VOLUME 8, ISSUE 20 | JUNE 19, 2012

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: Biomet reported better-than-expected sales growth last week and pulled the sector up. It is a measure of how low expectations have fallen when 4% sales growth is cause for celebration. Still, valuations are low and buyers added some larger cap, integrated ortho equities to their portfolios last week.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	ArthroCare	(0.67%)	16.54%	Up almost 20% in a month, ARTC has clearly bounced off its extreme lows. Does it have the legs to keep going?
2	6	Johnson & Johnson	24.93	3.61	JNJ and Synthes have frog marched all the way to the finish line and the good news is more accretion than expected.
3	9	Stryker	23.68	4.68	If Biomet can grow 4%, how high can SYK or ZMH go? Most buyers of SYK, ZMH assume they can do better. We'll see in a few weeks.
4	7	Zimmer	24.95	4.02	JNJ, SYK and ZMH found new strength last week as investors wound their way back around to large ortho.
5	1	Orthofix	16.23	(6.62)	OFIX held on to the #1 position a bit too long. This is not the time to fight the tape. OFIX remains the least expensive ortho equity.
6	NR	Smith & Nephew	21.50	1.25	Last week's return to ortho was the rising tide that also lifted SNN. Now, of course, the June results need to support these buyers.
7	3	Symmetry Medical	5.29	(1.08)	With all of the big, integrated and highly profitable ortho companies moving up, SMA came down to make room.
8	4	NuVasive	6.63	12.35	After nearly a 60-day run, NUVA is now among the more expensive ortho stocks. Still on the PR, however, with more upside possible.
9	5	Conmed	10.09	(2.34)	Investors may be "ho-hum" to CNMD, but the analysts are predicting 29% earnings growth in June quarter.
10	8	Integra LifeSciences	13.34	(2.72)	The problem is that analysts are forecasting exactly zero earnings growth this quarter.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	ArthroCare	ARTC	$28.68	$793	16.54%
2	NuVasive	NUVA	$21.65	$935	12.35%
3	MAKO Surgical	MAKO	$25.26	$1,075	9.83%
4	Tornier N.V.	TRNX	$22.50	$890	4.85%
5	Stryker	SYK	$54.15	$20,628	4.68%
6	RTI Biologics Inc	RTIX	$3.76	$210	4.44%
7	Zimmer Holdings	ZMH	$63.20	$11,132	4.02%
8	Johnson & Johnson	JNJ	$66.01	$181,288	3.61%
9	CryoLife	CRY	$4.92	$136	3.14%
10	Exactech	EXAC	$16.95	$223	1.92%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TranS1	TSON	$2.55	$69	-21.05%
2	Bacterin Intl Holdings	BONE	$1.39	$59	-14.72%
3	TiGenix	TIG.BR	$0.58	$53	-6.93%
4	Orthofix	OFIX	$37.25	$698	-6.62%
5	Alphatec Holdings	ATEC	$1.68	$151	-5.08%
6	Integra LifeSciences	IART	$33.65	$909	-2.72%
7	Conmed	CNMD	$27.15	$768	-2.34%
8	Medtronic	MDT	$37.77	$39,175	-1.18%
9	Symmetry Medical	SMA	$8.22	$301	-1.08%
10	Synthes	SYST.VX	$166.16	$19,817	-0.25%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$37.77	$39,175	11.38
2	Zimmer Holdings	ZMH	$63.20	$11,132	12.82
3	Johnson & Johnson	JNJ	$66.01	$181,288	13.15
4	Orthofix	OFIX	$37.25	$698	13.35
5	Stryker	SYK	$54.15	$20,628	14.21

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$20.70	$814	53.08
2	NuVasive	NUVA	$21.65	$935	50.35
3	Symmetry Medical	SMA	$8.22	$301	32.88
4	Kensey Nash	KNSY	$38.49	$335	26.92
5	Exactech	EXAC	$16.95	$223	23.87

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$37.25	$698	0.74
2	ArthroCare	ARTC	$28.68	$793	1.13
3	RTI Biologics Inc	RTIX	$3.76	$210	1.23
4	Stryker	SYK	$54.15	$20,628	1.32
5	Integra LifeSciences	IART	$33.65	$909	1.36

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$20.70	$814	6.30
2	NuVasive	NUVA	$21.65	$935	5.20
3	CryoLife	CRY	$4.92	$136	4.39
4	Symmetry Medical	SMA	$8.22	$301	2.74
5	Medtronic	MDT	$37.77	$39,175	2.31

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.68	$151	0.76
2	Symmetry Medical	SMA	$8.22	$301	0.84
3	Conmed	CNMD	$27.15	$768	1.06
4	Exactech	EXAC	$16.95	$223	1.09
5	CryoLife	CRY	$4.92	$136	1.13

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.58	$53	46.21
2	MAKO Surgical	MAKO	$25.26	$1,075	12.73
3	Synthes	SYST.VX	$166.16	$19,817	4.99
4	Kensey Nash	KNSY	$38.49	$335	4.67
5	TranS1	TSON	$2.55	$69	3.63

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

Dr. Richard Kaul: A "Public Danger" or Innocent Scope-of-Practice Pawn?

By Walter Eisner

Oscar Wilde wrote that every saint has a past and every sinner has a future.

The observation could be applied to Richard Kaul, M.D., a New Jersey anesthesiologist with a negligent manslaughter conviction in London in his past and future plans for treating spine patients in the Democratic Republic of the Congo and returning veterans from the wars in Iraq and Afghanistan.

But now the Attorney General in New Jersey is calling Dr. Kaul a, "clear and imminent danger" to the public and the state's board of medical examiners has temporarily suspended his medical license. Dr. Kaul told our Elizabeth Hofheinz that he is caught in the middle of a scope-of-practice controversy in the state between board certified orthopedic spine surgeons and interventionists.

A Hopeful Future

We first reported on Dr. Kaul's Spine Africa Project in our "On (and Off) the Record" column on May 8.

Dr. Kaul, founder of New Jersey Spine & Rehabilitation in Pompton Lake, New Jersey, told us he had been travelling to Africa and operating on patients since August 2011. He said patients travelled up to 700 miles to see him and he encountered "extremely advanced pathology." He also told us about back injuries women sustained from the sexual violence that had spilled into the Congo from the Rwandan civil war.

Richard Kaul, M.D.

Andrew Huth and RRY Publications LLC

It's not unusual for *OTW* to highlight the good works of physicians and Dr. Kaul has aggressively promoted his humanitarian work while building a seemingly successful business.

Misrepresentation?

But what happened next was unusual. A reader and board certified orthopedic spine surgeon informed us that Dr. Kaul had not properly represented himself. That, in fact, Dr. Kaul has no privileges to admit patients or perform surgery in any hospital in the state. "The fact that [this] imposter has the gall to represent [himself] as a spinal surgeon and then prey upon the most unfortunate of humanity makes me physically ill," said the surgeon.

