VOLUME 9, ISSUE 11 | APRIL 9, 2013

Orthopedics This Week

week in review

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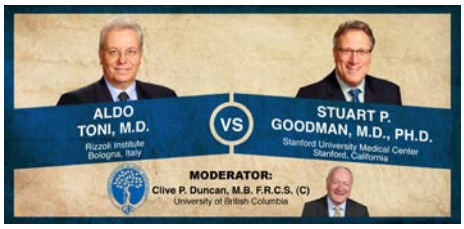

breaking news

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MAKO Beats **Blue Belt** in Court

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Wobbly start to the week. Or...weak. This market has signs of wanting to pull a few chips off the table and pocket its gains from these last several weeks. First came the weaker-than-expected jobs report. Then a return of the EU problems. With only monetary stimulus working, factors point to a weak week.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	NuVasive	7.08%	8.22%	With PODs under clear attack from OIG, distribution realignment favors NUVA's direct approach.
2	3	Conmed	10.51	7.04	The market's trying to say something when 30-day price movement is better-than-expected earnings growth.
3	5	Exactech	9.51	8.74	Last quarter's jump in operating profit margin setting stage for 2013's 6-8% sales growth.
4	6	Johnson & Johnson	25.58	6.01	DePuy + Synthes starting to show value through distribution power and synergy. Saw it at AAOS.
5	10	Symmetry Medical	8.26	12.58	SMA building new company on the platform of the #1 private label supplier. Buyers like what they see.
6	4	Stryker	23.68	(1.46)	1% earnings growth on 2% sales growth. That's all the Street is expecting for Q1. Nothing to get excited about.
7	7	Globus Medical	28.9	0.83	Figure $105 million for Q1 and around $0.20 EPS. But that's not the real story. Margins are GMED's driver.
8	9	Medtronic	28.65	0.54	The OIG's attack on PODS also benefits MDT. As we've said before, MDT spine is stabilizing.
9	2	Alphatec	(4.29)	(3.48)	Stock overhang on ATEC is sobering. Lots of stock sold at higher prices and patience is thin.
10	8	Orthofix	19.68	(7.81)	Usually 2-3 quarters under the new CEO required to catch investor's attention. A strong Q3 would be brilliant.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Symmetry Medical	SMA	$11.99	$447	12.58%
2	Exactech	EXAC	$20.03	$268	8.74%
3	RTI Biologics Inc	RTIX	$3.90	$218	8.64%
4	NuVasive	NUVA	$20.94	$922	8.22%
5	Conmed	CNMD	$33.14	$930	7.04%
6	Smith & Nephew	SNN	$57.55	$10,434	6.75%
7	Johnson & Johnson	JNJ	$82.04	$229,328	6.01%
8	CryoLife	CRY	$6.26	$172	2.62%
9	Globus Medical	GMED	$14.63	$1,344	0.83%
10	Medtronic	MDT	$46.28	$46,919	0.54%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MAKO Surgical	MAKO	$10.44	$493	-15.53%
2	Orthofix	OFIX	$34.96	$679	-7.81%
3	TranS1	TSON	$2.16	$59	-6.90%
4	Integra LifeSciences	IART	$38.20	$1,069	-6.65%
5	ArthroCare	ARTC	$34.37	$968	-4.05%
6	Alphatec Holdings	ATEC	$1.94	$188	-3.48%
7	Wright Medical	WMGI	$23.24	$1,086	-2.60%
8	MiMedx Group	MDXG	$4.94	$463	-2.56%
9	Tornier N.V.	TRNX	$18.03	$753	-1.74%
10	Zimmer Holdings	ZMH	$74.03	$12,537	-1.67%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$34.96	$679	11.54
2	Zimmer Holdings	ZMH	$74.03	$12,537	12.34
3	Medtronic	MDT	$46.28	$46,919	13.19
4	Smith & Nephew	SNN	$57.55	$10,434	14.31
5	Stryker	SYK	$65.00	$24,513	15.61

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$23.24	$1,086	211.27
2	NuVasive	NUVA	$20.94	$922	61.59
3	Symmetry Medical	SMA	$11.99	$447	36.33
4	ArthroCare	ARTC	$34.37	$968	22.46
5	RTI Biologics Inc	RTIX	$3.90	$218	21.67

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$34.96	$679	0.92
2	Globus Medical	GMED	$14.63	$1,344	1.21
3	Zimmer Holdings	ZMH	$74.03	$12,537	1.24
4	Conmed	CNMD	$33.14	$930	1.40
5	RTI Biologics Inc	RTIX	$3.90	$218	1.44

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$23.24	$1,086	19.21
2	CryoLife	CRY	$6.26	$172	5.22
3	NuVasive	NUVA	$20.94	$922	5.02
4	Symmetry Medical	SMA	$11.99	$447	3.03
5	Johnson & Johnson	JNJ	$82.04	$229,328	2.44

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.94	$188	0.96
2	Symmetry Medical	SMA	$11.99	$447	1.09
3	Bacterin Intl Holdings	BONE	$0.86	$36	1.11
4	Exactech	EXAC	$20.03	$268	1.19
5	Conmed	CNMD	$33.14	$930	1.21

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.13	$114	27.79
2	MiMedx Group	MDXG	$4.94	$463	17.12
3	MAKO Surgical	MAKO	$10.44	$493	4.80
4	TranS1	TSON	$2.16	$59	4.05
5	Globus Medical	GMED	$14.63	$1,344	3.48

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

Rock 'Em, Sock 'Em Ortho Robot Battle

By Walter Eisner

Blue Belt Technologies, Inc. an upstart orthopedic robotic system maker is being accused of stealing sales reps and trade secrets by MAKO Surgical Corp. and Stryker Corporation and has been hauled into federal courts.

Blue Belt angered MAKO and Stryker management by, allegedly, hiring away some of their former marketing executives to compete with their old companies. Stryker even convinced a federal judge to order one of its former executives, James Bruty, now working for Blue Belt, from attending the recent annual meeting of the American Academy of Orthopaedic Surgeons (AAOS).

Left to Right: James Bruty/Linkedin.com & Jeff Gellman/Linkedin.com

On February 19, 2013, MAKO filed a complaint in Florida against former employee Jeffrey Gellman and Blue Belt. Stryker filed its suit on March 18, 2013 in federal court in Michigan. Both suits allege breach of contract, misappropriation of trade secrets and tortious interference.

MAKO hasn't stopped at only suing Blue Belt to protect its assets. In March, the company filed a complaint against UK-based Stanmore Implants with the U.S. International Trade Commission and in two U.S. district courts, claiming Stanmore violated three patents

Morguefile and Seemann/RRY Publications LLC

related to MAKO's RIO system. Stanmore received 510(k) FDA clearance in February to market its Sculptor Robotic Guidance Arm for partial knee resurfacing. Ironically, the FDA granted Stanmore clearance based on its "substantial equivalence" to MAKO's RIO system.

Blue Belt Technologies, Inc.

Who is this upstart?

Blue Belt was formed in 2003 as a spin-off from Carnegie Mellon University in Pittsburgh, Pennsylvania. The company's plan was to release a computer assisted bone shaping product for spine, hip and knee-based procedures. In 2006, The Pittsburgh Life Sciences Greenhouse, a private/public partnership invested $100,000 into the company. In 2007, the partnership invested a total of $200,000 to continue the development of the company's Precision Freehand Sculpting (PFS) system.

Eventually the company closed on a $2.4 million private equity Series A round of financing.

On December 7, 2011, Healthpoint-Capital, LLC purchased the company for an undisclosed sum. Eric Timko was named president and CEO. Healthpoint is the New York investment bank that specializes in orthopedic company investments.

NavioPFS FDA Clearance

On November 30, 2012, Blue Belt received 510(k) clearance from the

Left to right: Sculptor Robotic Guidance Arm/Stanmore Implants; RIO Robotic Arm System/MAKO Surgical Corp.; NavioPFS System/Blue Belt Technologies, Inc.

FDA to market its Unicondylar Knee Replacement (UKR) knee system, called the NavioPFS. The system utilizes an advanced CT-free intra-operative registration, planning and navigation platform to aid surgeons in building patient-specific surgical plans.

By late January 2013, the company announced the first three UKR surgeries performed in the U.S. with the NavioPFS system by D. Kevin Lester, M.D. of Community Regional Medical Center in Fresno, California.

The company is currently located in Pittsburgh with 44 employees. In May, the company will open its new headquarters in Minneapolis, Minnesota. The R&D facility will remain in Pittsburgh.

Timko told *OTW* that the company believes MAKO's and Stryker's allegations are false and plans to vigorously defend itself in both actions. As usual in these cases, complaints are allegations and the accused will get their chance to defend themselves if and when a trial is scheduled.

MAKO Surgical Corp v. Jeffrey Gellman and Blue Belt Technologies, Inc.

MAKO says its former sales manager Jeffrey Gellman violated his non-com-

pete agreement and gave Blue Belt client data and trade secrets. Gellman allegedly used his work email, while still employed at MAKO, to send confidential information about MAKO's business to his personal email to help his new employer.

"Poaching" for Dollars

In the complaint filed in federal court in Fort Lauderdale, MAKO alleges that Blue Belt hired Gellman away to get an "improper leg up in the competition." They charge that Blue Belt actively solicited sales and marketing executives from MAKO in order to obtain confidential trade secrets, including information about its current and potential customers.

