carr who had management level experience at Stryker Holdings, Inc., DePuy Orthopaedics and Biomet, Inc.. They agreed to run his own orthopedic care franchise business, which he called OrthoNOW. Ferro serves as OrthoNow's president and Carr heads up sales and marketing.

The $14.5 Billion Urgent Care Business

According to *Forbes Magazine*, there are approximately 10,000 urgent care centers in the U.S. handling 160 million patients per year. But almost none of them are dedicated orthopedic care centers. The first orthopedic center in the U.S., Tria Orthopaedic Center, was started in Minnesota in 2008. There are now approximately 150 ortho urgent care clinics throughout the country.

The general urgent care industry has, according to *The New York Times*, mushroomed into an estimated $14.5 billion business. Humana, Inc. paid $800 million in 2010 to buy Concentra's 300+ clinics. The *Times*, in a July 9, 2014 article titled, "The Race Is On to Profit From Rise of Urgent Care," told of urgent care centers being derided as

Tria Orthopaedic Center/University of Minnesota Physicians

"Doc-in-a-Box" medicine. The *Forbes* July 21, 2014 article titled, "Drive Thru Healthcare, How McDonald's Inspired an Urgent Care Gold Rush," said that franchise model fits urgent care well and the long term trends are "undeniable, this market is going to shift toward a handful of large players."

OrthoNOW execs like the term, "Orthopedics-On-Demand."

Badia's OrthoNow Expands

After establishing the first flagship clinic in Doral, Florida, in May 2013, Badia's clinic was profitable in five months and has been growing at exceptionally rapid rates ever since. The team is building a second clinic in Miami (opening late 2014) and plans two more locations for 2015.

Ferro and Carr tell us they have 40 potential franchisees in the pipeline in the Northeast, Midwest and one in Beverly Hills, California.

Capturing the Patient

The typical patient is an amateur athlete or weekend warrior with a tennis elbow, golf injury or other sport injury. They're seen immediately by an orthopedic assistant who becomes a concierge-type portal to appropriate orthopedics services. If they require surgery, they can immediately go to the adjoining ASC (ambulatory surgical center) or leave with a scheduled surgery in hand.

Between May and November 2014, out of 448 surgical referrals made by the OrthoNOW clinic, 161 were for sports medicine, including knee injuries, 141 for upper extremity injuries, 87 for foot and ankle injuries and 50 for spinal injuries.

The typical referral flow from the clinic is 25% of the patients go to a rehab center for physical therapy, 17% go to an imaging center for an MRI, 16% go to the ASC for surgery and 3% to 5% are referred to a pain specialist. Those are all referrals and income streams that would have been lost to a hospital had that patient gone to the emergency room.

MRI Magnetic Resonance Imaging/OrthoNOW, LLC

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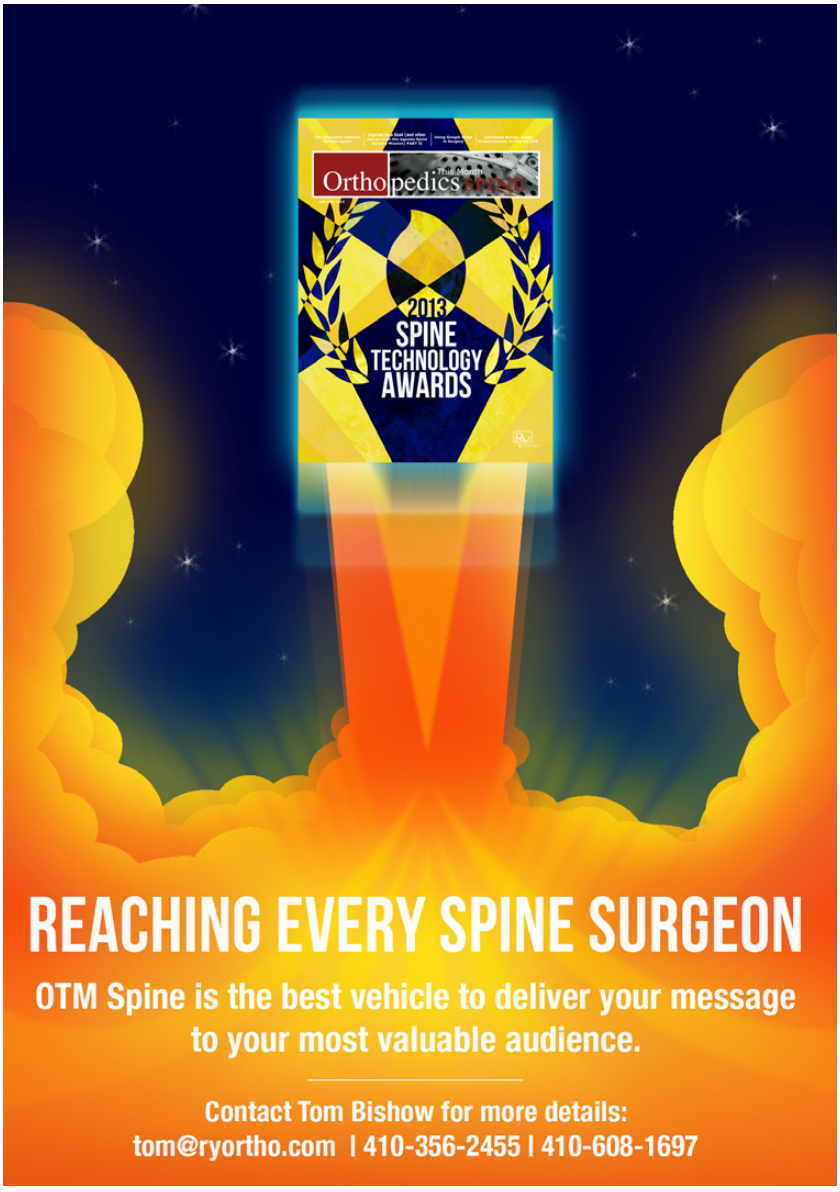
When the patient leaves the clinic, they know the costs (which are fully disclosed) and clinic staff deals with the insurance company on an out-of-network basis.

By the Numbers

If one assumes a clinic sees 750 patients per month with 16% going to surgery and assuming average reimbursement of $3,000, the monthly incremental net revenue can reach $350,000. With ASC profit margins between 45% and 60%, annual profits could be as high as $2 million or more. And that's only the 16% referred for surgery. The rest of the patients also remain within the ortho group's integrated network of services. The company says appropriate agreements are put in place to remain in compliance with the Stark law.

Ortho Urgent Care Models

According to Ferro and Carr, there are three models for establishing an orthopedic urgent care center.



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The first is an extension of an existing ortho clinic that expands its hours to hopefully increase volume to cover all sunk costs already in place. The execs say the benefit of the model comes from the fact that it uses existing space, equipment and employees. This approach is typically less costly and quicker to market. The downside is that the model does not capture patients from outside normal practice parameters.

The second model is a teaching hospital staffed by residents. The pluses of that model are that it is an excellent training ground for residents and can serve as a profit center for the hospital. The downside is that these institutions do not tend to be patient-centric; they bill at hospital ER rates and only benefit the hospital.

The third model is the stand-alone center. The big strategic benefit of that model is that the clinic captures patients from outside normal practice parameters, bills at urgent care rates and is a feeder source for integrated network downstream revenue. They are more costly to build out and take longer to open.

The Franchise Option

If a surgeon who owns his own clinic or ASC with ancillary services wants to use the franchise model for a stand-alone center, he or she can receive an exclusive single franchise location or an area development agreement over a larger patient population. The franchisee is usually required to open multiple sites in that area.

The current initial fee with OrthoNOW is $45,000 and a fixed monthly fee capped at $3,500 for a single location. Additional locations under an area development agreement are $52,500 with same monthly fee per location. We

have seen general urgent care franchise fees in the 6% to 8% range of collected monthly revenue.

According to OrthoNOW, typical start-up costs can range from $185,000 to $840,000 depending on how much capital equipment is needed. Staffing requirements include a medical director, orthopedic physician assistants, medical and x-ray technician, a business manager and front desk help.

The Value Proposition

Ultimately the clinic has to meet a market demand by offering something of value. For example, saving an injured worker time, an employer's money and a quicker return to work.

Let's go back to that previous painful wrist that got Dr. Badia thinking there had to be a better way.

Badia's clinic conducted a comparative analysis or a workers comp injured worker with excruciating wrist pain onset during working hours

The total cost when going to the hospital emergency room was $12,450 and 105 days for the worker to get back to work. The urgent care route cost $700 and got the worker back to work in 7 days. The biggest cost items for the clinic were two $250 charges for the examination to determine that patient was found to be tender at the radial wrist. The patient then received an ultrasound guided corticosteroid injection.