We did some checking.

It turns out the Attorney General for the State of New Jersey filed a complaint in April over Dr. Kaul's alleged, "flagrant disregard of his own lack of training and expertise and his continuing performance of surgical spinal procedures for which he is not qualified."


Jeffrey Chiesa, New Jersey Attorney General

A hearing on the complaint took place on June 13 and the board voted to temporarily suspend his license. Dr. Kaul had earlier agreed to an interim consent order prohibiting him from performing any more spine surgeries until the board voted.

Checkered Past

But this was not the first time Dr. Kaul was in hot water with the state's medical board.

In 2001, Dr. Kaul was convicted by a jury in London of negligent manslaughter after a woman he sedated during a dental procedure, went into cardiac arrest and died. Dr. Kaul had his medical license stripped in England and moved to New Jersey. He did not disclose the criminal conviction to the state's licensing board and began practicing medicine. He was later given a six-month suspension and subsequent probation by the state.

Complaint

What is currently at stake is whether Dr. Kaul has the proper qualifications to perform spinal surgeries. The complaint states that Dr. Kaul did not receive any training in spinal surgeries during his residency at Albert Einstein-Montefiore Medical Center in the Bronx.

He later took continuing education courses on spinal surgical procedures, including some that involved cadaver training. He also studied minimally invasive spinal surgeries during a two-week fellowship in Seoul, South Korea, a trip that "falls far short" of the training needed for spinal surgeries, the complaint states.

The complaint says that Dr. Kaul's facility in Pompton Lakes became "a one-room surgical office" in March 2011. He

also has practiced medicine at a number of facilities across the state, including locations in Clifton, New Brunswick, Piscataway, Bloomfield, Elizabeth, Newark and Jersey City.

Officials say doctors who operate in one-room clinics must have hospital privileges or board permission to perform that surgery. Dr. Kaul has neither, according to the complaint.

After hearing from our reader and discovering these past and current disciplinary actions, we contacted Dr. Kaul again and asked him about the charges that he has and is currently misrepresenting himself as a Board Certified Minimally Invasive Spine Specialist.

Scope of Practice Controversy

Dr. Kaul told us that there is a hotly contested scope-of-practice contest going on in New Jersey and orthopedic spine surgeons and neurosurgeons do not look fondly on physicians with his training opening the door for interventional pain specialists.

He told us that he was trained in general surgery, anesthesia, and did a pain fellowship, as well as a spine fellowship in Korea and has 70-80 hours of CME in spine. He also said he has done about 800 spine cases.

Dr. Kaul said his practice began to evolve starting in 2002 when he began doing endoscopic disc decompression; then he began doing cervical endoscopic decompressions and did multiple training courses on that; then he moved from endoscopic decompressions to endoscopic fusions. He told us that he is credentialed by the center that hired him and that he has a plenary license for medicine and surgery issued by the state of New Jersey. He said he agreed not to do these kinds of cases unless he gets hospital privileges.

His website includes a lengthy resume and video clips describing his charitable work in the Congo. Additionally, his website states he's donated $500,000 in services to The Spine Foundation for veterans of Iraq and Afghanistan.

According to a May 30, 2012 story in *Pain Medicine News*, expert reports for the Attorney General's complaint were provided by former North American Spine Society (NASS) President Greg Przybylski, M.D.,director of neurosurgery at the New Jersey Neuroscience Institute, JFK Medical Center, Edison, and professor of neurological surgery, Seton Hall University School of Graduate Medical Education, South Orange; and, Andrew Kaufman, M.D., assistant professor of anesthesiology and director, Pain Management Center, University of Medicine and Dentistry of New Jersey, Newark.

The article says the physicians provided details of five cases of complex spine surgery performed by Dr. Kaul, including a seven-hour surgery involving removal of old spinal hardware followed by lum-

bar interbody spinal fusion with mesh cages and bone allografts, and insertion of pedicle screws and rods. The complaint does not cite any adverse events from the surgeries.

David Solsberg, M.D., a Denver neuroradiologist who performs minimally invasive spine procedures, was asked by *Pain Medicine News* to review the New Jersey attorney general's complaint. He said the charges appear to have a legitimate basis, although he says he may change his mind if more objective data are provided.

"These are not minimally invasive procedures—these are big operations, not short snappers—and this is way outside of what would be seen in most communities as the scope of practice of an interventional pain physician," Dr. Solsberg told the publication. "For example, lumbar interbody fusion and allografting are way outside what a nonsurgeon would do."

Patient Safety and Disclosure

In a letter to the editor on *NorthJersey.com* on May 27, 2012, Paul Kovatis, M.D., a foot and ankle specialist in New Jersey wrote that the medical and public communities should, "shake their collective heads in disgust and amazement concerning the allegations that a nonsurgical physician, Richard A. Kaul, performed same-day neurosurgery."

Kovatis pointed to "several troubling aspects" regarding the state Medical Board of Examiners' deficient oversight of outpatient facilities and their definitions of scopes of medical practices.

"Compared with hospitals, ambulatory centers have fewer quality and patient safety checks and balances; most are owned or operated by those who perform procedures there. The surgeries noted in the article are not done at most hospitals due to scant peer-reviewed literature supporting their long-term success rates. They would not pass muster within their respective subspecialty hospital departments," wrote Kovatis.

Kovatis continued, "One should look askance at a physician who performs invasive procedures of this number but maintains no hospital privileges. It also boggles the mind that a doctor with such a checkered past was able to freely perform such high-risk procedures with no oversight."

The fallout from Kaul's behavior, says Kovatis, is ultimately not about trying him in a court of public opinion but about quality care and patient safety. "How many patients who have had outpatient spine surgery knew beforehand that it may be done by physicians who are not formally trained spine surgeons or surgeons at all?"

"This event is a clear and compelling example of why the state Board of Medical Examiners should mandate more stringent scope-of-practice regulations for medical professionals," concluded Kovatis.

An Example?

Following up on Dr. Kaul's assertion that he is caught in the middle of a scope-of-practice fight, we asked him why, given his past criminal conviction in London and disciplinary problems in New Jersey, he made himself such a public target by widely publicizing his practice and charitable work? Surely he must have known his past would be used against him.

We also asked him that knowing he would be a target, why didn't he get hospital privileges before performing surgeries he knew had that requirement?

We did not receive a response to our written questions.

The curious case of Dr. Kaul weaves together the drama of the past sinner, future saint and a professional fight over the practice of medicine in New Jersey.

If Dr. Kaul is an innocent pawn in this fight, he deserves his due. If, however the board agrees that he is a "clear danger" to the public and he used the debate over scope of practice as diversion to draw attention away from himself, then another famous saying by Samuel Johnson comes to mind. "Patriotism is the last refuge of the scoundrel." ♦

Medical Sales Moneyball?