Gellman joined MAKO in 2010 as a national sales manager. As part of his employment, the company says Gellman had to sign a non-disclosure and non-compete agreement that stated he wouldn't give MAKO's secrets to a competitor or assist a competitor with sales within a year of leaving the company.

Blue Belt began recruiting Gellman in late 2012, according to the lawsuit. In January 2013, while still employed at MAKO but with an agreement to join Blue Belt, Gellman allegedly sent over 45 emails from his work account to his and his wife's personal email accounts that contained confidential information. This included customer lists, marketing proposals, information about RIO and related software, financial statements and employee compensation plans.

Gellman Joins Blue Belt

MAKO alleges that he gave his information to Blue Belt after he resigned on January 25, 2013. Blue Belt announced Gellman's hiring as West Area vice president of sales on February 5, 2013.

Gellman is charged with breach of contract and breach of employees' duty of loyalty. Both Gellman and Blue Belt are charged with tortious interference, civil conspiracy and misappropriation of trade secrets. The company demanded damages and an injunction against the defendants from continuing to utilize that information.

According to the complaint, Gellman had full access to all of MAKO's highly confidential sales information through the company's SalesLogix computer system.

Rather than developing its own business and sales methods, MAKO claims Blue Belt, as a new entrant into the market with limited experience, tried to gain an unfair advantage by improperly obtaining confidential information. They claim Blue Belt specifically hired Gellman for the purpose of soliciting and taking the clients, accounts, and customers.

MAKO alleges that while still employed at MAKO, Gellman "engaged in an intentional and improper scheme to misappropriate, transfer and utilize MAKO's highly confidential, proprietary and trade secret business information."

Two days after the announcement that Gellman was working for Blue Belt, MAKO sent a letter to Gellman requesting that he "cease his wrongful conduct and contractual breaches." The company also sent a letter to Blue Belt informing them that Gellman was subject to a binding contractual agreement with MAKO, and demanding that Blue Belt "cease and desist from its continuing tortious interference activities."

MAKO is demanding a jury trial.

Stryker Corporation v. James Bruty and Blue Belt Technologies, Inc.

On December 28, 2012, James Bruty informed Stryker that he was resigning as a senior director of marketing to take a position with 4Web, a non-competitive startup company owned and operated by one of his friends.

Bruty's last day with Stryker was on Friday, January 18, 2013. On his last day, he was supposed to return his laptop computer and identification badge. Stryker claims he didn't return either of those things until Tuesday, January 22, 2013.

The Hard Drive

Stryker claims that it learned that an external hard drive was inserted into Bruty's computer for the first time on January 22, 2013. This was four days after Bruty resigned from Stryker, but before he returned his Stryker laptop computer. "The fact that he inserted an external hard drive on that morning

was highly suspicious," says the Stryker lawsuit.

Bruty's "My Documents" folder was allegedly transferred onto the hard drive. In addition, Stryker says that during a forensic examination of Bruty's computer, it was determined that the contents of his "My Documents" folder was entirely deleted after the downloading and the contents of his trash or "Recycle Bin" was emptied. "Such activities are consistent with an individual attempting to hide his downloading activity," claims Stryker

Bruty Joins Blue Belt

On January 31 he informed Stryker he was working for Blue Belt as its vice president of Sales and Marketing.

Stryker sent Bruty and Blue Belt letters on February 8 reminding them of Bruty's non-compete agreement which he had signed at Stryker. Stryker demanded to know how Bruty's new responsibilities did not violate "the plain language" of that agreement.

Blue Belt responded on February 14 and denied that Bruty was in a competitive position.

On February 21, 2013, Stryker sent a follow-up letter to the defendants, again demanding an explanation how Bruty's role with Blue Belt was not in violation of his non-compete agreement, demanding the external hard drive back, and additionally questioning the alleged recruitment of several Stryker Navigation sales representatives by Blue Belt in the weeks after Bruty left Stryker's employment.

The defendants replied, according to the suit, and claimed that Bruty returned the hard drive, that he was not soliciting Stryker's employees, and further claimed that his job was not navigation-related.

Immediate Threat

Stryker executives believed the risk that Bruty would use their trade secrets and confidential information was exacerbated by Blue Belt's launch of its NavioPFS orthopedic navigation equipment in the previous two months. Prior to this launch, Blue Belt did not offer a product competitive to Stryker's orthopedic navigation equipment.

"It [Blue Belt] now sells a system that competes directly with Stryker's orthopedic navigation product. It also offers other products that compete directly with Stryker Navigation's other main product offerings. Bruty also has significant relationships with some of Stryker's most prominent Navigation customers," states the Stryker complaint and request to stop Bruty from attending AAOS.

They cited Blue Belt CEO Eric Timko's announcement that Blue Belt intended to publicly launch its NavioPFS system at the American Academy of Orthopaedic Surgeons 2013 Annual Meeting.

"With the departure of Bruty and his knowledge of Stryker's confidential information, it [Stryker] stands to lose several millions of dollars in business and the loss of value of its goodwill, customer relationships, trade secrets and confidential and proprietary information, which cannot be adequately addressed at law," continued the complaint.

The judge ordered Bruty not to attend the AAOS meeting.

Awaiting Trial Date

In addition to asking the federal judges to order Blue Belt, Gellman and Bruty to stop their alleged wrongful actions, both complaints are asking for damages to be determined during a jury trial. No trial dates have been set.

There's at least one lesson here. Be careful with company computers.

Breaking News – MAKO Wins in Florida

After we wrote this story, it was announced that a judge in Florida issued an Order Granting Permanent Injunction keeping Blue Belt from employing Gellman and requiring the destruction of all proprietary MAKO business information in Blue Belt's possession.

See the accompanying news short titled "MAKO Beats Blue Belt in Court" for details and Blue Belt's reaction. ♦

Ceramic on Ceramic Hip Arthroplasty: The Debate

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

"Ceramic-ceramic is probably the best solution in terms of safety," says Aldo Toni. "Too many problems with ceramic-ceramic," counters Stuart Goodman. "Point loading, the shell-liner interface, the femoral head-trunion interface, etc."

This week's Orthopaedic Crossfire® debate is "Ceramic on Ceramic Hip Arthroplasty: A New Standard." For the proposition is Aldo Toni, M.D. from the Rizzoli Institute in Bologna, Italy. Against the proposition is Stuart P. Goodman, M.D., Ph.D. of Stanford University Medical Center in California. Moderating is Clive P. Duncan, M.B., F.R.C.S.(C) from the University of British Columbia.

Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Toni: "Our experience with ceramics started nearly 20 years ago, so we have gone through different materials and designs. The best material is probably Delta-Delta; it has the best mechanical properties. We have survival data on almost 10,000 ceramic-ceramic, 3,300 ceramic/metal-poly, 1,400 metal-cross-linked poly, and 1,100 metal-metal (this is about 16 years follow up). Up to seven years there is no difference in the materials; they are all fine."

"After seven years standard poly starts declining. The problem is the second decade. Complications leading to revision related just to ceramics are low: 1.2% revision at 15 years. And there is no osteolysis."

"The problem with ceramics is brittleness. We took the data from our original registry—ongoing since 2000—and found that out of about 5,700 ceramic heads we only had one failure. With the Biolox Delta specifically, out of nearly 11,000 cases there were no failures. Failure of the head is a forgotten problem nowadays."

"There are still problems related to ceramic liners; the overall incidence is 0.13%. But this problem is mainly related to surgeons, not to materials. If you look at the causes for liners chipping or other damage, we find malpositioning, microseparation as a result of instability, and neck-cup impingement (often a problem of malposition too)."

"The cup being malpositioned in terms of anteversion…this is the main cause of fracture of this material. Even noises are related to this—81% of noises we registered were related to a malpositioned cup. So the take home message is, 'Yes, ceramic may break, but this is very low; and only 0.5% complained about noise being a problem with ceramics (but never with the new Delta-Delta.)"

"There is no perfect prosthesis. The Australian registry showed us that using metal-metal—just switching from the smaller diameter to the 36 and 40 mm diameter, we had a jump in the revision rate…more than 20% after a few years. Bigger may be worse for metal, but maybe this isn't true for ceramic. If you look at the results of 28 and 32 mm heads, we see that metal-metal and ceramic-ceramic are performing better than others. And we can safely go up in diameter with no risk in increase of revision rates."

"As for poly, it's been through a lot of improvements in the last decade; after 10 years it's performing very well with the crosslinked poly. But we know that there is a tradeoff for this improvement: it's mechanical impairment. So if we go with a larger head and thinner poly liner you may risk mechanical failure. With metal there is the risk of ions and ALVAL [aseptic lymphocyte dominated vasculitis associated lesions] reaction. So nowadays ceramic-ceramic is probably the best solution in terms of safety… and the capability to take advantage of this solution without paying any price. So I think that ceramic-ceramic is a good standard for demanding patients."

Dr. Goodman: "We've heard all the advantages of ceramic-ceramic; the mechanical properties have also been shown to be very good. The newer materials give us a composite that is very wear resistant. But, do our expectations for ceramic-ceramic meet reality?"

"There are issues: difficulty with cup assembly, incomplete seating of the ceramic liner within the metal shell, liner canting and dissociation, as well as liner chipping and fracture. Then there is edge loading, striped wear, and squeaking, catastrophic head breakage (rare), and they're expensive."