The biggest cost items for the emergency room route included a $1,000 emergency room visit, $1,300 in physical therapy, $4,400 to undergo a tenosynovectomy release and $1,300 in post-op physical therapy.

Badia's Five Suggestions

Badia offers surgeons some advice if they decide to enter the orthopedic urgent care business through a franchise.

Clear Message

First, be sure the franchise's message is clearly conveyed to appeal to the right patients immediately. This was why he named his center, OrthoNOW.

Demand Support

Second, ask your franchisor to put you in touch with another owner on the franchisor's network. Then contact them and find out what level of support to expect. Inspect contracts closely and discuss your needs with the franchisor frankly before signing anything. Establish expectations with your franchisor up front and hold them accountable to providing whatever assistance they promise you in marketing, equipment purchases, location selection, staffing or otherwise.

Don't Rush In

Third, be prepared. He says you may be in a rush to open the doors and bring in patients—but moving too quickly can end up hurting you. Make sure you're prepared to accept insurance from a multitude of different payers. "At my first franchise, we ended up turning away a lot of people because our insurance situation wasn't prepared to handle all the different carriers," he told *CareCloud*.

Before you open, he says make sure you have effective processes established, a functional infrastructure in place and a staff trained to handle your protocols. Being operational from day one is key to generating success quickly.

Market Yourself

Fourth, market yourself. He says your franchisor's existing brand presence is a major asset to you. Failing to use it effectively can stunt your chances for success. "My franchisor emphasized the importance of good signage, but we didn't have it right away," Badia said. "I almost wish they hadn't let me open without it."

Offer Genuine Solution

Fifth, meet your mark. "Business success in this sector is borne from presenting a genuine solution to an existing issue," said Badia. "To do that, ensure that your business provides services that will truly benefit the patients you want walking through your doors." He added that partnering with an on-site surgical center makes all the difference. It provides the ability to have someone walk in the door with an injury, assess it immediately and take them to have surgery in the same building.

Whether orthopedic urgent care centers are called "Doc-in-a-Box," "Drive-Through Healthcare" or "Orthopedics-on-Demand" matters little. If they provide value to patients and payers, they'll be acquisition targets for insurers.

Oh, do you want fries with that? ♦

Meeting the Health Care Needs of Female Veterans

BY SOPHIE BODEK

Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) are unprecedented in the number of female service members present in combat zones as well as in the nature of their involvement. Women have traditionally been barred from serving in combat positions. In January 2013, the Department of Defense (DOD) rescinded that ban and female service members began carrying out a wider range of military duties. But with those new responsibilities have come increased risks of traumatic brain injury (TBI), posttraumatic stress disorder, depression, and chronic pain in female veterans.

Wikimedia Commons and SGGH

In order to set the groundwork for addressing future combat-related injuries among women in the military, Jomana Amara, Ph.D.; Katherine M. Iverson, Ph.D.; Maxine Krengel, Ph.D.; Terri K. Pogoda, Ph.D.; and Ann Hendricks, Ph.D. tackled the issues of deployment of women in combat positions, the growing number of female veterans, and gender differences in an landmark article titled: "Anticipating the Traumatic Brain Injury-Related Health Care Needs of Women Veterans After the Department of Defense Change in Combat Assignment Policy." The article appeared in the March 2014 issue of *Women's Health Issues*.

"The purpose of this paper is to summarize data pertaining to current health care needs and utilization practices among women veterans to set the groundwork for estimating future combat related injuries and subsequent Veterans Health Administration [VHA] utilization. Specifically, given the relevance of the current war injuries and follow-up care, we are focusing on a high-priority health care issue for veterans, namely, traumatic brain injury," wrote Amara and her colleagues.

The Evolving Role of Women in the Military

In 1998, the Risk Rule "excluded women from noncombat units or missions if the risks of exposure to direct combat, hostile fire or capture were equal to or greater than the risk in the units they supported."

In 1994, former Defense Secretary Les Aspin rescinded the Risk Rule and replaced it with the direct ground combat exclusion rule, stating that "service members are eligible to be assigned to all positions for which they are qualified except that women shall be excluded from assignment to units below the brigade level whose primary mission is to engage in direct combat on the ground."

In January 2013, former Defense Secretary Leon Panetta rescinded the direct ground combat exclusion rule that banned women from direct ground combat positions. Although the U.S. military is far from fully integrating women into combat roles, the new policy reviewed 53,000 positions in combat units and 184,000 specialty positions that had previously been closed to women.

"In life, as we all know, there are no guarantees of success. Not everyone is going to be able to be a combat soldier. But everyone is entitled to a chance," Panetta said. "By committing ourselves to that principle, we are renewing our commitment to the American values our service members fight and die to defend."

From 2003 to 2013, women comprised 10% to 20% of forces deployed in support of Operation Enduring Freedom and Operation Iraqi Freedom. In sheer numbers, women were nearly 300,000 of deployed troops over that decade.

Today, female service members make up a greater proportion of U.S. military forces than ever before.

42% of Deployed Women Have Been in Combat

With a historic number of female service members in the U.S. military, an increased percentage of veterans will be comprised of women. According to the Congressional Budget Office in 2010, 203,695 (14.4%) women were in the Active Duty forces compared to 1,213,675 men (85.6%). The Reserve Component that same year was comprised of 153,071 (17.9%) women compared to 704,186 (82.1%) men.

Not surprisingly, given the sharp increase in female service members, the number of female service members discharged after September 11, 2001, now comprises 21% of all living women veterans, while the proportion for men is 9.9%

According to the Defense Advisory Committee on Women in the Services, over half of women service members reported being deployed since 2001. Of these deployed women, half reported multiple deployments. Out of all women deployed, 42% stated that they had been involved in combat operations, compared to 58% of men. Women began serving in new and more dangerous positions in Iraq and Afghanistan, including leaving military bases, assisting combat soldiers, and coming under direct attack.

"Over more than a decade of war, they have demonstrated courage, skill and patriotism, and 152 women in uniform have died serving this nation in Iraq and Afghanistan," Panetta said.

VHA's Care for Women in the Military

Under the Veterans Programs Enhancement Act of 1998, the VHA offers health services to service members who have been on active duty in combat operations, including the reserves, for a period of five years after separation from active military service. With the increase in female service members and their participation in a wider range of combat activities, the VHA is clearly faced with the task of attending to more gender-specific care.

In 2010, the Department of Veterans Affairs estimated that 70.6% of surveyed female veterans received some VHA-connected care, compared to 15.3% who received non-VHA-connected care and 12.6% who received no medical care. Of the surveyed active duty women, 51.3% indicated they intended to use the VHA as their primary source of health care upon separation from the military. Only 47.7% of active duty men indicated the same intention.

"As women have been accessing the VHA in greater numbers since OEF/OIF, it has also become apparent that

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they not only have different health care needs, but they are also utilizing different services than their male counterparts. Specifically, it has been found that women veterans incurred higher outpatient and overall costs, and lower inpatient medical and surgical costs, than men," wrote Amara and colleagues. "Given increases in women's use of VHA care, it is essential to understand the factors that contribute to their health care utilization patterns."

Developing Gender Specific Care

The injury most associated with Operation Enduring Freedom and Operation Iraqi Freedom is traumatic brain injury (TBI), which the Department of Veterans Affairs and Department of Defense define as a structural injury and/or disruption of brain function caused by an external force resulting in the onset or worsening of clinical signs immediately post-event. Approximately 7% to 23% of all service members deployed in Iraq and Afghanistan have experienced at least one TBI during their time there. The improvised explosive devices (IED) associated with OEF/OIF are the most prevalent cause of TBI, followed by vehicular accidents and falls.