By Robin Young

This game of medical product sales is not fair and the deck, in terms of hospital access or reimbursement rules, is often stacked against the individual rep.

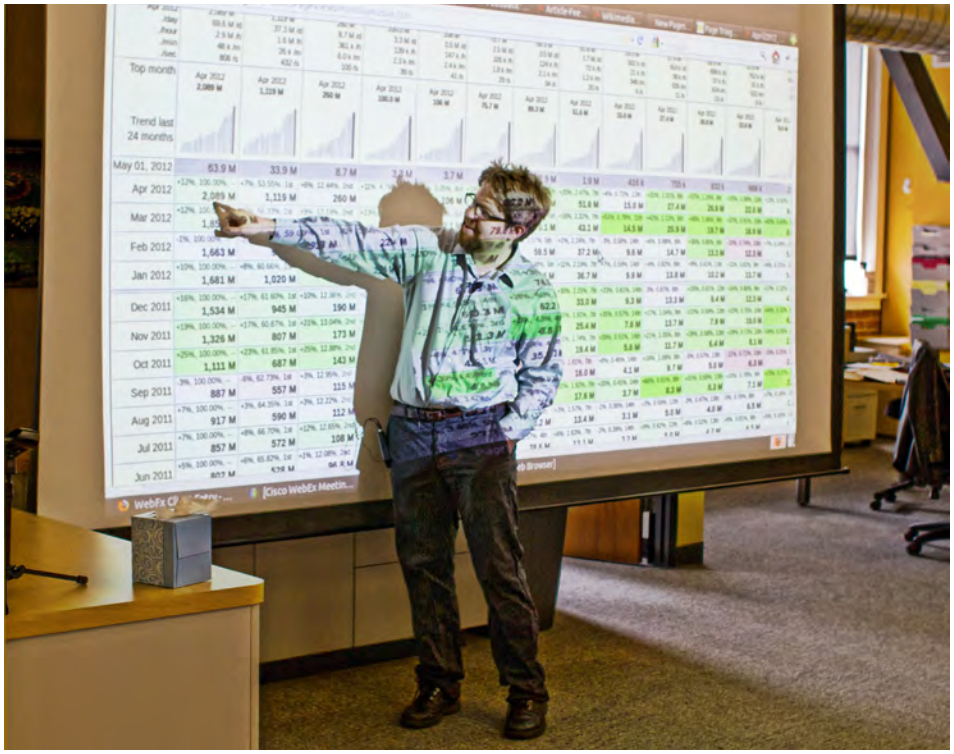
Moneyball: The Art of Winning an Unfair Game is the book by Michael Lewis published in 2003, which described a style of managing a pennant winning Major League team in spite of having to play in a very small market and with the league deck stacked against it.

Could *Moneyball's* lessons apply to the art and practice of selling medical products? This current era of medical product sales is characterized by PODS, rising hospital restrictions, new reimbursement schedules and shrinking budgets. How can a sales organization adapt to such a resource limited world?

Moneyball used the example of the small market team—the money-poor 2002 Oakland A's—to illustrate how an analytical, evidence-based, metric approach could create a pennant winning team despite such limitations. The film based on the book starring Brad Pitt was released in 2011.

The central premise of the book was that the collected wisdom of baseball's insiders (players, managers, coaches, and scouts) was subjective and often more wrong than right. Statistics such as stolen bases, runs batted in and batting average were outdated measurements of a player's value to his team.

So Bill James and other data obsessed fans created an entire new set of statistics—such as on-base percentage and slugging percentage—to measure offensive output or defensive success. In the case of the 2002 Oakland A's baseball team, these new metrics uncovered some overlooked players and exposed the weaknesses of traditionally valued player qualities like speed or contact.



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The book also touched on the politics of baseball including: insiders vs. outsiders (traditionalists vs. upstart geek proponents of sabremetrics); the democratization of data which in turn caused the flattening of hierarchies; and the "ruthless drive for efficiency that capitalism demands."

From SABREmetrics to SOSPRmetrics

Sabremetrics is the acronym which stands for Society for American Baseball Research. SOSPRmetrics is the acronym which stands for Society for Orthopedic Sales Professional Research. There is no SOSPR, but if it did exist, what metrics would it track? Here are some of our ideas which mirror the types of statistics developed by one of the pioneers of SABREmetrics, Bill James.

SOSPR STAT	Meaning	SABRE STAT	Meaning
PrS	Product sales is an estimate of the number of units a sales team "should" have placed in the OR given their component sales call statistics as well as the number of total products (implants, instruments, adjunct biologics) they or a competing sales person has available to place/allow in the OR	BsR	Base runs is an estimate of the number of runs a team "should" have scored given their component offensive statistics as well as the number of runs a hitter/pitcher creates/allows.
OASC	Order average on sales calls (OASC) is how many existing products are ordered by existing customers, or how many competitor product try outs are ordered by existing customers, excluding contractual purchase obligations.	BABIP	Batting average on balls in play (BABIP) is how many batter's balls in play go for hits, or how many balls in play against a pitcher go for hits, excluding homeruns.
DACP	Defense against competitor's products measures a sales person's effectiveness at keeping a competitor's products out of the OR. One of the most important skills a sales person possesses is knowledge of the competitor's products.	DIPS	Defense-independent pitching statistics measure a pitcher's effectiveness based only on plays that do not involve fielders: home runs allowed, strikeouts, hit batters, walks and fly ball percentage.
LQPS	Late quarter pressure situations (LQPS) is any sales in the last two weeks of a quarter when the quota for that quarter is off by 10% or more	LIPS	Late-inning pressure situations (LIPS) is "any at-bat in the seventh inning or later, with the batter's team trailing by three runs or less (or four runs if the bases were loaded)."
PE	PE estimates how many orders a sales team "should" have won based on the number of sales calls, emails, training sessions and other quality contacts.	PE	Pythagorean expectations (PE) estimate how many games a baseball team "should" have won based on the number of runs they scored and allowed.
NERD	Narration, Exposition, Responsiveness, Description (NERD). This is a quantitative measure of the expected effectiveness of a sales person's pitching skills. It measures the standard deviation from the mean of a sales person's DACP statistic, try-out percentage, overall sales call order percentage and the differential between a sales person's earned order average and PrS.	NERD	Narration, Exposition, Reflection, Description (NERD) is a quantitative measure of the expected attractiveness of a pitcher or a team's pitching. It measures the standard deviation from the mean of a pitcher's DIPS statistics, swinging strike percentage, overall strike percentage and the differential between a pitchers ERA and xFIP.
DF	Defense Factor (DF) is calculated by dividing the number of incrementally ***new*** procedures in a given territory by the number of competitor's products used in those new procedures. This is also a measure of ***incremental*** market share. DF also measures the competition's new technology in-roads in any territory.	RF	Range Factor (RF) is calculated by dividing putouts and assists by the number of innings or games played at a given defense position.
SC	Sales Created (SC) is a measure of how many sales resulted from all aspects of the sales process. So, for example, a sales person may have an "average" NERD rating but due to a high repeat order rates and long-term customer loyalty may be the most important sales creator in a company.	RC	Runs Created (RC) is a measure of how many runs a player contributed to the team's overall number. So, for example, a .270 hitter may seem "average" but due to a combination of walks, base running and extra-base hits may in fact be the most important run contributor on a team.