"Issues with the liner: the titanium shell may deform, the liner can seat in a canted position, and it can lead to liner dissociation. These issues vary with different designs. Incomplete seating of the liner can happen due to soft tissues, bone, or hydroxyapatite particles, which can lead to asymmetric stresses, dissociation, or fracture. Chipping can also occur when you put the implant together."

"Edge loading is secondary to this hard edge which is created where the lead-in surface intersects with the more ground and polished bearing surface. The edge of the bearing surface is recessed a few millimeters from the face of the implant. As that head runs over that hard edge onto the bearing surface you can get edge loading. When the contact area moves over this hard edge there is wear and potential damage leading to striped wear."

"Microseparation can also lead to striped wear. During a gait cycle there is impaction of the head on the rim during heel strike; this can also cause striped wear. Ceramic-ceramic bearings are very sensitive to implant position. And squeaking? It's an impulse where there is stick slip friction from the bearing surface. It's probably due to a number of causes: lack of lubrication, edge loading, bearing damage, impingement, debris, and high contact stress. This can be amplified, especially with certain implants. Squeaking can also occur due to impingement."

"In general, ceramic-ceramic bearings have decreased range of motion (ROM) compared to a metal-polyethylene. Issues with the femoral head: We've heard about catastrophic head breakage—it is very rare. But when it occurs it necessitates revision surgery. So, what bearing should we choose after that? If there are retained ceramic particles they can destroy a metal bearing surface."

"Ceramic-ceramic bearings are susceptible to point loading if there is debris. There are issues with the shell-liner interface, the femoral head-trunion interface, and one must have a clean assembly. It can also lead to particulate disease. This is very rare, but has been reported."

"I think we've already heard that highly crosslinked polyethylene seems to be doing very well—at least after 10-12 years. Crosslinking decreases the number of free radicals that are available for oxidation and degradation. And at least in one center with 15 years of data the results are spectacular."

"There are many randomized controlled clinical trials that show a reduction in wear of 40-98% compared to conventional polyethylene. With conventional polyethylene the penetration rate was 0.137; with highly crosslinked polyethylene it was 0.042 mm per year. There are even newer and probably better polyethylenes that are currently not only in clinical trials, but are being used on a daily basis. Please consider the pros and cons of different bearing surfaces."

Moderator Duncan: "Stuart, do you think that a nickel allergy exists? Are there patients in your practice in whom you must consider a ceramic head?"

Dr. Goodman: "I have never seen a case of nickel allergy. In the general population over 10% has a nickel allergy… and there have been millions of total hip replacements done over about 40 years. If it were as common as one might think, then we should see a lot more allergy. One must keep in mind that the skin macrophages are totally different than the deep macrophages. So whether someone has a cutaneous nickel allergy has very little bearing—that's why patch testing is almost irrelevant."

Moderator Duncan: "If the middle aged, anxious, female patient from California tells you she has a reaction to metal jewelry, will you convince her to have a metal on polyethylene or would you consider using a ceramic head against poly?"

Dr. Goodman: "I sit down with the patient and have a discussion, and I've not yet put in a ceramic-poly head for someone with a nickel allergy cutaneously. If they insist on it I would do it. As I tell my residents, I practice psycho-orthopedics."

Moderator Duncan: "Aldo, this is a message to your colleagues in the audience who inherit a fractured ceramic-ceramic. Bring them through the surgical steps that are important in the analysis of that pre-op and intra-op, what they should do and what bearing surfaces they must consider."

Dr. Toni: "They must take into consideration making a wide synovectomy because debris is going to be all over when they do the revision of the fractured ceramic case. Also, I strongly support the idea that they should not use metal-poly afterward because we've seen bad cases where the ceramic debris

are entrapped in the new poly and it is grinding the new head. So if you have to do a revision of a ceramic fracture always use ceramic-ceramic or ceramic-poly…never metal-poly."

Moderator Duncan: "If the cup is malaligned you would advocate that they change the cup in every case?"

Dr. Toni: "The CTs already show you if there is an anteversion, and during surgery you can check for any possible contact/impingement. Now we have an instrument that can give you the chance to take the cup out without doing any major damage to the bone."

Moderator Duncan: "How about the trunion? What information do they need pre-op and how do they examine that and decide whether or not to remove a well-fixed stem?"

Dr. Toni: "If the trunion is severely damaged then you should not use any solution involving ceramic. The recent option—the titanium sleeve—should only be used only if the trunion is not severely damaged. Otherwise you only have the choice of metal-metal."

Moderator Duncan: "Thank you both." ♦

Please visit www.CCJR.com to register for the 2013 CCJR Spring Meeting, May 19 – 22 in Las Vegas, Nevada.

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Better Sex Through THR and TKR; Significant New Antimicrobial Coating from Penn and MIT; The Costs of Obesity in TKA, and more

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

Significant New Antimicrobial Coating From Penn and MIT

What happens when a large animal orthopedic surgeon pairs up with researchers from MIT? Antimicrobial magic. Ever since he started building the translational research program in orthopedic trauma and sports medicine at the University of Pennsylvania School of Veterinary Medicine New Bolton Center, Thomas P Schaer, VMD has engaged in cross-disciplinary collaboration to address periprosthetic or device-associated infections. He tells *OTW*, "My colleagues and I took our antimicrobial technology and escalated its application from the laboratory bench to the next stage of translational validation. We did so by functionalizing the surfaces of commercially available off-the-shelf trauma products (fracture plates) with antimicrobial properties."

Wikimedia Commons and Schmidtke

Dr. Schaer, who will be a delegate for the upcoming International Consensus Meeting on Periprosthetic Joint Infection in August 2013, says, "I began this work after observing the devastating consequences of implant infection in long bone fracture repairs in horses. I approached Dr. Alexander Klibanov at MIT, and together we started the translation of an antimicrobial coating that was developed in his laboratory. Here is the critical point: veterinarians are trained to approach treatment from a frugal perspective because in many cases, exorbitant costs are a nonstarter. So, we knew how to design a coating that would be simple and inexpensive (something that is increasingly important in human medicine). In the Comparative Orthopedic Research Laboratory (CORL) at New Bolton Center, we have evaluated surface modifiers for orthopedic implants that target surgical site infection in humans; some were potent, complex chemical surface modifications, while others were very simple coatings that can easily be applied at the time of surgery."

"One of the notable things about this work is that often, early stage technologies rest on solid basic findings, yet the successful and often arduous translation into clinically relevant models has yet to be completed. I am pleased that we were able to evaluate both the safety and efficacy of this technology in a clinically relevant large animal infected fracture healing model."

"Specifically, we demonstrated that the presence of a N,N-dodecyl,methyl-PEI coating on the surface of a metal implant was effective in eliminating the clinical signs of infection in-vivo in a large animal infection model. It was also exciting to find that the coated plates supported bone healing even in the presence of significant bacterial contamination and completely prevented biofilm formation. We are currently designing the next phase for the translation of this technology into human and veterinary clinical patients, and are reaching out to interested industrial partners."

New Study Says 98% of TKA Patients Get Back to Work Total joint surgeons to insurers and the government: our surgeries DO make a difference in quality of life! Adolph V. Lombardi, Jr., M.D., F.A.C.S. is president of Joint Implant Surgeons, Inc. in New Albany, Ohio. He is on the threshold of publishing his new work on total joint patients and return to work. Dr. Lombardi tells *OTW*, "The patient population for total joint surgery continues to be younger individuals, so my colleagues and I decided to look at the literature on return to work. We found that most of the existing articles were written on patients over 60 years of age. We looked at people who were working prior to knee replacement and people who had undergone a total knee from 1-5 years ago. Using an independent survey center, our team explored five high volume practices in the U.S. and obtained 661 participants, whose average age was 54. We found that 75% of the participants had been employed three months prior to surgery, and of those, 98% went back to work after surgery…and 89% successfully returned to the same job. We used U.S. Department of Labor definitions: sedentary, light work, heavy work, very heavy work. Prior to surgery, physical demand categories of the patients' jobs were sedentary 12%, light 10%, medium 24%, heavy 24%, and very heavy 30%. The return to work rate for those employed during the 3 months prior to surgery by physical demand category was sedentary 95%, light 91%, medium 100%, heavy 98%, and very heavy 97%. We were truly pleased by these results; and for the patients; of course, there is a certain amount personal satisfaction they get from going back to work and continuing to earn an income for their families. We often hear that we aren't doing much for patients' quality of life, so it is important to share this data with insurers and government officials."

80% of THR, TKR Patients Report Better Sexual Function Bravely going where few orthopedic researchers have gone, a team of surgeons from New York have found that total hip (THR) or total knee replacement (TKR) surgery improves sexual function in 80% of patients. José A. Rodriquez, M.D. is an orthopedic surgeon and chief, Center for Joint Preservation and Reconstruction at Lenox Hill Hospital in New York. Asked why he chose to explore this topic, Dr. Rodriguez told *OTW*, "When I was training a woman in her late twenties came in with severe arthritis of the hip; she asked for a hip replacement. The senior surgeon told her that she was too young and he began to leave the room. Then he heard her cry-

ing. She told him that it was not just the physical pain that was affecting her life, but the lack of intimacy. She was concerned that her marriage would fail. He listened…and he did the operation. Many people feel awkward discussing this topic, and it's hard to quantify the unhappiness that pain with intimacy can cause."