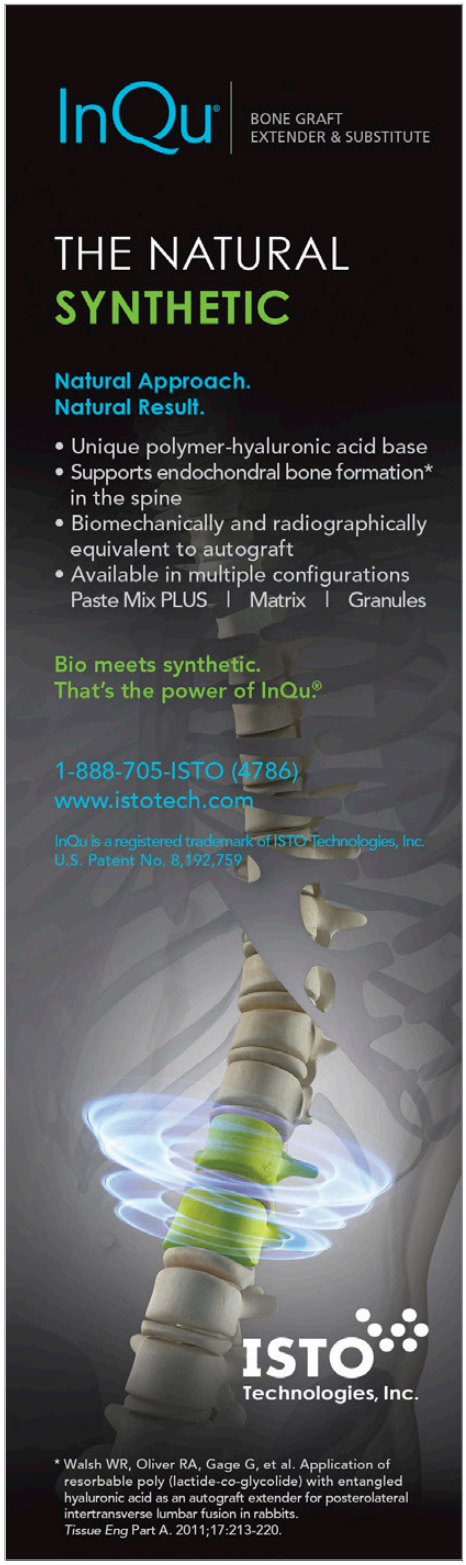
Due to more protective body armor and advances in military medicine, many injuries are no longer fatal and increasing numbers of male and female service members are surviving TBI. However, signs of TBI may not be recognized immediately as a result of a more severe injury or if the head injury was less severe. In order to better treat TBI, the VHA mandated that all OEF/OIF veterans seeking VHA services be screened for TBI. The VHA offers a comprehensive traumatic brain injury evaluation (CTBIE) to those veterans with a positive screening.

A 2011 study by Krengel and associates examined the administrative records of 36,106 veterans who served in Iraq and Afghanistan. Krengel determined that both men and women who underwent a CTBIE sought high levels of VHA health care. Regardless of TBI diagnosis, female veterans had higher total clinic visit rates and more medical health care visits. Women with a positive TBI diagnosis attended fewer mental health care visits in the year after their CTBIE. Other rates were similar between the genders.

Another 2011 study by Iverson and colleagues analyzed VHA administrative records for 12,605 veterans with deployment-related TBI. Iverson found that posttraumatic stress disorder (PTSD) was the most common psychiatric disorder and women were as likely as men to develop PTSD after exposure to a blast. When compared to men, women were 2 times more likely to be diagnosed with depression, 1.3 times more likely to develop a non-PTSD anxiety disorder, and 1.5 times more likely to develop PTSD with comorbid depression. Women also reported more severe somatosensory, cognitive, and vestibular symptoms.

Both Krengel and Iverson's studies underscore the importance of understanding and catering to the different needs of men and women with TBI as well as addressing the other conditions associated with TBI in female veterans. With an increasing number of women serving in combat, the VHA can expect more female veterans seeking services.

"If the VHA is to deliver high-quality care to all of its patients, structural changes are needed to provide the care necessary for female veterans," wrote Amara and colleagues. "The VHA needs to anticipate an increasing rate of utilization of outpatient services by women while simultaneously integrating the provision of medical and mental health care. ♦



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Acid Test of NASS's Clinical Guidelines in Boston // 100% Diagnosis of PJI Available // The Case FOR Outpatient Knees, Hips

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

Photo creation by RRY Publications/Jade and Morguefile

Will Payers Follow NASS' Clinical Guidelines? Boston Hospitals to Find Out Christopher Bono, M.D., chief of spine at Brigham and Women's Hospital, headed up the North American Spine Society (NASS) Coverage Task Force and now is putting those coverage guidelines to the test. Dr. Bono (who is also deputy editor of *The Spine Journal*), tells *OTW*, "Here at Partners Health system—namely, Massachusetts General and Brigham and Women's Hospital—we have begun to implement the NASS coverage documents. In particular, we are applying these to lumbar fusion via a special algorithm known as PrOE. We are implementing all of the criteria and that will be used for approval or non-approval."

Ok, but will the payers play along?

"Thus far" says Dr. Bono, "we have buy-in from Blue Cross Blue Shield so if we follow those guidelines then they should give the Partners system blanket coverage."

"With this algorithm—which is essentially a decision tree—we are looking, for example, at lumbar fusion for stenosis with spondylolisthesis. The provider will have to answer questions like: Does a given patient have imaging findings that are in agreement with the results of the physical exam? Has he or she undergone 6-12 weeks of nonoperative treatment? We assign the patient to green (appropriate for fusion), red (inappropriate) or yellow (requires further evaluation). So a year from now we will be looking back at these and seeing how many yellows, reds, and greens were performed, why there were xyz number of reds, and who is not following the protocol."

In the past, payers seemed to be following their own algorithm. Why would they change?

"The challenge thus far has been to convince insurers. Our initial algorithm was based on Oswestry Disability Index scores, but basing coverage on such numbers is new and insurance companies were uncomfortable with that."

And physicians? Will they want to comply with an algorithm?

"Going forward the challenge will likely be the new relationship between physicians and hospitals. If there is a surgeon doing something marginally indicated then this algorithm will capture it; how surgeons and hospitals will handle these situations is yet to be determined."

100% Diagnosis Rates for Periprosthetic Joint Infection? A test for periprosthetic joint infection (PJI) that employs biomarkers is gaining ground in hospitals around the United States. The test for synovial fluid alpha defensins was developed by CD Diagnos-

tics, Inc. in Claymont, Delaware. Carl Deirmengian, M.D., an orthopedic surgeon at the Rothman Institute in Philadelphia, who conducted much of his research with Javad Parvizi, M.D., director of research for The Rothman Institute, tells *OTW*, "Synovasure PJI has proven itself, not only in our studies that included 158 synovial fluid samples, but also in two independent studies. In our study comparing the leukocyte esterase (LE) test strip to the alpha defensin test, we found that the alpha defensin test accurately diagnosed 100% of patients, while the LE test was only correct 78% of the time. Particularly exciting was our finding that alpha defensin test is even accurate among patients with inflammatory diseases and those on antibiotics."

"Zimmer has made the Synovasure PJI commercially available and we are seeing a significant adoption of the test among centers in the United States. Just last week we presented the alpha defensin results at the Scientific Meeting of the Musculoskeletal Infection Society because we had many inquiries from people who wanted to know if the test is accurate for every bacterial type. We undertook a retrospective review of 1,937 synovial fluid samples; samples were collected from 418 surgeons in 42 states. We found that alpha defensin is consistently expressed in response to all types of bacteria, including Gram (+), Gram (-), yeast, less virulent organisms, and oral pathogens. Another question we received was whether the test would be accurate for patients who had a spacer block then reimplantation. Our ongoing studies are demonstrating a normalization of the Synovasure PJI test after treatment of the infection with an antibiotic spacer block."

"Additionally, CD Diagnostics is also offering diagnostic tests for native infection through a pilot program and blood metal ion testing. We are also developing diagnostic tests for bacterial detection. With the greater availability of simple tests in orthopedics, as well as other fields, we hope that patients benefit from more rapid and accurate diagnoses."

Out Patient Hips, Knees Very Doable!

When it comes to outpatient (OP) hip and knee surgery these days, all eyes

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are on Adolph V. Lombardi, Jr., M.D., F.A.C.S. Along with his partners, Dr. Lombardi, president of Joint Implant Surgeons, Inc. in New Albany, Ohio, has performed over 1,000 knee, hip, and partial knee surgeries on an outpatient basis. Dr. Lombardi tells *OTW*, "We have traditionally kept hip and knee patients in the hospital for 36–48 hours after total joint surgery. When I started practicing 28 years ago patients stayed for 10–15 days! Now, barring any complications, they are home in several hours. Naturally, patients are very enthusiastic about shorter length of stay."

"It all starts with a solid patient education program, with well trained staff who begin to advise patients preoperatively. Also critical is that we have adopted new anesthetic techniques; specifically, for knee procedures, we use an adductor canal block that doesn't block the motor component of the femoral nerve. The typical anesthesia team can be slow to adopt this type of block, but with proper training this becomes less of a problem."

"If someone has insurance coverage, is generally healthy with no significant cardiac history or sleep apnea then they should be appropriate for these OP surgeries. The patients see an internist and we consult with other team members in order to verify that patients are meant for the OP procedure. Diabetics can undergo the surgery if their disease is under control, and if someone can get through the surgery with minimal nausea then they can go home right after the surgery. At present we cannot do these procedures in the Medicare population because there is no code for outpatient knee surgery. There is some talk about changing that, but the American Hospital Association is not fond of that idea."