Source: RRY Publications

VORP/VORSP

Finally, Value Over Replacement Player/Sales Person (VORP/VORSP). In the baseball world this refers to how much a player contributes to his team's success as compared to a fictitious "replacement player" who is an average fielder and a below average hitter. In the orthopedic sales world this refers to a how much a sales person contributes to his company's success as compared to a fictitious "replacement sales person" who is an average sales person in terms of activity and has a below average NERD rating.

VORP/VORSP's usefulness is the fact that it measure contribution at the margin—marginal utility. Other stats tend to compare job performance to an overall average, which is fine. But such company or industry-average comparisons break down when considering a sales person's total, composite contribution to sales.

Orthopedic product sales is a zero-sum game; in other words, in any given surgical procedure your company's product is used only if another company's product is not. Your company wins by doing this more often than your competitors.

It follows, then, that a contribution of any sales helps a company to win market share, no matter how small the contribution. Orthopedic product sales are growing ever more competitive and external factors are becoming greater and greater determinants of sales success or failure. In such an environment, even the "average" sales person is a valued commodity.

Medical Moneyball

The rules of the medical game are changing—in part from legislative action, in part from payer decisions and in part from market developments such as PODS or medical tourism. Is it time for a new framework of rigorous statistical analysis, a new set of metrics that better describe value and contribution of people and products in orthopedics? Is it time to acknowledge that orthopedics is also subject to the "ruthless drive for efficiency that capitalism demands."?

Probably so and Medical Moneyball just might have some fresh ideas for sales people and sales teams to use in this changing medical product sales world. ♦

June 15, 2012
Retraction of the Week – Senzaki's Tainted Evidence

By Walter Eisner

Each week, *OTW* publishes a recent scientific journal retraction arising from shoddy, lazy or downright fraudulent research. These are examples of researchers who omitted or falsified data, used data out of context, or employed such awful logic that they were forced to retract their study.

These examples are collected by *Retraction Watch* and we are honored to be able to present them with permission from Retraction Watch to our readers. *Retraction Watch* was started in 2010 by Adam Marcus and Ivan Oransky, M.D.

Circulation's Retractions

Lying about obtaining ethics approval for your studies will get your papers retracted, but will it invalidate the evidence?

Retraction Watch reported on June 13 that the American Heart Association's (AHA) journal, *Circulation*, has retracted four articles by Hideaki Senzaki, M.D., of Saitama Medical University after the association was contacted in April by the University and published a retraction at their request.

Hideaki is accused of misleading the publication on IRB (Independent Review Board) approval. He is a highly-published investigator who trained at Johns Hopkins for a time.

Retraction Watch tried to reach Senzaki for comment but did not hear back from him. They also left word with the

circ.ahajournals.org/ and Photo creation by RRY Publications LLC

Journal of the American College of Cardiology, which has published papers by Senzaki, to find out whether it, too had been contacted by Saitama officials. There was no response yet from the publication.

According to the *Circulation* notice:

The four articles listed below have been retracted due to ethical violations. The corresponding author's institution, Saitama Medical University, reported to the editors of Circulation, that Dr. Hideaki Senzaki did not receive approval for these studies from the institutional internal ethics committee. Furthermore, in each of the articles referenced below, it was determined that Dr. Senzaki misinformed the editors and readers of Circulation by stating that the studies had received the necessary approval from his institutional review board.

- *Ventricular–Vascular Stiffening in Patients With Repaired Coarctation of Aorta: Integrated Pathophysiology of Hypertension. Circulation. 2008;118:S191–S198, doi:10.1161/CIRCULATIONAHA.107.757096*
- *Arterial Hemodynamics in Patients After Kawasaki Disease. Circulation. 2005;111:2119–2125, doi:10.1161/01.CIR.0000162483.51132.25*
- *Ventricular Afterload and Ventricular Work in Fontan Circulation: Comparison With Normal Two-Ventricle Circulation and Single-Ventricle Circulation With Blalock-Taussig Shunts. Circulation.*

2002;105:2885–2892, doi:10.1161/01.CIR.0000018621.96210.72

- *Circulating Matrix Metalloproteinases and Their Inhibitors in Patients With Kawasaki Disease. Circulation. 2001;104:860–863, doi:10.1161/hc3301.095286*

Circulation, established in 1950, is published weekly by Lippincott Williams & Wilkins for the AHA and is circulated to over 23,000 cardiologists, cardiovascular surgeons, and others practicing cardiovascular medicine.

According to Microsoft Academic Search, Senzaki has been credited with 62 publications and 527 citations. The four papers listed above have been cited ranging from 9 to 67 times, according to Thomson Scientific's Web of Knowledge.

Tainted Evidence

Retraction Watch's Ivan Oransky, M.D., writes, "Certainly, violation of research ethics is a profound problem that journals must take seriously. But some observers raised a provocative and interesting point: What if a study lacks IRB approval but produces impressive (and reproducible) results? Is retraction really the only option? Should other researchers be denied the chance to learn from the tainted finding?"

One has to ask, what's in the best interest of patients and researchers? If a physician finds something in the tainted literature which may help her patient, is she obligated to share it with her patients? Tell us what you think. ♦

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On (and Off) the Record

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

Data Tower of Babel Hurting Ortho Research?…Medical Cowboy vs. Playing it Safe…Controversy in Kyphoplasty/Vertebroplasty...Steven Barna, M.D. Joins Florida Orthopaedic Institute and more.

Bedlam in the Research Arena? Tom Errico, M.D., is chief of the Spine Service at NYU Hospital for Joint Diseases. He tells *OTW*, I just had a meeting with yet another group with a database that wants our hospital to participate. Two weeks ago it was a group of neurosurgeons. There are just too many entities out there coming up with databases, and it has created this 'Tower of Babel' situation. For example, all lower back patients need Oswestry Disability Index scores, but how various programs are going about it is different—how are we ever going to determine that one process will win out over another? The challenge is that hospitals need something that will provide researchers with meaningful information, while at the same time not be so onerous that patients are turned off. We need to find out the most important questions…it's almost like we need to decide which is going to be the dominant language. The minimally invasive (MI) society only wants to collect data on MI procedures; many surgeons don't want to collect data on psychosocial factors, but the nonoperative physicians want that information included. And on and on…In the end the winner is going to be the database that delivers the most results. Once people are pointing at a database program and saying, 'Look at how effective that is. They have high follow-up with meaningful results,' then other hospitals will want to join in. Research drives our field…and if the

data collected is flawed or insufficient, then it's garbage in garbage out."