"I began addressing this issue with my patients when appropriate. It is a delicate subject, so I would say something along the lines of, 'You may return to activities as your body feels comfortable, including exercise or intimacy.' Patients would often see that as an opening and would then ask me intimacy-related questions. I then took the issues they raised and created a questionnaire. I had patients rate the different aspects of their lives before surgery, six months later, and one year later; we used a completely blinded format so that patients felt comfortable telling the truth. We asked how the arthritis affects their self-esteem, general well-being, and sexual self-image. We mailed 392 questionnaires out and received 103 in return."

"We found that 57% of participants felt that arthritis had affected their self-esteem; 68% felt that their self-esteem had improved after surgery, and 72% were able to perform household chores and activities of daily living. There were separate questions on sexuality that included questions about frequency, duration, occurrence of orgasm, and libido. We found that 59% of participants felt that the frequency was diminished because of the arthritis; 12% had a decline in sexual function after surgery—of those more than half were worried about damaging the implant—which may be a misconception that can be addressed with discussion."

"While most orthopedic surgeons are aware that these issues exist, whether they feel comfortable talking about them is another thing entirely. At least with these results we have something concrete to say. We can tell patients, for example, 'This is the likelihood of your sexual activity increasing after surgery.' What patient wouldn't want to hear that?"

Obesity Increases Costs in TKA

There are more and more obese patients undergoing total knee arthroplasty, so it's more critical than ever that we know the costs involved. Hilal Maradit Kremers, M.D. is associate professor of epidemiology at Mayo Clinic in Minnesota, and holds appointments in the departments of health sciences research and orthopedics. She gave *OTW* details on her new study, "The Effect Of Obesity On Direct Medical Costs In Total Knee Arthroplasty." Dr. Kremers: "We examined 8,129 patients who had undergone 6,475 primary and 1,654 revision TKA procedures at a large U.S. medical center over an eight year period. Our goal was to examine the effect of obesity on length of hospital stay and direct medical costs. We calculated direct medical costs using standardized, inflation-adjusted costs for services and procedures billed during hospitalization and the 90-day window."

"One dramatic finding was how the prevalence of obesity has increased so much in such a short period of time. The prevalence of obesity in knee patients increased from 50% in 2000 to 60% in 2008. Obese patients have a lot of comorbidities and a higher risk of complications. Thus we asked, 'Does obesity increase costs because of the comorbidities?' We accounted for the comorbidities and the complications and found that obesity was still associated with higher costs."

"The bottom line is that obesity is associated with longer hospital stays and costs in TKA. If one considers this from a population perspective, as opposed to an individual patient perspective, you're talking about an enormous financial burden…it's only $200 for Mr. X's surgery, but multiply that by the huge number of obese patients undergoing surgery these days, and it's obvious that this is a real problem." ♦

company

MAKO Beats Blue Belt in Court

MAKO Surgical Corp. has won its court battle with Blue Belt Technologies, Inc. and former employee, Jeff Gellman.

On April 4, 2013, MAKO announced that it had obtained an Order Granting Permanent Injunction keeping Blue Belt from employing Gellman and requiring the destruction of all proprietary MAKO business information in Blue Belt's possession.

Blue Belt hired Gellman, MAKO's former sales manager, on January 30, 2013 as West Area vice president of sales. MAKO sued Gellman and Blue Belt to enforce a non-competition agreement between MAKO and Gellman. MAKO also accused Gellman of taking trade secrets to Blue Belt and wanted to prohibit the use or disclosure of that information.

By court order dated April 4, 2013, Gellman is prohibited from working for Blue Belt in any capacity until August 2013, and may only work in a limited capacity thereafter until 2014. Furthermore, according to the MAKO press release, both Blue Belt and Gellman have been ordered to certify under penalty of perjury that all MAKO proprietary information in their possession has been permanently purged. The U.S. District Court retained jurisdiction of the matter to ensure compliance with its order.

"MAKO is pleased with the sweeping and substantial injunctive relief we obtained on an expedited basis," said Maurice R. Ferré, M.D., president and CEO of MAKO. "We will remain vigilant in protecting the substantial investments made in becoming the leader in the field of robotically assisted orthopedic surgery."

MAKO Surgical Corp./Blue Belt Technologies, Inc./Image creation by RRY Publications LLC

The Order for Permanent Injunction was entered contemporaneous to a separate settlement agreement among Blue Belt, Gellman and MAKO, which provided MAKO with the described stipulated order, along with additional relief and future protections.

Eric Timko, Blue Belt's CEO, released a statement on April 4 saying the company had resolved the lawsuit filed by MAKO.

"We believe that this lawsuit was without merit and MAKO failed to prove that Blue Belt engaged in any wrongdoing. In fact, MAKO failed to substantiate many of the allegations it made in its complaint and we are confident that Blue Belt would have prevailed had the litigation continued. At the same time, however, Blue Belt determined that it is in our best interest to compete with MAKO by selling our new robotic technology in the marketplace, instead of competing in the courtroom, where no surgeon or patient can benefit. We have established great momentum since officially launching NavioPFS in the U.S. We fully expect to continue rapidly expanding our presence in the marketplace as more physicians and hospitals see the benefits that NavioPFS can bring to their patients and facilities at an economically friendly price point."

Timko told *OTW* that the company is confident that this short-term resolution will not disrupt their business in any way.

Blue Belt is involved in a similar case in federal court in Michigan with Stryker Corporation over Blue Belt's hiring of former Stryker employee James Bruty. The federal judge had granted Stryker's motion for a temporary injunction to keep Bruty from attending the recent annual meeting of the American Academy of Orthopaedic Surgeons. As of this writing, no permanent settlement has been announced in that case.

—WE (April 7, 2013)

BiosCompass Acquires Anti-Adhesion Gel

Rochester, Minnesota-based BiosCompass, Inc. has acquired the IP (intellectual property) for Adcon Gel from AaP Implanate AG and EMCM B.V.

The product is a biocompatible, resorbable gel that provides a physical barrier to inter-tissue adhesions by inhibiting fibroblast migration onto and around neural or tendinous structures.

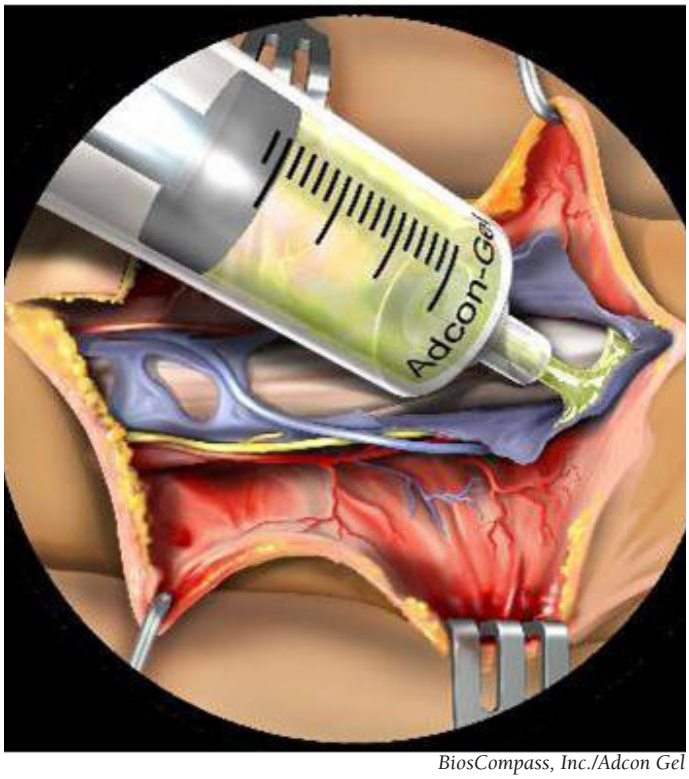
According to the company, the design of the gel is based on the concept of establishing a temporary basal lamina by combining an absorbable, collagen-derived material with a resorbable polyglycan ester. A major function of basal lamina is to provide a physical barrier to certain cells and molecules (including fibroblasts). Adcon Gel is the combination of polyglycan ester with porcine gelatine and buffered saline.

BiosCompass CEO Fred Hardwick said, "Years ago I would have given anything just to sell Adcon Gel as a commission rep in Birmingham, Alabama. Today we own it. We feel proud but humble, as if we are newly adoptive parents of a brilliantly gifted child. We are intent on relaunching Adcon Gel in the U.S. market as we continue to grow and help more surgeons and patients around the world prevent painful, debilitating post-op adhesions."

Adcon Gel has been on the international market for over 12 years with more than 10 clinical studies done and over 300,000 anti-adhesion procedures.

BiosCompass is privately held and has been the exclusive world distributor of the gel for the past three years with distribution in more than 30 countries. "Having acquired the Alcon Gel IP and with the world market for anti-adhesion products projected to exceed $435 million by the year 2015, BiosCompass, Inc. is now more focused to continue as the world market leader in surgical adhesion," stated the company press release.

—WE (April 4, 2013)



BiosCompass, Inc./Adcon Gel

Help Wanted: Bacterin CEO

Bacterin International Holdings, Inc. is looking for someone to replace company founder Guy Cook.