And if other institutions want to begin doing OP hip and knee surgery? "You need a dedicated anesthesiologist who wants to learn different anesthesia techniques. Also, many surgical centers are not equipped with the proper sterilization units, so that would have to be addressed. Other than that, it just requires a dedicated team of people who are interested and enthusiastic about outpatient surgery."

"There are only about six institutions in the U.S. that are doing these surgeries. I will be giving a talk on OP surgery at the Knee Society meeting in October, however, and we expect the interest level to continue to increase. ♦

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The Social Media Advantage for Post Market Device Performance Data: Part II

BY JORDAN P. MCAFEE, BSC., JOHN P. MCAFEE, ESQ AND PAUL C. MCAFEE, M.D., MBA

This article was written by guest authors Paul C. McAfee, M.D., MBA, Chief of Spinal Surgery University of Maryland St Joseph Medical Center; Jordan McAfee, a recent Syracuse University graduate, who is volunteering at NYU Hospital for Joint Disease and is in his final year of Post-Bac Medical studies at Fordham University Lincoln Center; and John P. (JP) McAfee, a cum laude graduate with honors from the University of Pennsylvania and a magna cum laude law school graduate from the University of Baltimore School of Law, was editor for the University of Baltimore Law Review, a Steven L. Snyder Litigation Fellow, and a member of the Heuisler Honor Society. Mr. McAfee clerked for the Honorable James R. Eyler in the Maryland Court of Special Appeals.

In Part I we described how social media (Facebook, Twitter, Google Plus or Stumbleupon, for example) had become a new, powerful force for uncovering pharmaceutical or medical device adverse event information.

The FDA, which had been slow off the mark in past instances, has been making significant progress and clearly embraces social media as an information source. Peer review journals, however, have been strangely and troublingly silent.

This week, in Part II, we take a deep dive into the pros and cons of such established adverse event databases as MAUDE and social media as a source of medical device information.

Wikimedia Commons and Marksenizer

Bias and Conflicts in Social Media

Operating in their own self-interests, plaintiff's attorney groups have been able to harness the power of social medial to circulate and publicize the negative results of post market approved devices like the DePuy ASR from the UK and Australian registries and to recruit litigants (Figure 2).

While the raw information in social media is useful, it is also subject to the same limitations that Sedrakyan et al. found when they examined the professional voluntary reporting systems such as the MedWatch program, the MAUDE (Manufacturer and User Facility Device Experience), and the MedSun (Medical Product Safety Network).

> "These reporting systems have important weaknesses, such as incomplete, inaccurate, or non-validated data, reporting biases related to event severity, concerns that reporting may result in adverse publicity or litigation, and general underreporting of events. Most importantly, denominator data are missing, which makes evaluation of the incidence or prevalence of a safety-related event impossible."

The FDA, which has made a conscientious effort to incorporate social media and first warning signs into their database, also acknowledges the limitations of these formal, professional reporting processes and agrees that it is suboptimal, stating:

> "Although MDRs [medical device reports] are a valuable source of information, this passive surveil-

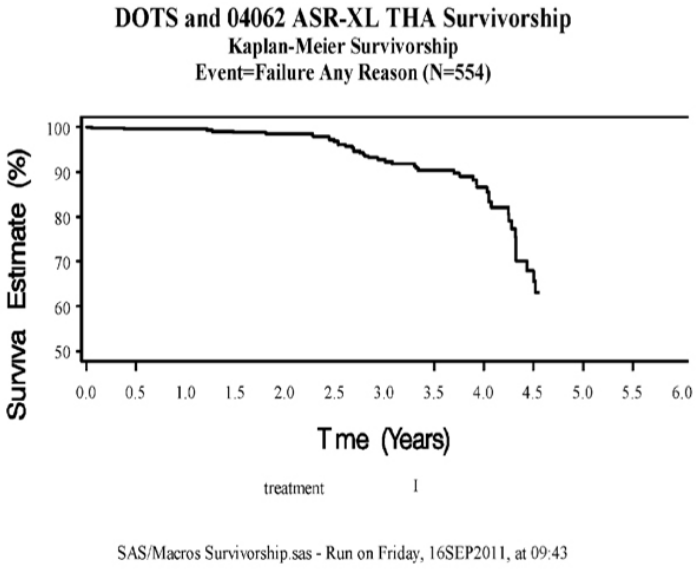

Figure 2

lance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA's several important post market surveillance data sources."

A Robot Shows MAUDE's Limitations

The best documented illustration of the limitations of MAUDE concerns the da Vinci robotic procedures.

Intuitive Surgical, Inc., the developer and manufacturer of the da Vinci system, reported that its system has been used in as many as 150,000 procedures annually (Figure 3) and has increasingly been selected by U.S. hospitals as an important surgical tool over the past decade.

Martin A Makary and colleagues from Johns Hopkins conducted a study of da Vinci's post market performance. In their study, the investigators cross-matched the reports of legal judgments on LEXIS-NEXIS with court cases which found device failure with da Vinci robotic procedures. One area where the investigators found a comparatively high number of successful plaintiff rulings was regarding "damage to viscera" which had an insulation problem resulting in inadvertent bowel cauterization and injury.

Makary and his fellow researchers found eight da Vinci cases which qualified for self-reporting under the FDA's guidelines but which did not in fact appear in the MAUDE database. Here is a direct quote from Makary's study:

> "Our search found eight cases (3% of reported cases) where incidents were not appropriately filed with the FDA. In five of these cases, no FDA report was ever filed. In one case, the FDA report was filed 1 year after the patient's death, 2 weeks after a *Wall Street Journal* article ran citing the case (Carreyrou, 2010). The report includes an event date that matches the month and day of the patient's death, but gives as the year 2010 rather than 2009. It is difficult to know if the incorrect event date was a mistake or a deliberate change following a nearly year-long delay in reporting the death. In another case, despite an injury being reported to an Intuitive representative, the Intuitive supervisor failed to file the FDA

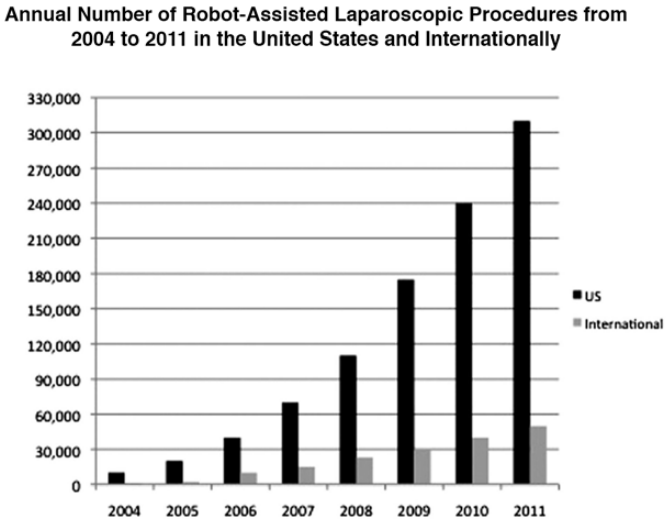

Figure 3

report. Our findings demonstrate that FDA reporting was not prompt or standardized."

Gaming the MAUDE System

Ninety percent of MAUDE's listings are self-reported, self-policing statements filed by manufacturers—the remaining 10% are filed by hospitals or healthcare providers. Patients who feel they are the subject of a medical device failure may file information on the FDA's MedWatch site.

When we (the authors) analyzed the MAUDE database we found a positive correlation between the size of the company, as defined by annual sales in 2013, and the number of reports on MAUDE. The larger the company, logic holds, the more likely the number of filings for medical device failures should be higher—and we found that to be generally true.

There was one surprising exception to this rule, however, and it was Medtronic, Inc. According to MAUDE, Medtronic (annual sales in excess of $16 billion) had fewer self-reported medical device failures than K2M, Inc. (annual sales $163 million).

So to investigate this further the authors searched the MAUDE database for a specific Medtronic device recall—the September 11, 2008 recall of the "Medtronic Sofamor Danek CD Horizon Spinal System AGILE Dynamic Spinal Stabilization Device."

In that specific instance, the FDA listed the recalling manufacturer as "Medtronic Sofamor Danek USA, Inc." Searching the MAUDE database from June 1, 2005 to June 1, 2014 using the brand name "AGILE" uncovered some interesting results. Specifically, of the 51 AGILE complaints listed on MAUDE, 1 was from "Danek" (8/27/10); 4 were from "Medtronic" (9/8/08, 10/2/08, 3/19/09, and 9/30/10) but the overwhelming number (46) came under the name "Warsaw Orthopedics, Inc."

We searched the 2013 Medtronic Annual Report and could not find a reference to Warsaw Orthopedics listed as one of the 10 business units of Medtronic nor as an intangible asset, or listed under legal proceedings.