Thomas Prescott and Thomas Wilder Join Benvenue Board Benvenue Medical, Inc. is welcoming Thomas M. Prescott and Thomas C. Wilder to its Board of Directors. Prescott is president and CEO of Align Technology, Inc., and Thomas C. Wilder is president and CEO of Sequent Medical, Inc. Prescott, who will serve as chairman of the board, has been president and CEO of Align since 2002. The company is the inventor of Invisalign and an innovator in digital dentistry, and it has grown significantly under his leadership. Previously, Mr. Prescott was president and CEO of Cardiac Pathways, where he successfully led a turnaround prior to its acquisition by Boston Scientific Corporaton. Prior to Cardiac Pathways, Mr. Prescott held various sales, marketing, management and executive roles at Nellcor Puritan Bennett, GE Medical Systems, and Siemens. Prescott earned a Master of Management from the Kellogg Graduate School of Management at Northwestern University and a bachelor's degree, with emphasis in Civil Engineering, from Arizona State University.

Tom Wilder has served as the president and CEO of Sequent Medical, Inc., a privately held medical device company focused on developing innovative devices for the treatment of neurovascular disease, since 2010. Prior to joining Sequent Medical, Wilder was president and CEO of Photothera, Inc., a private company developing transcranial laser therapy for the treatment of acute ischemic stroke. His experience also include being president and CEO of Micro Therapeutics, a publicly traded company that provided a broad range of advanced interventional products to neurovascular specialists. Prior to Micro Therapeutics, Wilder held several management positions during an 11-year tenure at Medtronic, Inc. He holds a Master of Management from the Kellogg Graduate School of Management at Northwestern University, and a BA in Economics from Stanford University. He also serves on the Board of Endologix, Inc.

Steven Barna, M.D. Joins Florida Orthopaedic Institute Dr. Steven Barna, an interventional pain physician, is bringing his expertise to the Florida Orthopaedic Institute, and will treat patients in the areas of conservative and non-surgical minimally invasive spine care. Prior to joining Florida Orthopaedic Institute, Dr. Barna worked for more than 10 years as an academic educator at Harvard Medical School. While there, Dr. Barna was an assistant clinical professor of medicine at Brigham and Women's Hospital and an assistant clinical professor of anesthesiology and medical director of the Center for Pain Medicine at Massachusetts General Hospital. Dr. Barna is board certified by the American Board of Anesthesiology, is a medical graduate of Case Western Reserve University School of Medicine and is currently an assistant professor of orthopedics and sports medicine at the University of South Florida College of Medicine. Previously, Dr. Barna served as secretary of the Massachusetts Society of Interventional Pain Physicians, was an editorial board consultant for the American Journal of Geriatric Pharmacotherapy, and was content leader of pain management for HealthTank, a publishing company in Virginia.

Be a Medical Cowboy or Play it Safe? Paul Girard, M.D. is an orthopedic traumatologist with the University of California, San Diego. He tells *OTW*, "There is a movement in orthopedics to have us 'own' the treatment of fragil-

ity fractures associated with osteoporosis. It has traditionally been left up to individual surgeons to determine what they are most comfortable doing on their own versus getting input from their medical colleagues. We are split into at least two groups—those who attempt to handle all of the medical part of fragility fractures and those who tell the patient, 'Talk to your primary care physician.' I typically start the patient on calcium and Vitamin D, have them learn about fall prevention, and *then* refer them to a primary care doctor or endocrinologist."

"The leaders in orthopedics tend to be in the more aggressive camp, either taking the route I take or totally doing it themselves. There are several high profile orthopedists who are big proponents of taking total control the entire process. The issue is that to properly manage the medical aspects of this condition you need a full metabolic bone disease service. As for patients, they like to walk out of a doctor's office with something in hand, whether it's a recommendation for a dose of calcium or a Dexascan. This carries more weight rather than if the surgeon says, 'Just talk to your primary care physician.' I recommend that surgeons in the emergency department who do fracture work try to develop a system to identify patients at risk of an osteoporotic fracture, and then *do something* for them."

Botched Vertebroplasty/Kyphoplasty? Adam Wollowick, M.D. is an adult and pediatric spine surgeon at Montefiore Medical Center in New York. "A hot issue now," Dr. Wollowick tells *OTW*, "is how to approach vertebroplasty and kyphoplasty research. The studies from the last few years, in particular the two *New England Journal of Medicine* articles from 2009, still have people shaking their heads and saying, 'How did they come to those conclusions?' Each of these studies has significant limitations which has increased the controversy. One study had significant crossover of patients into the vertebroplasty group and both had relatively small numbers. It's not clear if the results of those studies are valid for a larger sample size and for patients with more acute injuries. Furthermore, it appears that at least some of the patients were not so profoundly affected by their fractures. Many of us, on the other hand, have patients that are almost bed ridden because of their fractures. In my experience, they do very well with cement augmentation, so we need studies that address the patients that are most profoundly affected by vertebral compression fractures."

"Part of the problem is the difficulty in removing the various forms of bias, including the influence of industry, from these studies. Those interested in this issue need to do studies independently, either looking at two treatments head to head or a noninvasive/nonsurgical treatment versus an invasive procedure. We need better multicenter trials with large numbers of patients stratified by activity level. Patient selection is critical in terms of time from injury as well as impact of injury on the person's life."

Physicians Lagging in Concussion Education Dr. Kathleen Weber, M.D. is the director of Primary Care/Sports Medicine and Women's Sports Medicine at Rush University Medical Center. Dr. Weber is also the only female Major League Baseball (MLB) team physician, and serves on the MLB concussion committee. She tells *OTW*, "I have been very surprised to see that despite the MLB being very forthright and proactive in addressing concussions, there are many lay people who are still not taking concussions as seriously as they should be. It's often the parents who want the player to get back in the game because their child has a big tournament…and while you can see a broken bone on an X-ray and can tell them the return to play timeline, you can't say the same of a concussion. But it's also been interesting to see that survey results we've collected from targeted physician specialties on their understanding of concussion management—the ones that are suppose to be clearing athletes for play—revealed that some of these physicians don't have a good understanding of how to treat these injuries. My colleagues and I are now in the process of putting several publications together on concussion for the MLB… articles that will definitely add to the literature. While it used to be a badge of courage to get your bell rung, nowadays it beginning to be seen as a potentially serious injury." ♦

Brems Debates Galatz on Open Rotator Cuff Repair

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

"Open repair provides better outcomes…not just pain relief, but tendon quality and tendon healing," says John Brems. "But watch out," says Leesa Galatz, "The complications of an open repair can be quite devastating."

This week's Orthopaedic Crossfire® debate is "Open Repair of a Torn Rotator Cuff: Optimizes Outcome." For the proposition was John J. Brems, M.D. from Cleveland Clinic. Against the proposition was Leesa M. Galatz, M.D. of Washington University Medical School; moderating was Thomas S. Thornhill, M.D. of Harvard Medical School.