NYSE.com/Bacterin at New York Stock Exchange

In an April 1, 2013 SEC filing, the company stated that Cook has provided notice of his intention to resign as president and CEO once a successor is selected. The company is retaining an executive search firm to identify potential candidates. Cook will continue to work with the company as a consultant and chairman of the company's board after the new CEO is hire.

Ivory Tower to Wall Street

Bacterin was founded in 1998 as a sole proprietorship by Cook as a spinout of the Center for Biofilm Engineering at Montana State University (CBE). Today, the company has over 150 employees and sales in over 15 countries.

Revenues were historically derived from testing services and milestone payments from collaborative product development agreements with various blue chip medical manufacturers. Today, the company generates revenue from a number of sources including:

- Sales from products developed and manufactured by the company
- Sales of products manufactured by a third party and sold and distributed by the company

- Contract revenue from analytical testing and development services provided to medical device manufacturer clients, which tailor Bacterin's coating process to the client's specific product/medical application

Bacterin has developed and currently manufactures and sells several human tissue-based products, primarily allografts, through the company's biologics division. In addition, the company also manufactures and sells, directly under its own name and indirectly through distributors, various coating and surgical drain products through its medical devices division.

Guy Cook

Cook began his career as a product specialist in the Image Analysis Department for Laboratory Equipment Company in Chicago. He later became president of Delta Resources in Crystal Lake, Illinois, which specialized in developing customized image analysis solutions for the academic community. In 1996, he moved to Montana and worked as a Confocal Microscopist for the CBE.

"When starting this company over 15 years ago, we focused on utilizing the best technology for improving our products. It is extremely rewarding to see Bacterin evolve into a leader in regenerative biologics. We have created an expanding, diversified product portfolio that has positioned the company for continued growth," said Cook.

Revenue and DOJ Challenges

Cook's announcement comes just five days after the company announced less than stellar quarterly financial results. The company's revenue declined from $9.1 million in the fourth quarter of 2011 to $8.1 million for the fourth quarter of 2012. Losses climbed from $2.7 million to $3.5 million over the same time period. Revenue for the year was a record $33 million, up 9% compared to approximately $30.1 million for 2011. The increase during the period was primarily attributed to the higher sales from the company's sales force combined with improved penetration into its existing accounts.

It was also announced on February 11, 2013, that the company received a subpoena from the Office of the Inspector General of the U.S. Department of Health and Human Services in connection with an investigation into possible false or otherwise improper claims submitted to Medicare.

The Right Timing

"The timing is right to begin this process," said Cook, "and I feel fortunate to have had the opportunity to lead the company during a period of fantastic growth. There remains a tremendous market opportunity for our business; both domestically and internationally. The successor to this role will have the skill set to navigate this evolving healthcare environment and thereby transition the company towards the next phase of growth."

—WE (April 2, 2013)

Tenex Health Lands 510(k) Device Clearance

Tenex Health, of Lake Forest, California, has received 510(k) clearance from the Food and Drug Administration for its TX1 Tissue Removal System. The system is used in surgical procedures where tissue fragmentation and aspiration are required. The company reports that the components of the TX1 System are for single use and are completely disposable.

According to its March 25 press release, the company is currently marketing the TX1 system to address damaged tendon tissue associated with chronic tendonitis pain. The hand-held instrument is the size of a writing pen and allows physicians to deliver ultrasonic energy through a needle that specifically cuts and debrides diseased tendon tissue only. The entire procedure is completed through the use of ultrasound image guidance and in an out-patient setting under local anesthesia in less than 20 minutes. Company officials say that physicians can now utilize the TX1 Tissue Removal System for removal of pain-generating degenerated tissue and to restore natural tendon and soft tissue function for their patients.

Jagi Gill, founder and CEO for Tenex Health, said, "I am particularly excited about this FDA clearance as the expansive indications for use provides us an opportunity to bring our platform technology and product pipeline to the market for other compelling applications. We have observed through the successful launch of our TX1 System to address tendon injuries that the technology delivers a definitive treatment with very little potential for complication. The technology also allows for consideration of intervention at an earlier date, which reduces the morbidity for the patient and permits a rapid return to full activity."

TENEX HEALTH

Courtesy of Tenex Health

—BY (April 2, 2013)

Rochester, NY Medical #1 in Ortho Research Funding

Which U.S. institution receives the most National Institute of Health funding for orthopedic research? According to data released by the Blue Ridge Institute for Medical Research, the University of Rochester Medical Center's (URMC) Department of Orthopaedics and Rehabilitation, New York, ranks Number 1. The department received $4.86 million in peer-reviewed NIH research grants in 2012 surpassing institutions such as Washington University, Johns Hopkins and Duke University. Over the previous four years the Centers for Musculoskeletal Research (CMSR) came in Number 2 in orthopedic funding.

"This is a testament to the caliber of URMC's orthopaedic research endeavors and our stellar class of investigators," said Edward M. Schwarz, Ph.D., Director of the Center for Musculoskeletal Research and the Burton Distinguished Professor of Orthopaedics. "Our funding success is due in large part to a programmatic organizational design, a strong emphasis on collaboration across departments, and the diverse research interests of our faculty."

Seven URMC orthopedic researchers made the 2012 Blue Ridge list of individual funding recipients. They are:

Morquefile and Clarita

- Regis J. O'Keefe, M.D., Ph.D., Chair of the Department of Orthopaedics and Rehabilitation, who ranked Number 3 in the nation
- Edward M. Schwarz, Ph.D., who ranked Number 4
- Matthew J. Hilton, Ph.D., Number 16
- Hani A. Awad, Ph.D., Number 67
- Michael J. Zuscik, Ph.D., Number 77
- Xinping Zhang, B.M., Ph.D., Number 94
- Roman Eliseev, M.D., Ph.D., Number 114

Among the research projects the faculty is working on is the development of a vaccine to prevent life-threatening methicillin-resistant staphylococcus (MRSA) infections following bone and joint surgery. They have developed an antibody that appears to offer about 50% protection against the bacteria.

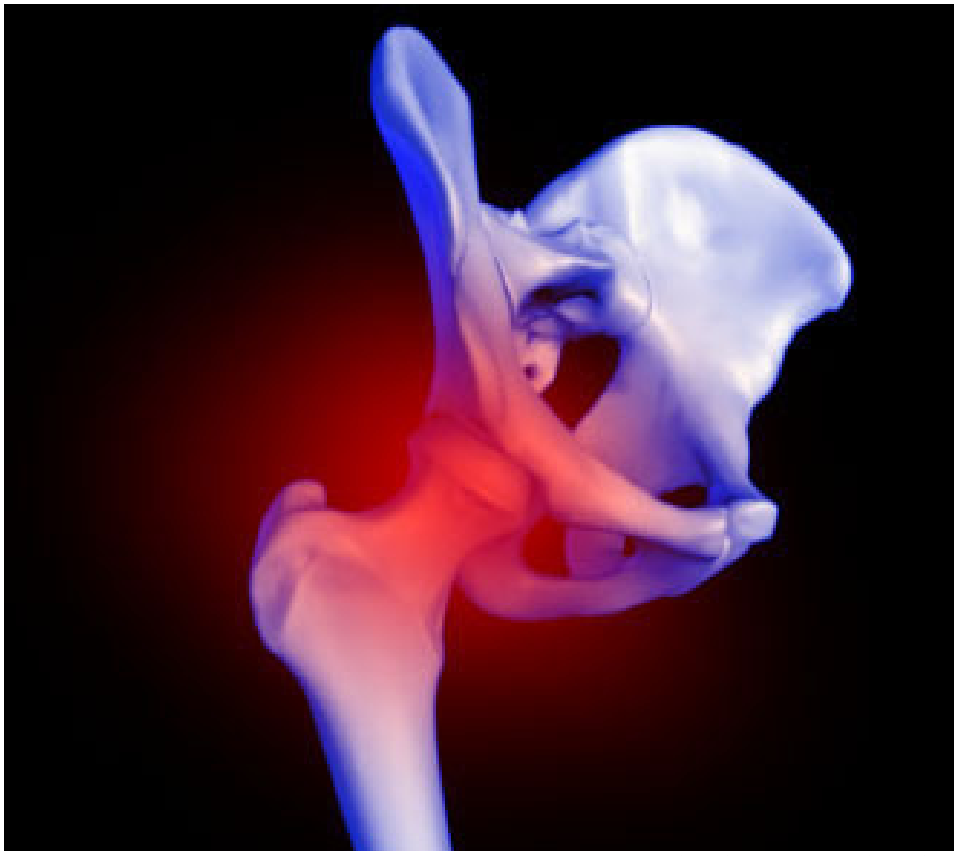
Another is the identification of a drug that can enhance bone repair after traumatic injury by marshalling bone marrow-derived mesenchymal stem cells (MSCs), the earliest cells that form cartilage, bone and connective tissue. Investigators are exploring ways to control, expand and keep MSCs in a state of extended infancy, so they can be used for tissue and joint repair.

—BY (April 2, 2013)

Left to right): Regis J. O'Keefe, M.D., Ph.D.; Edward M. Schwarz, Ph.D.; Matthew J. Hilton, Ph.D.; Hani A. Awad, Ph.D.; Michael John Zuscik, Ph.D.; Xinping Zhang, B.M., Ph.D. and Roman Eliseev, M.D., Ph.D./ University of Rochester Medical Center

large joints

MoM Hips: Unexplained Pain Probably Tissue Damage



Wikimedia Commons and Protohiro

Hospital for Special Surgery (HSS) researchers have revealed the results of their new study showing that the cause of unexplained pain among metal-on-metal hip implant patients is more likely to be tissue damage than wear of the implant. The study was performed by Dr. Danyal Nawabi, an orthopedic surgery fellow, along with research collaborators from HSS.