The MAUDE database is flawed due to underreporting. But, as the Medtronic example indicates, it is also vulnerable to fragmented reporting information with some companies listing subsidiaries (who may or may not have overhead, or salesforces, or inventory) as manufacturers of record for implant related adverse events. One interpretation is that companies are gaming the system in order to protect the parent company's name.

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The FDA Embraces Social Media

On June 17, 2014 Thomas Abrams, director of the FDA's Office of Prescription Drug Promotion in the Agency's Center for Drug Evaluation and Research (CDER) introduced three new guidance documents regarding social media:

> "Our first guidance provides recommendations for the presentation of risk and benefit information for prescription drugs or medical devices using Internet/social media sources with character space limitations, such as Twitter and the paid search results links on Google and Yahoo. These recommendations address the presentation of both benefit information and risk information in this setting—
> http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf
> "Our second guidance provides recommendations to companies that choose to correct third-party information related to their own prescription drugs and medical devices. This draft guidance provides FDA's recommendations on the correction of misinformation from independent third parties on the Internet and through social media sites—
> http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf

FDA sees social media as an important resource for industry and is committed to developing additional guidance for drug and device manufacturers that outline the agency's current thinking. We do all of this work with the best interest of patients in mind—
http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm397791.htm

What to Do Now

Physicians can help detect early widespread medical device failures by checking websites like MedWatcher when they are presented with a device failure. If, upon checking, the physician finds reports similar to their own experience, they can help expedite the process of publishing peer-reviewed literature covering a medical device failure.

Patients are taking to social media to report their complications because the alternatives are not optimal. MedWatch is one option, but even after filling out the form patients may well feel as if their voices are unheard.

Furthermore, valuable patient data becomes scattered throughout the Inter-

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net because when a patient does a web search for issues related to their medical problem, they find Facebook groups, online petitions and web forums. In the midst of such a fragmented environment, the task of searching and filtering this patient data becomes overwhelming.

Is there a role for the FDA to create and monitor web forums for patients who wish to post and discuss their pharmaceutical or device problems? Could the FDA, for example, develop search algorithms that monitor Facebook, Twitter, web forums and other sites?

Large hospital, social media, and FDA databases can be searched for patient symptom terms such as "dizziness," "blurred vision," "shakiness" and "hypoglycemia." These terms could be hypothetically cross-referenced with "emergency hospitalization" and one might find a five- or six-fold increase in reports in September 2007, for example. This might also correlate with a particular manufacturer's serum glucose monitor malfunctioning and relaying artifactually high readings to patients.

The surveillance of big data analytics would be the first societal warning sign for a root cause analysis and focus the providers on the specific serum glucose monitor—in turn, the patients utilizing this brand of medical equipment would be emergently contacted, hopefully averting more hypoglycemic crises.

We advocate a balanced approach—a first phase data analytics approach for speed and rapid recognition of medical device problems followed by a second phase conscientious peer-reviewed Evidence-based medicine follow up.

With speed comes imprecision. There is excessive noise in most mega databases. Proper data mining requires an astute programmer who can dissect out terms that are close to symptoms but are not indicative of medical device failure.

Return to Evidence-Based Medicine?

Evidence-based medicine is a more refined and accurate approach than brute force data mining.

In four social media papers on vaginal mesh presented at the American Urologic Society Meeting in 2013 the authors demonstrated a highly progressive approach towards incorporating social media.

Alas et al. analyzed the content of Facebook, Twitter, and YouTube for key words "urogynecology," "pelvic organ prolapse," "stress incontinence," "urge incontinence" and "incontinence" and related them to vaginal mesh adverse events.

Searching over a 13-month period the authors were able to show a stable amount of useful information and an increase in the number of health professionals providing content on the social media sites. However, of the 817 search results, only 406 (50%) were deemed useful. Only 28% of all the social media comments were written by health professionals, but of the informative results, 56% were written by health professionals.

The authors of these studies also found that a majority of patients who'd monitored social medial sites misinterpreted the FDA Advisory regarding transvaginal mesh issued on July 12, 2011. The patients thought that the FDA had recalled vaginal mesh, which they had not.

In conclusion, the need for more physician input on social media sites is clear. In addition, we (the authors) advocate for application of data analytics to uncover early warning signs from social media sites of potentially serious medical device failures. ♦

ILLUSTRATIONS

Figure 3. The annual number of Robot-Assisted minimally invasive surgical (MIS) procedures both in the US (dark bar) and internationally (grey bar) was dramatically increasing from 2004 through 2011 partly due to marketing by Intuitive Surgical's da Vinci system.

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COMPANY

Symmetry Medical Selling OEM Solutions

Symmetry Medical Inc. will be selling its OEM Solutions business to Tecomet; it will also be transferring its Symmetry Surgical business to its shareholders. Tecomet, owned by Genstar Capital, is a contract manufacturing, engineering and metal fabrication technology company based in Wilmington, Massachusetts.

Symmetry President and CEO Thomas J. Sullivan stated in the August 4, 2014 news release, "We are excited to reach this agreement with Tecomet, which will recognize the value of the OEM Solutions business and enhance the growth potential of Symmetry Surgical. It also provides liquidity for our shareholders along with the upside potential of Symmetry Surgical as a well-positioned, standalone company focused on the large global market for surgical instruments."

Mr. Sullivan added, "The proposed transaction has significant benefits for Symmetry Medical's OEM Solutions customers and Symmetry Surgical customers. The merger with Tecomet will create an OEM business that can provide better service based on broader and more comprehensive capabilities. As a standalone company, Symmetry Surgical will be uniquely attentive to the needs of its customers across the breadth of the surgical instrument market with a distinct clinical and health economic focus without the distraction of implant or other more regulatory demanding product lines."

Sullivan told *OTW*, "Subject to regulatory approval, we are pleased at the opportunity to create a new standalone Symmetry Surgical business and capture value for our shareholders through the sale of our OEM Solutions business to Tecomet, a Genstar Capital portfolio company. We believe that the combined $400+ million Symmetry Surgical/Tecomet business will be a strategic supplier that serves more than 450 customers worldwide with an enhanced "one stop shopping" offering in implants, instruments, and cases with more robust business continuity resources across Orthopedics, along with other medical device categories and aerospace."

As for the timing, he noted, "There has been increasing interest in the orthopedic sector and contract manufacturing coupled with recent transactions imply a risk of customer and contract manufacturer consolidations."

"At this time our focus is on closing the transaction and we will not speculate on any future plans. We will continue to operate the businesses separately until the transaction is closed." — *EH*

Symmetry Medical Inc.

CORE Institute Signs Agreement With Arizona Neurological Institute

The CORE Institute has announced that it has signed an agreement with The Arizona Neurological Institute, an entity with nine Phoenix area locations. As indicated by The CORE Institute, the agreement combines the largest orthopedic and neuroscience practices in Arizona. As of October 1, 2014 Arizona Neurological Institute physicians and staff will be formally employed by The CORE Institute.

The CORE Institute, The Arizona Neurological Institute

"We're thrilled to partner with the talented team at The Arizona Neurological Institute to expand and enhance the specialties that we can offer to our patients," said CORE Chairman and CEO David J. Jacofsky, M.D. in the August 7, 2014 news release. "The CORE Institute is very proud to have grown into the largest orthopedic practice in Arizona and this partnership allows us to also become the largest comprehensive neuroscience practice providing accessible outpatient and

inpatient neurological, physical and rehabilitative medicine services."

"We view partnering with The CORE Institute as an important opportunity for our patients, our physicians and our staff creating an excellent fit combining their orthopedic expertise with our neuroscience expertise," said Atul Syal, M.D., president of Arizona Neurological Institute. "The CORE Institute has earned an excellent reputation nationally as an innovative industry leader maximizing best practices to benefit its patients and we look forward to furthering that mission as the organization continues to grow in Arizona and nationally. We are excited about using The CORE Institute platform and infrastructure to continuously improve our quality and grow our services. Musculoskeletal care, rehabilitation and the neurosciences are deeply intertwined and many conditions require the integrated approach of both specialties, making this a natural partnership." — *EH*

Smith & Nephew Goes Rep-Less With Some Hips and Knees

Smith & Nephew, plc (SNN) expects to cut some orthopedic implant prices in half with a "no-frills" option called Syncera that excludes logistical support or an onsite technician and replaces them with an iPad app.

The program was announced by company CEO Olivier Bohoun at the end of July. Bohoun said the Syncera program could reduce hip and knee device prices by 40% to 50% for the target market of 5% to 10% of U.S. hospitals.

When Wright Medical Group, Inc. offered a similar program in 2013, Bank of America analyst Bob Hopkins called it the "Death of the Device Salesman." But Wright had less than 5% of the hip and knee market and subsequently sold its ortho business to MicroPort Orthopedics.