Wikimedia - KaihsuTai and Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Brems: "We have a specific case that walks into all of our offices. He is a 45-year-old male, avid tennis player with two years of symptoms and a large rotator cuff tear (RC) who has exhausted nonoperative management. The degree of fat replacement muscle atrophy is significant. Some cuff tears can be treated with arthroscopic technique, but not all should be."

"So why would open technique be the better option in this case? Consider multiple factors: tear size, tear configuration, tissue quality, degree of fat replacement, bone quality, and the effect of delamination. We don't often see acute tears…retraction is an orthopedic myth. In large chronic tears, which we commonly see, the tendon is *gone*. The bony footprint in these large chronic tears is often osteopenic and anchor failure is not uncommon. So now we recommend a double row technique, but more recent studies show that by putting more and more pressure on the tendon on the footprint, you can cause hypovascularity and have healing issues as well."

"Open technique permits large bone tunnels and a transosseous fixation with a low risk of fixation failure. In those cuff repairs that I go back in on, I don't think I've ever seen a bone tunnel fail, nor have I seen a suture fail… the issue is always the tissue that fails (around the suture or bone tunnel)."

"Arthroscopic technique is more like spot welding versus the seaming that occurs in a normal healing. In a paper that was just published in April 2012 the authors looked at arthroscopic cuff repairs and did MR [magnetic resonance] arthrography and found that despite the fact that there was not much clinical correlation, that 15/17 had leakage at the MR arthrogram at an average of 48 months after the repair. So even though it's not clinically symptomatic, the tendons are not healing."

"I think there are three major differences between open and arthroscopic technique. Arthroscopic has better incisions; length and permanency of the scar can be very real in patients who are more conscious about these issues. Difference two: arthroscopic is a temporary winner…how long you hate your doctor. While arthroscopic tears are much less painful, pain can be a good thing in keeping them from actively using their arm before they should.

Difference three: open is the clear winner…definitely better outcomes…not just pain relief, but tendon quality and tendon healing."

"What is *not* different? Patients do not heal faster, nor return to work sooner, nor return to sports any sooner; patients should not resume strengthening any sooner because the rate limiting step is that the RC tendon must heal to the bone…and that's independent of technique."

"Dr. Altchek in 2009 did ultrasounds of 127 patients with arthroscopic repair and found that as the tear size became larger the likelihood of re-tear increased by at least nine times. In another group of patients—47 shoulders with two-year follow up—postop MRI scans at two years showed 22% re-tear. But because the patients weren't feeling any worse they market it as a very good operation. My esteemed colleague [Dr. Galatz] did a study in 2004 on 18 patients—small series—two-year follow up…94% failed in terms of ultrasonography."

"Open repairs do stand the test of time, and this is supported by several studies showing that these patients have excellent outcomes at long-term follow up."

Dr. Galatz: "There are historical reports of an open rotator cuff repair that show excellent outcomes, both anatomically and clinically. Dr. Brems referenced this study [by Dr. Galatz] that was followed up at two years; then when I was his fellow we followed these patients at 10 years and found 92% good to excellent results. Open repair is a good operation."

"However, complications can potentially be quite devastating. We see increased stiffness, deltoid dehiscence (and thus far we don't have a good answer for this), infection…and iatrogenic anterior superior instability (ASI) is a significant problem and there are many patients with large tears who lose elevation after surgery."

"The trend toward minimally invasive approaches is based on less scarring, less trauma to the deltoid, decreased incidence of ASI, cosmesis, and decreased pain. But the problem with an arthroscopic approach has always been healing. In my study: remember that this is very early experience, they were all older patients with a single row and early repair technique, yet we still had good results."

"In an open repair we don't have 100% healing. In Harryman's study in 1991 we had a 60% healing rate and the failure rate was higher in larger tears. The healed tears did better and age

was a significant factor. We looked at this series of studies where we had a large failure rate at 10 years to see how they were doing. The patients were now an average of 75; 10 men, five women. Only two of them had had subsequent surgical procedures. There are no major differences in function or ASES [American Shoulder and Elbow Society] score, and this is in spite of a significant increase in the Hamada, or the glenohumeral joint degenerative changes. So we did see significant changes, yet most of them were still doing well. In the long term I think it's safe to say that we did no harm."

"There are many studies in the literature that show equal or equivalent rates of healing with modern techniques. We do have better healing now with double row techniques. Looking specifically at studies on open versus arthroscopic repair—32 open, 32 arthroscopic—there was improvement in both groups and no difference. So I'm not here to say that an arthroscopic repair is necessarily better, but I'm arguing that at this point with modern repair techniques we have approached equivalence."

"Getting back to the complications of an open RC repair…in a patient with an aggressive acromioplasty and a takedown of the deltoid, we ended up fusing her because we couldn't get her comfortable any other way. We used muscle transfers for salvage operations for these patients in revision situations. To have iatrogenic ASI which would necessitate something like this postoperatively is quite unusual."

"So in the case of the male attorney, right hand dominant, tennis player… we see fatty degeneration and changes, but in the literature there is nothing to support that healing in this severe case is better with an open repair. In summary, healing is more likely related to the biology of the patient and the muscle tendon unit than the surgical approach; the complications are fewer and far less devastating, and they preserve your future reconstructive options."

Moderator Thornhill: "Both of you mentioned studies where there was a high incidence of re-tear or lack of a repair, yet the patients did well. Do we repair too many RCs, Leesa?"

Dr. Galatz: "We're getting better at identifying patients who will benefit from a repair. Our trend is to be more aggressive in the younger patients with smaller tears because we have an opportunity with those people to intervene in the natural history of that shoulder. We used to do a lot of surgeries in older people and are now realizing that the likelihood of healing is quite low and perhaps those patients are better treated nonoperatively."

Moderator Thornhill: "John, what about someone with a documented RC tear?"

Dr. Brems: "First of all, as Leesa just said, we can't change the biology of the tendon. In a younger person the effort should be to repair a cuff tendon if possible. But in the older population I think we *are* doing too many repairs. We know from many autopsy studies that many people have cuff tears as incidental findings. And the mere presence of an MRI scan proven-tear does not mandate that it should be attacked sur-

gically in any form. The older population doesn't need cuff repairs except as a pain operation. Patients can function relatively well despite anatomic loss of integrity after repair. My concern is in a 45-year-old gentleman… that I would make every effort—and if there's going to be anatomic integrity I could get it better open than arthroscopic."

Moderator Thornhill: "John, if you have a high incidence of re-tear and a high incidence of good results is it the decompression aspect of it that makes them better…and the tear is incidental."

Dr. Brems: "I don't know where the pain comes from in RC disease. We see large tears that are pain-free, and we see small tears that are disabling because of the pain. I would treat pain as the primary aspect for surgery."