The research group, which did not have any ties to hip implant manufacturers, was led by Douglas Padgett, M.D., chief of the Adult Reconstruction and Joint Replacement Division and chief of the Hip Service at HSS, and Hollis Potter, M.D., chief of the Division of Magnetic Resonance imaging (MRI). They compared 50 patients who came to HSS for revision surgery because of unexplained pain, to a control group of 48 patients who came to HSS for revision surgery because of loosening, malalignment, infection or fracture.

The investigators combined results from clinical examinations, MRIs, wear analysis studies on the removed implants, and pathology studies, including the degree of aseptic lymphocytic vasculitis-associated lesions (ALVAL), a sign of adverse tissue reactions to metal debris.

Thirty patients with unexplained pain (60% of the group) had an ALVAL score of at least 5 on a 10-point scale, indicating moderate to high adverse tissue reactions; 12% of patients had some buildup of metal deposits in their soft tissue. The average synovial thickness was three times higher in the unexplained pain group compared to the control group, and the average synovial fluid volume was five times higher in the unexplained pain group compared to the control group. Ten times as many patients in the unexplained pain group had high-grade tissue damage scores compared to the control group. Researchers found no differences between the unexplained pain group and the control group in terms of age, sex, body mass index, length of implantation, or size or positioning of the implants. Implants in both groups showed similar signs of wear.

"We found that some patients had a significant amount of tissue damage but not a lot of wear," Dr. Wright said, "suggesting that factors other than wear are contributing to the problem regardless of whether the patients have pain. We have used the information from our study to develop guidelines for patients and surgeons."

Asked what work remains to be done and how it should be approached, Dr. Padgett told *OTW*, "The real underlying question that remains is as follows: Are there unique patient characteristics that make some more susceptible to this reaction as opposed to many others who seem to have no problem with metal-on-metal bearings? Our research group is pursuing this line of investigation by looking at possible genetic factors. This work is made possible through our tissue registry at HSS. This is an exciting next step in understanding patients' response to prosthetic implants."

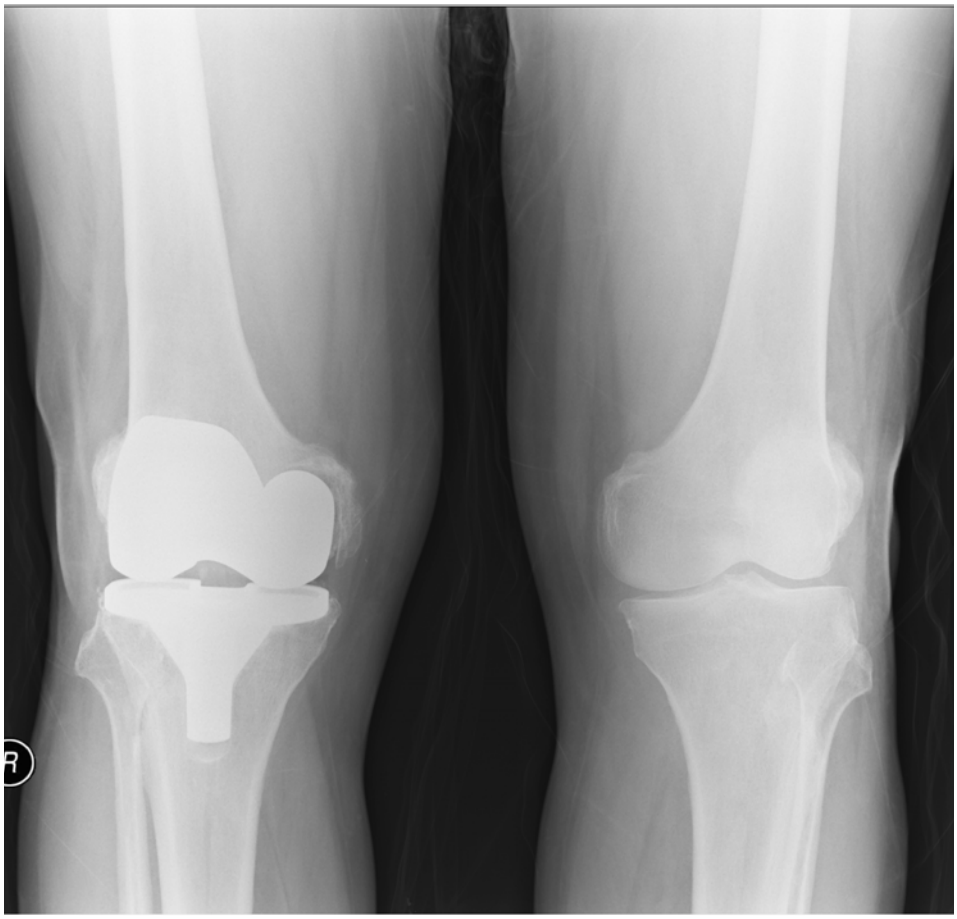
—EH (April 4, 2013)

New Study Tackles Surgeon Technique and Implant Failure

Are surgeons' techniques a partial cause of the failure of implanted knees? William Schroer, M.D. of the St. Louis Joint Replacement Institute in St. Louis, Missouri, believes that they are.

As reported March 24 by Nancy Walsh, staff writer for *MedPage Today,* Schroer's group collected data from six centers between January 2010 and December 2011 and conducted a retrospective review, looking to discover why primary knee implants failed in almost 700 cases. They also looked at the time frames in which the failures took place.

During the first two years, surgeons at the six centers performed 243 knee revisions. Between years two and five, they performed an additional 172 while between years 5 and 15 they performed 199. They performed a total of 67 after 15 years.



Wikimedia Commons and Nevit Dilmen

In 85% of the cases Schroer and his team were able to determine whether the implant was initially successful or was never successful. He and his fellow researchers found that aseptic loosening, responsible for 31% of surgical revisions, was the most common cause of joint replacement failure. Walsh reported that 60% of the revisions for aseptic loosening were done within the first five years of the initial implantation surgery.

After aseptic loosening, the most frequent reasons for failure were instability (21%), infection (13%), polyethylene wear (11%) and arthrofibrosis (9%). Significantly, aseptic loosening was the only cause of failure that occurred consistently over time.

Walsh quoted Schroer as saying, "This is often a catch-all diagnosis, including multiple different implants and techniques. It sometimes results from an initial failure of fixation, when the implant was never secure, and sometimes happens later after the initially secured implant loosens." He added that instability leading to revision most often occurred during the first two years after implantation. "In this study, two-thirds of the instability failures were classified as never having been successful," he said.

Schroer's study concluded that surgeons can influence the infection rate through patient selection and an emphasis on quality control and operating room protocols. When the reason for failure was arthrofibrosis, surgical factors such as component malpositioning or poor ligament balancing often contributed.

Schroer reminded attendees at the March 2013 American Academy of Orthopaedic Surgeons (AAOS) convention where he presented the results of his study that, "Polyethylene wear used to be the main cause of primary knee arthroplasty failure, but poly is now made and sterilized better, with improved articulation and locking mechanisms.," He lamented the fact that researchers are still using data from 2001 that implicates polyethylene wear as the primary cause of failure in total knee arthroplasty.

—BY (April 2, 2013)

Canada Fast on Repairs, Slow to Replace Joints

Wikimedia Commons and Benoit Rochon

How long does a patient have to wait to get a hip or knee tended to in Canada? If a patient fractures a hip in Manitoba, 86% of the repairs are done within the health service benchmark of 48 hours. Across Canada 81% of hip fracture repairs were completed within the benchmark, according to a report in the *Winnipeg Free Press*.

Getting a knee or hip replacement is another story. According to the *Free Press*, while Manitoba is one of the quickest to repair hip fractures, it performed only 56% of its hip replacements and 46% of knee replacements within the health service established benchmark six-month period last year.

The Canadian Institute for Health Information (CIHI) reported that waits for joint replacement surgery vary greatly among provinces. More than half of the provinces—including Manitoba—reported a reduction in the percentage of procedures meeting the benchmark time frames over a three year period. The reason may be that the number of hip and knee replacements performed in Canada increased by 15% between 2010 and 2012, costing the health care system more than $100 million.

The *Free Press* report quoted Health Minister Theresa Oswald as saying that the province had cut waits for hip and knee replacements by 40% over the last two years—thanks to increased surgical capacity and a more streamlined system. Those needing non-emergency orthopedic surgery are now receiving them within the medically recommended benchmark—if they are willing to go to the first available surgeon.

Oswald told the *Free Press* that only 1,200 Manitobans are now awaiting non-emergency knee and hip replacement surgery, compared with 2,000 two years ago. More than 3,600 replacement surgeries were performed in Manitoba last year—more than twice the number performed in 2004.

—BY (April 2, 2013)

trauma

Smoking Slows Fracture Healing

Another reason to stop smoking, as if another were needed: Broken bones take longer to heal if the victims are smokers, reports Nancy Walsh, staff writer for *MedPage Today*, on March 24. In a systematic literature review and a random effects model meta-analysis that included 20 studies with 6,500 patients and 1,500 smokers, conducted by Mara Schencker, M.D. and her colleagues at the University of Pennsylvania, Philadelphia, they found that individuals who smoked had a 15% higher risk for the nonunion of fractures of the long bones and periarticular long bones than did nonsmokers.