Institutional Drivers

Leaders at Wright had hired Baine & Company to figure out how to segment the 6,000 hospital market in the U.S. The Bain report concluded that about 10% of the U.S. hip and knee procedure market is institutionally driven. That was up from about 5% only two or three years ago. The report further concluded that the institutional numbers were going to be 15% to 20% in the next couple of years. "So there's a clear drift towards institutions gaining more control over the purchasing decisions," said the report.

Syncera "fulfils the unmet needs of customers searching for a different value proposition, namely by offering 2 hip implants and 2 knee implants combined with cutting-edge technology that streamlines the supply chain and logistics and enables technical support in the operating room," according to a Smith & Nephew press release. The company expects to start shipping devices shortly.

Piper Jaffray analyst Matt Miksic said that in a nutshell, SNN will continue to market and price its current line of implants in the same way, serviced by the same rep in the operating room. Syncera will offer older and approved systems with a "'leaner' technology-enhanced service model at a substantial discount."

Syncera and iPad App

Syncera will have its own brand, separate from the traditional orange and white Smith & Nephew brand. The existing business, according to Miksic, will continue to focus on its latest innovations (e.g. Journey II, Verilast, etc.),

Andrew Huth/Photo creation by RRY Publcaitons LLC

while the Syncera offering will center on two prior generation lines: the Genesis II knee and the Synergy hip and Reflection cup. Hospitals signing up for Syncera will purchase instrument sets and inventory, as opposed to having them provided by the manufacturer. The rep will be replaced by an iPad app that the surgeon will be able access during the procedure.

The sales teams for core Smith & Nephew will operate independently, with protocol in place as to which targets within a region Syncera can approach freely, and on which accounts they would need to consult with the regional Smith & Nephew distributor.

"To characterize it as 'bold' would be understatement," wrote Miksic.

Unintended Consequences

However, added Miksic, the alternate pricing/service model may raise more questions than answers. Smith & Nephew may "find the unintended consequences of its Syncera strategy to be a handful."

Miksic writes that key questions and challenges face Syncera.

1. *If hospitals can already negotiate aggressively with manufacturers for their current and prior implant lines, with full service, instruments sets and inventories included, why would they want to subject themselves, their surgeons and their patients to the risks associated with 'leaner' technology based service in the OR?*

2. *If surgeons can already match the demand of a patient with various implant designs, why would they want limit themselves to older generation implant systems?*

3. *If both Syncera and core Smith & Nephew bid on a new account, how do they ensure they present the best value proposition to the center, while avoiding bidding against each other on the one hand and appearing to collude; on the other?*

4. *How will patients know when they are getting access to the most recent innovations available from a range of competing manufacturers, and when they are likely to receive 'older' (albeit 'proven') technology, based on a cost control strategy put in place by the hospital in which they are being cared for?*

5. *Is the Syncera strategy likely to make a traditional recon sales rep more interested or less interested in working for Smith & Nephew's core recon business?*

There is a need for "out-of-the-box" thinking on recon service delivery and pricing, writes Miksic. "But it's our simple observation that whatever the future of pricing and service looks like for recon, it's unlikely that one flavor will satisfy the full spectrum of different types of customers and centers (and patients)." — *WE*

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LEGAL

FDA User Fees Drop 3% for 2015

FDA medical device user fees are going down by 3%.

Medical device companies pay the fee to have their products reviewed the agency. The cuts are for the government's 2015 fiscal year.

The CDRH (Center for Devices & Radiological Health) division of the agency said on July 30, 2014, it proposes to cut the fees 3% for both large and small businesses regardless of the company's annual revenue.

According to the *Federal Register*, the fiscal 2015 rates would see PMA (premarket approval) applications cost $250,895 for large companies (down from $258,520), with small-business PMAs running $62,724 (down from $64,630). Applications for 510(k) clearances would cost $5,018 (down from $5,170) for large firms and $2,509 (down from $2,585) for small businesses. Set to go into effect October 1, 2014 the new fees would generate an estimated $131.2 million for the FDA.

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device User Fee Amendments of 2012 (MDUFA III), authorizes FDA to collect user fees for certain medical device submissions and annual fees.

Savings Start October 1

But don't count your savings just yet. You still have to pay the old amount until October 1.

To avoid delay in the review of your application, the agency says you should pay the standard fee before or at the time you submit your application to FDA. The fee you must pay is the fee that is in effect on the later of the date that your application is received by FDA or the date your fee payment is recognized by the U.S. Treasury. If you want to pay a reduced small business fee, you must qualify as a small business before making your submission to FDA.

To read the details of the new fee schedule visit http://www.gpo.gov/fdsys/pkg/FR-2014-07-30/html/2014-17902.htm — *WE*

Photo creation by RRY Publications LLC/Logo courtesy of FDA

LARGE JOINTS

Oxford University Weighs in – TKR or UKR?

The debate goes on—which is better, a partial knee replacement (UKR) or a total knee replacement (TKR). A study out of Oxford University in England comes down on the side of the partial knee surgery but with some concerns.

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Researchers matched 25,334 UKRs to 75,996 TKRs on the basis of propensity score. They found that UKRs had worse implant survival both for revision and for revision and reoperation than did TKRs at eight years. However, mortal-

ity was significantly higher for TKRs at all time points than it was for UKRs.

According to the study, people who have a total knee replacement are twice as prone to blood clots, deep infection, or heart attack and are three times more likely to have a stroke than are partial-replacement recipients. Though risk of death following knee surgery is small, a patient is four times more likely to die within the first month of a total reconstruction and has a 15% greater chance of dying in the next eight years than is someone who has a partial operation.

"Total knee replacement is a bigger, longer operation with more blood loss, more bone resection, and significantly more damage to the soft-tissue envelope that surrounds the knee," said study co-author and surgeon Alexander Liddle, M.D. "The entire knee is exposed, and the ligaments have to be 'balanced' by releasing them at their insertions. This causes more blood loss, which puts strain on the heart, and makes blood clots more likely. This translates into a much higher rate of heart attack, stroke, and death after total knee replacement. We believe that the higher mortality rate is simply a reflection of the greater likelihood of complications that put stress on the body."

Liddle added, "We already know that people recover more quickly, have better functional outcomes, are more likely to return to work or sports, and have a more 'normal' knee after partial knee replacement compared to total. This is probably because the anterior cruciate ligament (ACL), which is vital to normal knee function, is retained in partial knee replacement. — *BY*

New Treatment for Torn Meniscus

Surgeons at a United Kingdom hospital are pioneering a new treatment that they hope will prevent the development of arthritis and extend athletes' sporting careers.

The procedure, called ABICUS (Autologous Bone Marrow Implantation of Cells University Hospital Southampton), involves coating damaged cartilage with stem cells, taken from a patient's hip, and mixed with gels, acids and surgical glue.

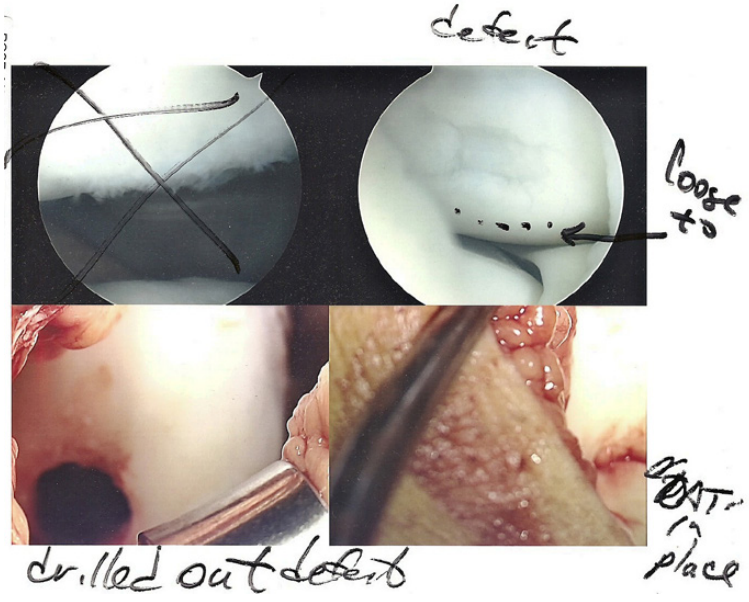
During the 30-minute procedure, the bone marrow sample is spun in a centrifuge in the operating theater to create a concentrated amount of the patient's stem cells. The cells are then mixed with platelet gel, glue and hyaluronic acid to create a substance which is painted over the cartilage defect and allowed to set.

Microfracture is currently the most commonly used procedure to repair knee injury. This involves trimming damaged tissue and drilling holes in the bone beneath the defect via keyhole surgery to promote bleeding and scar tissue to work as a substitute for the meniscus.