Moderator Thornhill: "Leesa, when you have a 75-year-old with a large tear when can you predict whether that patient is going to go on to cuff tear arthropathy?"

Dr. Galatz: "When we looked at our patients long term we did see significant progression of degenerative changes on X-ray, but we didn't have enough patients to identify factors associated with that. If a patient is 75 and they don't have a lot of changes thus far I think it's safe to assume that the tear has been there for a long time, and if he doesn't have changes by that point it's unlikely. If you're going to start to see changes those likely occur earlier, so maybe at 65 it's a question, but if someone is 75 and they're bumping along just fine they'll likely continue to do so."

Moderator Thornhill: "You both discuss fat replacement in the musculature. Is that best determined by MRI/CT/Ultrasound?"

Dr. Galatz: "This case is a good example. This person has a lot of changes which are likely irreversible. However, muscle is very pliable and is filled with pluripotential cells and thus far we don't know when someone—especially at the age of 45—has reached the point of no return. Certainly in an older person if I see a lot of fatty degenerative changes, I counsel them that these are likely irreversible, that their tear is unlikely to heal, and we should do what we can to treat them without surgery. In a younger, active person, though, maybe we should be more aggressive."

Moderator Thornhill: "Doing it either way you must be accomplished at doing it, and the evidence based studies are going to help guide us on what to do in the future. Thank you both." ♦

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

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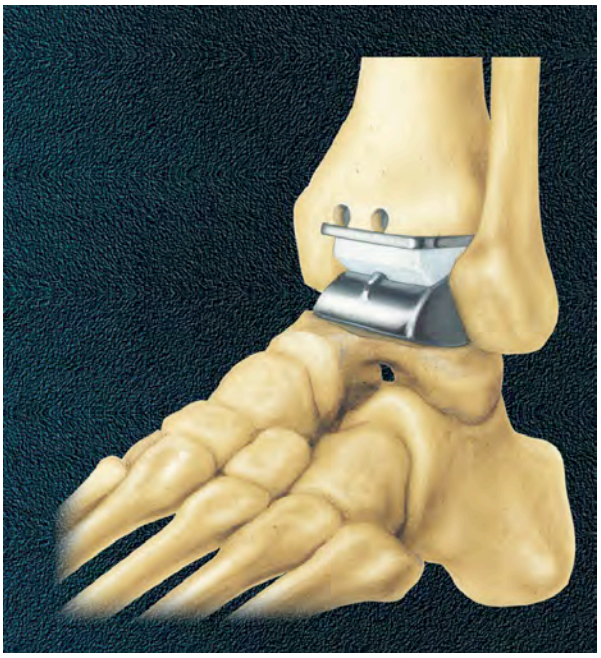
company

STAR Ankle Gets Thumbs Up in Oklahoma

Small Bone Innovations, Inc. (SBi) is reporting that the Oklahoma Department of Labor's Workers' Compensation Court Insurance Department (OWCC) is recommending SBi's STAR total ankle replacement implant when meeting certain patient guidelines. It is the only total ankle system being recommended by the OWCC based upon its adopted medical treatment guidelines.

The STAR ankle, which has been implanted in more than 20,000 patients worldwide, is the only total ankle replacement system approved through the U.S. Food and Drug Administration's (FDA) Premarket Approval (PMA) process. In the PMA process, the STAR ankle's safety and effectiveness was compared with ankle fusion in a multi-center, multi-year, Investigational Device Exemption (IDE) study, which was published in 2009. As indicated by SBi, the study showed the STAR to be superior in efficacy and comparable in safety to fusion. The IDE and other subsequent studies show that, compared to fusion, the STAR ankle has better pain relief, greater clinical success, less blood loss and a shorter operating time. To date, there are more 700 U.S. surgeons who are qualified to perform the procedure.

Michael P. Simpson, president and CEO of SBi, said: "Since FDA approval of the STAR in 2009, we have successfully expanded national coverage of the STAR from a single insurer to favorable policies among all major insurers based on these clinical data. The STAR-exclusive DWC recommendations in Texas, Oklahoma, and Kansas reflect a growing recognition of the device as the superior ankle replacement system," he added.



Small Bone Innovations, Inc.

Anthony G. Viscogliosi, founder and executive chairman of SBi added: "Oklahoma joins Texas and Kansas in endorsing disability management guidelines for workers' compensation programs that specify the STAR ankle as the only suitable ankle replacement solution. This supports a nationwide trend that emphasizes evidence-based medicine as a critical element in delivering the highest level of care to patients."

—EH (June 14, 2012)

FTC Approves J&J/ Synthes Superpower

The final regulatory barrier to Johnson & Johnson's $21.3 billion acquisition of Synthes, Inc. was cleared on June 11, as the U.S. government gave its official blessing.

The Federal Trade Commission (FTC) cleared antitrust concerns of the deal by requiring that J&J divest itself of its trauma division. Biomet offered to buy the business for $280 million in April. J&J has agreed to the price. The FTC specifically mentioned J&J's DePuy Orthopaedics' wrist fracture system, called DVR, saying the combined companies would control more than 70% of the market for such systems.

Federal Trade Commission

In the fourth quarter of 2011, DePuy's trauma sales were $50 million, a slight increase over the previous year.

European antitrust official approved the acquisition deal on April 19.

New Superpower

Combining DePuy with Synthes creates the world's largest orthopedic company. At 28% estimated market share, the new DePuy/Synthes combination will have twice the share of its nearest two competitors—Stryker Corporation at 14% share or Zimmer Holdings, Inc. at

13% share. The merger affects 17,000 employees throughout the world.

The new Superpower will be the #1 or #2 supplier in every major orthopedic sector with 21%, 22% and 19% market share in knees, hips and spine, respectively.

The deal is now expected to close within the week.

—WE (June 12, 2012)

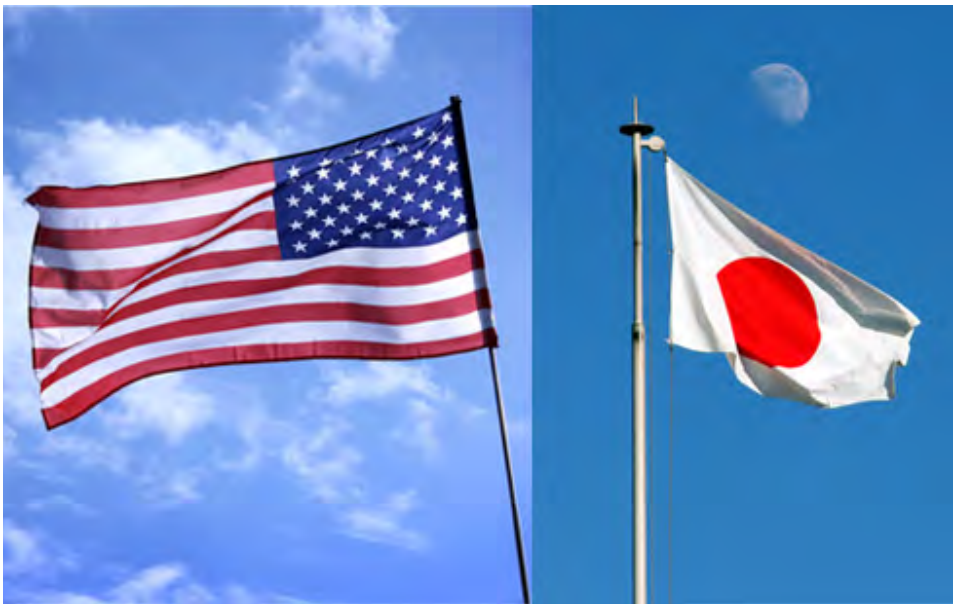
Symmetry Partners With Japan Surgical Specialty