"It's been proposed that smoking may be detrimental to healing through mechanisms including vasoconstriction, platelet aggregation, direct inhibition of cell function, and decreased collagen synthesis," said Schencker. Together, she added, these effects have been implicated in higher rates of nonunion both in arthrodesis and fracture studies and in greater complications in all surgical subspecialties.

Healing times for all fractures averaged 24.1 weeks for nonsmokers and 30.2 weeks for smokers, and times for tibia fractures were 25.1 weeks versus 32 weeks. Walsh reported that for tibial nonunions, smokers had a 15% higher risk and for open-fracture nonunions, the risk was increased by 12%, Schencker reported. There also were non-significant trends for increased incidence of infections. For deep infections, the rate was 7% for smokers and 2% for nonsmokers while the rates of superficial infections were 7% and 4%, respectively.

—BY (April 2, 2013)

Wikimedia Commons and Che

extremities

FOI: First TSA With e+

Florida Orthopaedic Institute has announced the first ever total shoulder arthroplasty with the use of e+, a vitamin E infused polyethylene component. Mark Frankle, M.D., director of the shoulder and elbow fellowship at Florida Orthopaedic Institute, performed the surgery at Tampa General Hospital. The patient is a 71-year-old retired postal worker and retired U.S. Navy jet engine repairman. e+, which prolongs the life of total joint replacement and received FDA approval in 2013, was developed by DJO Surgical. Testing showed a 57% reduction in wear, compared to a standard component.

While a number of products on the market are infused with vitamin E, (the vitamin E is added after it is manufacturing), e+ is blended directly into the resin for a more uniform distribution of the vitamin E within the polyethylene. This helps the material retain improved mechanical and wear properties throughout the product.

Dr. Frankle told *OTW*, "We anticipate using e+ in all

DJO Surgical

total shoulder surgeries for our active and young patients. What makes e+ effective is that the plastic part of the replacement is more resistant to wear, which is why it's an ideal product for patients who have a high activity level. We have scheduled 12 total shoulder surgeries with the use of e+ in April alone. Dr. Mark Mighell, who specializes in shoulder and elbow surgery at Florida Orthopaedic Institute, will also perform shoulder replacement surgery with e+."

Bryan Monroe, Senior Vice President, General Manager, DJO Surgical, told *OTW*, "A lot of hard work went into launching many products at this year's AAOS [American Academy of Orthopaedic Surgeons]. As with all projects, there were hurdles in the development process, but we are thrilled with the final outcome of each of the new products. We are excited to expand our e+ blended vitamin E polyethylene into our shoulder line. e+ has been a part of our knee line for over a year, and the initial results have been fantastic. We are confident that e+ will benefit patients that receive the device. e+ differs from other vitamin E polyethylene products in the way that the vitamin E is introduced into the polyethylene material. While a number of products on the market are 'infused' with vitamin E, meaning the vitamin E is added to the part after it is manufactured, e+ is blended directly into the resin for a more uniform distribution of the vitamin E within the polyethylene. This should help the material retain improved mechanical and wear properties throughout the part. Additionally, DJO Surgical has incorporated this technology into additional product offerings to be released later in 2013."

—EH (April 5, 2013)

New Study on Youth Sports: Diversify!

Researchers from Chicago have found that specializing in one sport at an early age isn't going to make your child an elite athlete. What might work? Diversifying participation in a multitude of sports and not playing year-round. This is in line with what is promoted by the STOP Sports Injuries Campaign.

Recent research published in *Sports Health: A Multidisciplinary Approach*, analyzed articles from 1990 to 2011 looking for information about whether sports specialization actually helps or hurts kids. The researchers also utilized recent work conducted by the article's lead author, Dr. Neeri Jayanthi, the medical director of primary care sports medicine at Loyola University Chicago. Dr. Jayanthi's research looked at injury rates in 519 tennis players ages 10-18 who spent, on average, 11 to 15 hours per week training.

Their results highlighted that children who specialized in tennis were 1.5 times more likely to get an injury, regardless of their total training time. The researchers also found that in sports like cycling, swimming, and skating, those who started significant training around age 15 were more likely to become elite-level athletes than their peers who started training earlier.

"Kids often receive pressure from their parents or coaches to be the best in one given sport, when in reality participating in free play and a multitude of sports from an early age is the best strategy to create an outstanding athlete," said William Levine, M.D., chair of the STOP Sports Injuries Advisory Committee, in the April 2, 2013 news release.

Dr. Jayanthi told *OTW*, "As a health care provider to a young athlete, your recommendations must be specific and have some scientific support to impact change, rather then just saying 'play less sports.' You can identify risk by some simple questions such as: Did you quit all other sports to focus on one? Do you train in sports more than 16 hours/week? Do you train and compete in sports more than nine months/year?' Counseling can happen at the individual level in the office, and more pro-active sports-specific efforts within sports organizations in your community. If each of us play a small role in education on those young athletes at risk, we can make some big changes together."

April is Youth Sports Safety Month and the STOP Sports Injuries campaign has several free resources and events available to help educate parents, coaches and athletes on preventing sports injuries and keeping kids in the game for life. Please visit www.stopsportsinjuries.org/.

—EH (April 3, 2013)


Wikimedia Commons, Camw, Pascaloue, and Salmaboskey boskey

XIAFLEX: Positive Results for Adhesive Capsulitis

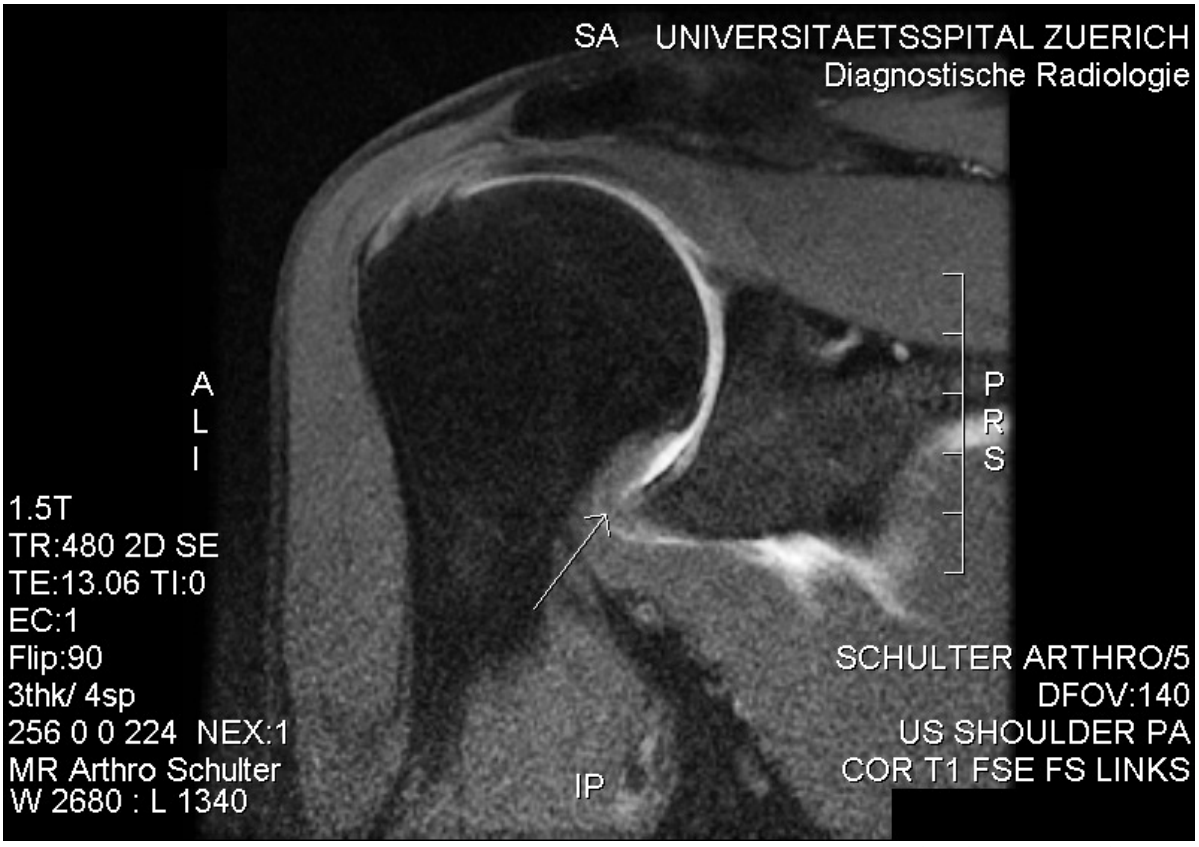
BioSpecifics Technologies Corporation has announced positive, statistically significant top-line data from the Phase IIa study of XIAFLEX for the potential treatment of adhesive capsulitis (frozen shoulder).

"We are very encouraged by these positive results and look forward to progress in this program which Auxilium expects in the second half of this year," reflected Thomas L. Wegman, president of BioSpecifics, in the March 26, 2013 news release. "We believe there is strong potential for XIAFLEX in frozen shoulder as there are few optimal treatment strategies and no approved therapies available. These data further support the vast potential of XIAFLEX for many conditions and diseases caused by collagen accumulation, in addition to the five indications in clinical development and the sBLA under review at the FDA for XIAFLEX for Peyronie's disease."