Patients who undergo the ABICUS operation have their cartilage cut and also undergo microfracture but then have their remaining tissue treated with the stem cell applications.

Gorav Datta, a consultant orthopedic surgeon at Southampton General Hospital and the study's principal investigator, said, "The development of this technique and the study we are conducting could revolutionize the treatment of common cartilage injury by creating a like-for-like, identical cartilage replacement for the first time."

Around 10,000 people a year in the UK suffer cartilage damage serious enough to require treatment. Victims experience pain, "locking" and reduced flexibility. If left untreated, it can progress to arthritis and severely impair leg movement. — *BY*



Wikimedia Commons and Dr. Gregory Engle

EXTREMITIES

OsteoSponge Improves Ankle Pain and Disability in Study

The Journal of Foot and Ankle Surgery has published clinical results of Bacterin International Holdings, Inc.'s OsteoSponge SC Allograft that show positive clinical outcomes at two years post-op.

The study, "Role of Demineralized Allograft Subchondral Bone in the Treatment of Shoulder Lesions of the Talus: Clinical Results with Two-Year Follow-up," followed the use of OsteoSponge in the treatment of medial shoulder lesions of the talus. The talus has two "shoulders" which are the outer edges of the talus, a bone in the ankle joint commonly injured as a result of an ankle sprain.

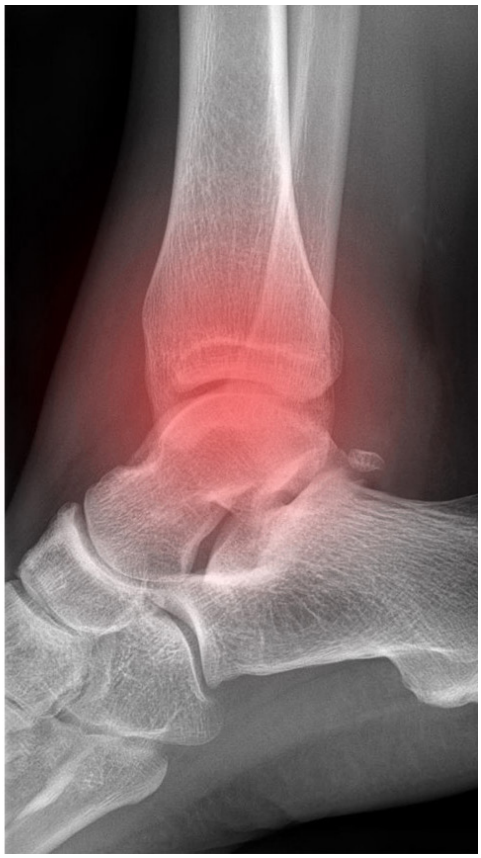
Clinical Outcomes

The article details the clinical outcomes of OsteoSponge to treat medial shoulder lesions of the talus. The study evaluated a retrospective review of 12 adults who had previously failed microfracture, presented with defects of the talus, and underwent a malleolar osteotomy with the use of OsteoSponge SC allograft. A company press release stated, "The results demonstrated statistically significant improvements in pain and disability observed postoperatively within the patient series at 24 months. The one-year post-operative results of this study were published earlier this year in the journal *Foot & Ankle Specialist*, titled "The Role of Demineralized Allograft Subchondral Bone in the Treatment of Talar Cystic OCD Lesions That Have Failed Microfracture."

The application of OsteoSponge SC for regeneration of subchondral bone in the talus "represents yet another proven clinical use of this revolutionary bone graft material," said Gregory Juda, chief scientific officer for Bacterin. "The simplicity and cost effectiveness of this procedure relative to other available treatment options has the potential to change the way surgeons approach the repair of talar shoulder lesions."

OsteoSponge SC

OsteoSponge SC is approved as a bone void filler to treat bony defects in the subchondral region of articulating joints.



OsteoSponge SC Allograft/Talus/Bacterin International and Wikipedia Commons

The OsteoSponge procedure, according to the company, has the potential to address defects associated with subchondral bone pathology, which includes failed microfracture procedures and other treatment modalities. The company estimates the total U.S. market for knee and ankle microfractures in 2014 is approximately 410,000 procedures. They claim to be the only company in this market with a product specifically positioned to address repair of the subchondral bone in treating these defects, and has demonstrated clinical evidence to support the unique approach. — *WE*

Intratissue Percutaneous Electrolysis Mends Pectoral Tear

Although injury to the pectoralis major muscle is uncommon, doctors have seen more muscle tears in recent years due to an increased interest in lifting and sports. In 1989, Kretzler and Richardson[1] conducted the largest series published to date, reporting 19 pectoralis major ruptures. In 2001, Hanna et al.[2] found about 114 cases of pectoralis major tears in the world literature. Despite the infrequency of pectoralis major injuries, those who suffer from a tear must endure lack of function and pain in the chest and upper arm. Care of the torn muscle usually consists of either surgical repair or conservative treatment.

The pectorals major muscle is located in the chest and is responsible for rotating, flapping, and swinging the arm. The two parts of the muscle originate from the sternum and clavicle and come together at the pectoralis major tendon, which attaches to the humerus bone. Injuries usually happen when the muscle is lengthened and contracted to its full extent and a sudden overload occurs, often in sports like weightlifting, wrestling, and football. Doctors use imaging technology to determine where the muscle is torn. An avulsion closer to the tendon usually requires surgical repair while myotendinous junction lesions, smaller tears, are frequently treated with conservative treatment. In order to investigate the effectiveness of using Intratissue Percutaneous Electrolysis (EPI) as a conservative treatment, the developers of EPI and their colleagues conducted a case study that was published in the *Journal of Sports Medicine & Doping Studies* in May 2014. Ferran Abat, M.D., Ph.D.; Pablo Eduardo Gelber, M.D., Ph.D.; Juan Carlos Monllau M.D., Ph.D.; and Jose Manuel Sanchez-Ibanez, P.T., Ph.D. from Cerede Sports Medicine and the University Autonoma of Barcelona authored the case study. Sanchez-Ibanez developed the EPI technique and now works with Abat at EPI Advanced Medicine, where they research and improve EPI technology.

Wikimedia Commons and jason.lengstorf

The doctors treated a 30-year-old male patient with a significant tear in his pectoralis major. They first determined the location of the avulsion using ultrasound and radiographic imaging and performed a functional assessment on the patient. According to Tietjen's classification, the patient had a type II injury to the mid-portion of the muscle. They then treated the patient using a weekly application of ultrasound-guided EPI, which applies a high-intensity galvanic current that encourages healing and regeneration in the targeted tissue. This technique reduces scarring and therefore reduces the risk of reinjury. The patient also performed eccentric exercises twice a week as part of the healing regimen.

Four weeks after the treatment began, the patient returned to the same pre-injury activity level, which was 8 points on the Tegner scale. According to the functional assessment detailed by Bak et al.[3], the patient showed good results after 1 month and excellent results after 2 months. The rating remained at excellent for 12 months and the follow-up ultrasound showed correct arrangement of muscle fibers with no evidence of scarring. Although incidents of pectoralis major injury are rare, the Spanish doctors have shown that ultrasound-guided EPI is effective in treating a large partial tear of the pectoralis major muscle. — *SB*

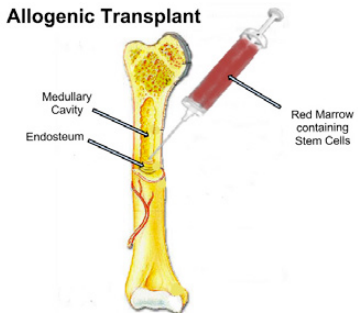
1. Kretzler HH, Richardson AB. Rupture of pectoralis major muscle. *Am J Sports Med*1989;17:453–458.
2. Hanna CM, Glenny AB, Stanley SN, Caughey MA. Pectoralis major tears: comparison of surgical and conservative treatment. *Br J Sports Med*2001;35:202-206
3. Bak K, Cameron EA, Henderson IJ. Rupture of the pectoralis major: a meta-analysis of 112 cases. *Knee Surg Sports Traumatol Arthrosc*2002;8:113-119

Stem Cells for Shoulder Repair

Houston, Texas, surgeon David Lintner, M.D., uses a slurry of stem cells to aid healing after his repair of a torn rotator-cuff. As reported on July 23 by Kyrie O'Connor for *Chron* (Houston Chronicle), Linter drills holes in his patient's bone and extracts bone marrow. While Lintner is suturing the muscles and tendons that keep the shoulder stable to the bone, the bone marrow and blood from the holes in the bone is taken to the other end of the operating room where it is spun into a bloody slurry containing stem cells.

When he has finished with tying down the tendons Lintner takes the prepared stem cell mixture and injects it into the shoulder. The prepared bone marrow, he says, which contains stem cells, platelets and growth factors, will act "like fertilizer" on the shoulder repair to accelerate healing. "There are lots of wonderful things in there that are helpful for healing," he says.

The patient, a man of 54, reported that he had full range of motion in his shoulder at three months and was 100% recovered at the end of four months. He had had the same operation on his other rotator cuff in 2009. The surgeon



Wikimedia Commons and Mugwump12

and surgery had been the same except that no stem cells were used in the prior operation. The patient said that it took him almost a year to recover from that surgery. The second repair also required much less physical therapy than had the first. — *BY*

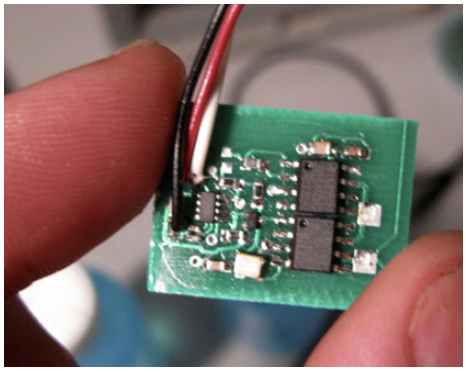
Ultrasound – Drug-Free Treatment for Muscular Pain

It undoubtedly all started when George K. Lewis, a director of the Analogic Corporation, Peabody, Massachusetts, took his middle school age son, George, Jr. to work with him. He set young Lewis up at a lab bench with other technicians, introduced him to electronics and soon had him wiring and soldering together his inventions. Lewis, Senior, worked with ultrasound and Junior earned his Ph.D. in biomedical ultrasonics. His thesis was titled "Ultrasound Assisted Drug Delivery to the Brain."

When he was 25 years old Lewis, Jr. founded ZetrOZ, a medical manufacturer of therapeutic ultrasound devices. Lewis told *OTW* that their device, called "sam", is the smallest, portable, therapeutic ultrasound system on the market and in the world—a noninvasive, drug-free alternative for treating chronic pain. "sam" is the first long-duration, therapeutic ultrasound device to receive 501(k) clearance from the FDA. In doing so, Lewis says, the FDA defined a whole new branch of medicine—one dealing with sustained acoustic medicine.

"sam" is available in the United States only with a prescription from a licensed healthcare provider. In Canada and in Europe, where it is CE-marked, it can be purchased over-the-counter.

The fledgling company's first product was not "sam", but an ultrasonic treatment for race horses called Ultroz. In 2011 Ultroz went with the Olympic Equestrian Team to London where trainers used it to treat overuse injuries and strained muscles in the horses.



Courtesy of ZetrOZ

The device, "sam", operates on the same principal. It uses high frequency ultrasound energy waves to produce deep mechanical stimulation within the body. It "increases circulation, reduces inflammation, is clinically proven to be an effective deep therapeutic treatment for select medical concerns and, when used daily, provides added therapeutic benefit for chronic pain sufferers," Lewis said. The National Institute of Health has given a major grant to ZetrOZ to support clinical trials of "sam" for knee osteoarthritis pain.

"The use of therapeutic ultrasound to treat a variety of conditions, including musculoskeletal pain, offers great promise for patients," said Thomas M. Best, M.D., professor and Pomerene Chair, Division of Sports Medicine, Ohio State University. "In particular, this low intensity, iPod-sized, wearable, battery powered device and its early success in a series of pilot studies, represent a breakthrough in our abilities to treat patients in a user friendly convenient manner." — *BY*

TRAUMA

Doctors Lead as Organ Donors

Doctors should reach around and pat themselves on the back.

There are more doctors—twice as many as the general public—who are registered organ donors.

That information came out of a study authored by Alvin Ho-ting Li. He cross-referenced data on 15,000 active physicians in Ontario, Canada, in 2013 and matched them with 60,000 residents who were similar in age, sex, income and residential neighborhood. He found that more than 43% of the doctors were registered organ donors, compared to 30% of their matched comparison group and 24% of the general public in Ontario, according to Katheryn Doyle, writing for *Reuters Health.*

Doctors who were younger, female and lived in rural communities were more likely to be registered donors, the study found. Claire Wakefield M.D., of Sydney Children's Hospital in Randwick, Australia, told *Reuters Health* that, "Many physicians see the ramifications of the organ donation shortage first hand in their patients, so they may be more motivated to contribute to the shortage if possible."

"We hope that these results will generate further discussion and awareness, and encourage everyone to sign up for organ and tissue donation," Li said. Currently almost 123,000 people in the U.S. are waiting for an organ transplant, most commonly for a kidney or liver, according to *Reuters Health*. — *BY*

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REIMBURSEMENT

2015 CMS Ortho Hospital Payments Up Slightly

Payments from CMS (Centers for Medicare & Medicaid Services) to hospitals will decline by $756 million for 2015. Payments for orthopedic DRGs (diagnostic related groups), according to Wells Fargo analyst, Larry Biegelsen were up 0.3% vs. the final 2014 rule.

On August 4, 2014, the agency issued their 2015 Inpatient Prospective Payment System (IPPS) 2,442-page final rule. Overall, CMS will pay hospitals an increase of 1.4%. However, in a news release the agency said that after accounting for penalties for hospital readmission and other factors, the actual payments will decline by approximately 0.6%.

CMS.gov

One of the new provisions required under the Affordable Care Act is requiring more hospital price transparency. Each hospital must establish and make public a list of its standard charges for items and services.

Orthopedics

BMO Capital Market analyst Joanne Wuensch and her team pored over the rule to tease out the orthopedic related payments. Notably there were no add-ons for any orthopedic devices this year.

Wuensch reported that lower extremity joint replacement (including hip and knee) with major co-morbidities decreases 0.3% and without the co-morbidities decreases 0.4%. Upper extremity joint replacement (e.g.,

shoulders) with the co-morbidities decreases 7.6%.

Hip or knee revision procedures with co-morbidities decrease 1.2% and without co-morbidities increases 1.2%. Spine procedures with co-morbidities increase 0.4%. Artificial discs were up 3.6%

Biegelsen noted that the agency also finalized the collapse of two upper extremity replacement codes (483 & 484) into the 483 code. It also created three new DRGs (518, 519, 520) for cervical discs and deleted existing cervical disc DRGs 490 and 491.

To see the entire rule, start your access with an agency fact sheet with a link to the entire rule: http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-08-04.html?DLPage=1&DLSort=0&DLSortDir=descending — *WE*

SPINE

NuVasive Announces Nerve Monitoring Technology

NuVasive, Inc. is announcing NVM5 V2.0, a new nerve monitoring technology designed to further reproducible outcomes in spine surgery. The company believes that the procedural integration of neurophysiology and computer-assisted surgical technologies facilitates these reproducible outcomes.

This second generation technology has new capabilities that include the sensory monitoring modality, somatosensory evoked potentials (SSEPs) for multi-modality monitoring of the spinal cord and peripheral nerves, as well as refinements to the recently launched spinal rod bending technology called Bendini.

As indicated by Nuvasive, the device provides information directly to the surgeon, to help assess a patient's neurophysiologic status. NVM5 provides this information by electrically stimulating nerves via electrodes located on surgical accessories and monitoring electromyography (EMG), transcranial motor evoked potential (TcMEP), or SSEP responses of nerves. The system also integrates Bendini software used to locate spinal implant instrumentation for the placement of spinal rods. All technologies are designed to seamlessly integrate into NuVasive procedural solutions designed to help increase surgical efficiency and reproducibility.

Pat Miles, president, Global Products & Services, told *OTW*, "NVM5 V2.0 leverages the experience that NuVasive has accumulated through the past 12 years, with more than 250,000 spine surgeries utilizing this proprietary monitoring platform." — *EH*

NuVasive, Inc.

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410-356-2455 • 410-608-1697

Orthopedics This Week | RRY Publications LLC

Robin R. Young, CFA
Editor and Publisher
robin@ryortho.com

WRITERS

Elizabeth Hofheinz, M.P.H., M.Ed.
Senior Writer
elizabeth@ryortho.com

Walter Eisner
Senior Writer
walter@ryortho.com

Biloine W. Young
Senior Writer
bgwy@msn.com

Sophie Bodek
Writer
sophiebodek@yahoo.com

ADVERTISING

Tom Bishow
Vice President of Sales
tom@ryortho.com

PRODUCTION

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Email, Web, & Conference Coordinator
jayme@ryortho.com

Dana Bader
Graphic Designer
dana@ryortho.com

---

116 Ivywood Lane • Wayne, PA 19087
TOLL FREE: 1-888-749-2153
www.ryortho.com