This open-label, Phase IIa study was conducted at 11 sites in the U.S. by BioSpecifics' strategic partner Auxilium Pharmaceuticals, Inc. The goal was to assess the safety and efficacy of XIAFLEX for the treatment of Stage 2 unilateral idiopathic frozen shoulder in comparison to an exercise-only control group.

This study involved 50 adult men and women; 4 cohorts of 10 patients each received up to three ultrasound-guided extraarticular injections of varying doses of XIAFLEX separated by a minimum of 21 days. All patients were instructed to perform home shoulder exercises. The fifth cohort of ten patients received no XIAFLEX injections and only performed home shoulder exercises. The study's primary endpoint was the change (in degrees) from baseline to the day 92 follow-up in active forward flexion in the affected shoulder compared to the exercise-only cohort. Safety assessments were made during all study visits and immunogenicity testing was performed at screening and day 92.

Both the 0.58mg and 0.58mg dosing arms showed positive, statistically significant improvement from baseline in forward flexion vs. the exercise-only group. The 0.58mg dosing arm also showed statistically significant improvement from baseline in shoulder abduction vs. the exercise-only group. Positive trends with improvement in degrees were also seen in other active range of motion assessments versus the exercise-only group. Patients were also assessed using the American Shoulder and Elbow Surgeons Scale for function and pain. Both the 0.58mg and 0.58mg cohort demonstrated statistically significant improvement in pain and function over baseline scores versus the exercise-only group.



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—EH (April 2, 2013)

reimbursement

Wells Fargo: Procedure Volume to Offset Device Tax

The cumulative benefit to U.S. volume surgical procedures due to Obamacare will increase 3.6% by 2022 and will likely offset the 2.3% medical device tax under the new healthcare law.

That's not the political rhetoric of a partisan political pundit, but the result of a new analysis from one of Wall Street's top orthopedic analysts, Larry Biegelsen of Wells Fargo Securities. And we don't think Larry was kidding, even though he announced the new analysis on April 1, 2013.

Tax and Pricing Pressures Offset

Biegelsen said device companies will be able to offset the tax based on their average gross margins of 60–70%. Biegelsen also expects procedure volume benefit to "offset at least some of the potential incremental pricing pressures from implementation of Accountable Care Organizations (ACOs) and bundled payments."

Based on an update of a Wells Fargo January 15, 2013 analysis, Biegelsen estimates the increased healthcare coverage of newly insured patients, "represents a 1.5% tailwind to U.S. volumes across 10 key device categories in 2014 versus our previous estimate of 0.6%." Why the change? Biegelsen said his previous analysis used the Medicaid population instead of the overall insured population. Children account for over 50% of the Medicaid population.

Orthopedic and Spine Winners

In general, Biegelsen believes incremental utilization benefit in 2014 is greater for orthopedic procedures at 1.8% vs. cardiovascular procedures at 1.0%. He noted that orthopedic procedures may be considered elective and thus may not be affordable for the uninsured. In contrast, some of the cardiovascular procedures are performed on an emergency basis regardless of healthcare coverage.

"Across the five orthopedic procedure categories—hips, knees, spine, shoulders and lower extremities—that we evaluated, the median incremental utilization impact was 1.8% in 2014 and 0.7% in 2015...spine procedures are estimated to see the greatest incremental volume benefit at 3.4%."

Among the large orthopedic device makers, Biegelsen says company's like Zimmer Holdings, Inc. and Medtronic, Inc. will see median incremental sales growth of 0.8% in 2014, "which represents an 18% increase over our current 4.5% estimate." He says those two manufacturers have the potential to increase their current low-to-mid single-digit top-line growth rate by over 20% in 2014 as a result of the increased device utilization.

NuVasive, Inc., based on its business mix and applying a 3.3% utilization rate for spinal fusion, looks like a big winner in 2014. The potential for NuVasive, says Biegelsen, "Yields upside potential of $20 million or 2.9% in sales."

AdvaMed: Device Tax is "Toxic"

Stephen Ubl, president and CEO of AdvaMed, said on February 26, 2013 that the device tax is already having a


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Equity Research

Healthcare Coverage Expansion A Shot In The Arm For MedTech

Medical Technology

Wells Fargo Securities

"toxic effect on innovation, jobs and U.S. leadership of the medical technology industry." Ubl said repealing the device tax, "is critically important to companies large and small that already are living with the real-world harmful impact this tax is having—including layoffs, cuts in R&D and delayed expansion plans. While we understand and support action to address the deficit, the negative impact of the tax is compounded exponentially by the repeated cuts to the industry and the customers it serves."

Repealing the tax, while Congress tries to reduce the deficit, is an uphill battle, particularly when Wall Street and Ortho Main Street send mixed messages. The Wells Fargo analysis was titled: "Healthcare Coverage Expansion A Shot In The Arm For MedTech."

Biegelsen said he'd be happy to send the Wells Fargo analysis to *OTW* readers by emailing him at: Lawrence.Biegelsen@wellsfargo.com.

—WE (April 2, 2013)

spine

Number of Lumbar Spine MRIs Questioned

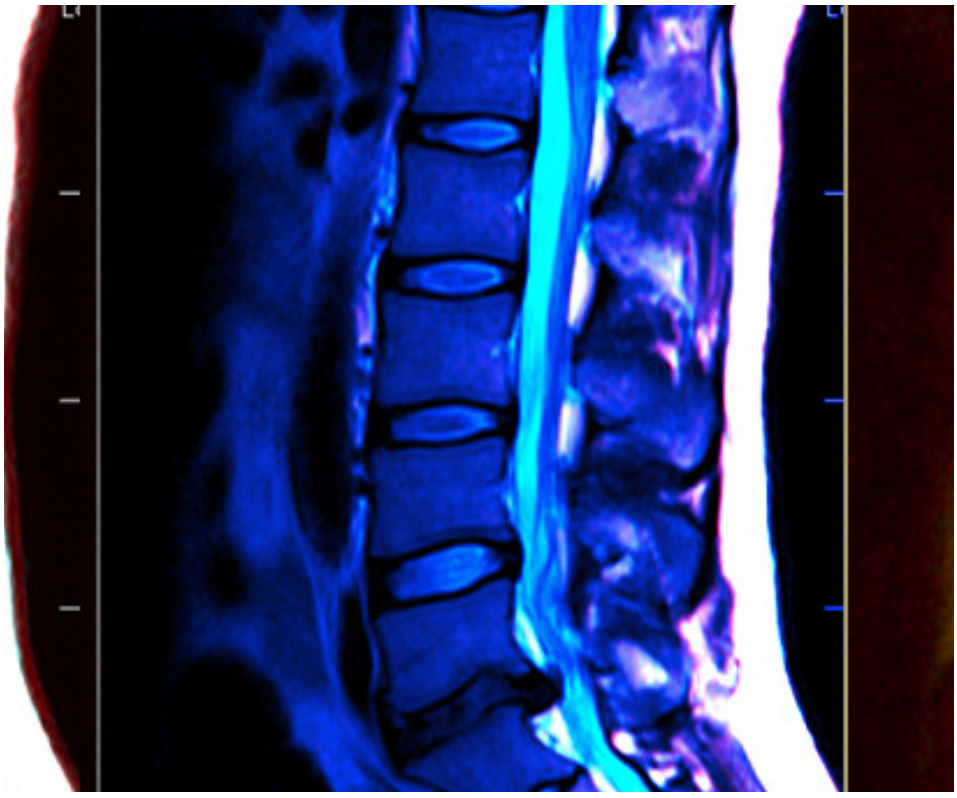
Family physicians are ordering too many lumbar spine MRI scans, according to a Canadian study reported March 26 by Crystal Phend, senior staff writer for *MedPage Today*. Only 34% of lower back scans ordered by family physicians were considered appropriate compared with 58% ordered by physicians in other specialties. Derek Emery, M.D. and his colleagues at the University of Alberta in Edmonton, found that when MRIs were analyzed by an expert panel, 29% of the MRI referrals to two large teaching hospitals were deemed inappropriate and a further 27% were of "uncertain value."

"Eliminating inappropriate scans and some of uncertain value could reduce the harm that accrues from unneeded investigations and result in significant cost savings," they wrote in an online research letter to *JAMA Internal Medicine*. Emery noted that lumbar spine scans have risen dramatically to account for about a third of all MRIs done in some regions, despite the poor correlation between its findings and clinical signs and symptoms, Phend reported.

"Overuse is driven by many factors, including patient expectations, physician concerns about litigation, and lack of physician accountability for cost," Emery said. "Solutions will require strict adherence to appropriate guidelines and better education of patients."

The only indication for lumbar spine MRI among the 1,000 outpatient referrals that Emery and his fellow investigators examined that routinely received a rating of "appropriate" by the expert panel was postoperative leg or back pain. These cases accounted for only 17% of the lumbar spine MRI orders. The rest were three times more likely to receive an uncertain or inappropriate rating than to be judged appropriate. Phend reported that neurosurgeons were most likely to order appropriately (76%), whereas Emery and colleagues deemed that fewer than half of the referrals by neurologists and orthopedic surgeons were appropriate.

—BY (April 2, 2013)



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