A partner across the seas…Symmetry Medical Inc. has announced that its subsidiary, Symmetry Surgical, has completed an agreement with Japan Surgical Specialty (JSS) Corporation to distribute its medical device brands in Japan. This continues Symmetry Surgical's global broadening of its recently expanded business, which includes brands from Symmetry Surgical, formerly Codman Surgical Instruments, and SSi.

JSS is part of the Intermed Japan Group and is focused on meeting the needs of the surgical market in Japan with clinical and service support for innovative and high quality medical devices. JSS has a national distribution network and a dedicated logistics and service facility.

Chris Huntington, Chief Operating Officer of Symmetry Surgical, told *OTW*, "With the creation of Symmetry Surgical, our goal is to build a global network of international distributors to complement our strong presence in the U.S. Market. Japan is the world's second largest medical device market and our strong existing Symmetry Medical relationship with JSS made it a priority as we drive growth with the expansion of the Symmetry Surgical portfolio to all regions throughout the world."

—EH (June 11, 2012)



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ISTO's Fusion Osteobiologic Granted Patent

The U.S. Patent Office has issued a fundamental U.S. patent for the technology on which St. Louis-based ISTO Technologies, Inc.'s InQu Bone Graft Extender & Substitute is based. The product is a molecular entanglement of hyaluronic acid and a synthetic polymer to create a three-dimensional scaffold with a cell-friendly environment for bone growth.

InQu Bone Graft/ISTO Technologies, Inc.

The U.S. patent (No. 8,192,759, "Matrix Made of Polyester Polymers Entangled with Hyaluronic Polymers Useful for Supporting Tissue Repair"), filed in July 2005 and granted on June 5, 2012, covers the unique biosynthetic structure of ISTO's product. The inventors are company President and CEO Mitchell Seyedin, Ph.D., and Robert Spiro.

Patent Abstract

The Abstract for the patent states:

The present application discloses matrix compositions to support the repair of tissue defects such as an osteochondral

injury. A matrix described herein comprises a polyester polymer entangled with a polysaccharide polymer. Also disclosed are methods of preparing a matrix, and methods of using a matrix in the repair of tissue. In certain configurations, a matrix can comprise polyester cross-linked with a polysaccharide, which can be an oxidized polysaccharide. In some configurations, a matrix can further comprise one or more additional components, such as a growth factor.

InQu

InQu is a platform technology for tissue regeneration and is used primarily as an osteobiologic product in spinal fusion applications and is manufactured and marketed in a variety of forms—granules, paste, putty and strip—to meet surgeons' needs for a variety of surgical applications. Hyaluronic acid is a biological molecule with multiple functions not shared by other biomaterials, such as collagen-based products or mineral-based ceramics that have traditionally been used for bone regeneration. InQu has received 510(k) clearances as a bone graft extender and substitute, and since its launch in 2008, it has been used in over 17,000 orthopedic and spinal procedures to date.

Seyedin said the patent further protects and solidifies the company's leadership position in leveraging the properties of hyaluronic acid for orthopedic biologic applications. "We intend to further build on the 17,000 procedures to date to provide more patients and surgeons with our cost-effective, safe and efficacious product," according to the June 5, press release.

—WE (June 11, 2012)

legal

Orthofix Settles Bone-Stim Civil and Criminal Cases

Orthofix International N.V. has resolved all outstanding legal issues regarding the marketing and sale of the company's bone growth stimulators.

"We're glad to finally get this behind us," Bob Vaters, president and CEO of Orthofix told *OTW* after the announcement by the U.S. Attorney in Boston on June 7 that a settlement had been reached with the company. Vaters became CEO and president of Orthofix in 2011.

Criminal Fine and Whistleblower Settlement

The company will pay a $7.65 million criminal fine and $34.23 million to resolve civil allegations under the False Claims Act. The company also agreed to plead guilty to obstructing a federal audit. The civil settlement resolves claims brought against Orthofix in a whistleblower lawsuit filed by Jeffrey Bierman under the qui tam provisions of the False Claims Act in 2005.

The civil settlement addresses four issues alleged by Bierman relating to Orthofix's promotion of its bone growth stimulator products.

Those issues are:

- Improper waiver of patient co-payments, thus misstating their true cost and resulting in overpayments by federal programs;
- Submission of falsified certificates of medical necessity to support federal payments;
- Failure to advise patients of their right to rent rather than purchase; and
- Offering or paying kickbacks, characterized as fitter, referral, and other comparable fees, to induce the use of products.

Orthofix International N.V. and U.S. Attorney's Office

Bierman, the owner of a Missouri billing service, will receive payments totaling slightly more than $9 million. He originally sued in 2005 questioning Medicare billings for bone-growth stimulators by Orthofix and other makers.

Orthofix has not conceded liability or wrongdoing as part of the civil settlement.

As part of the settlement, Orthofix has also agreed to enter into an expansive corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services.

Investigation Casualties

The U.S. Attorney's Office released a statement saying the investigation has (to date) resulted in a number of felony charges against former executives, employees and contractors of Orthofix, including the following:

- Thomas Guerrieri, a former vice-president of sales, pleaded guilty on April 9, 2012, to paying kickbacks to induce a doctor and a physician's assistant to prescribe Orthofix products;
- Mitchell Salzman, a former regional sales manager, pleaded guilty on Dec. 14, 2011, to making a false declaration to a federal grand jury about Orthofix conduct;
- Derrick Field, a former territory manager, pleaded guilty on March 22, 2012, to falsifying patients' medical records to fraudulently induce Medicare to pay for Orthofix bone growth stimulators;
- Michael McKay, a former territory manager, pleaded guilty on May 11, 2012, to falsifying patients' medical records to fraudulently induce Medicare to pay for Orthofix bone growth stimulators; and
- Michael Cobb, a physician's assistant, pleaded guilty on April 19, 2012, to accepting kickbacks from Orthofix in return for ordering Orthofix bone growth stimulators.

The U.S. Attorney said the investigation is ongoing. Orthofix, however, appears to have bitten the bullet and put the matter to rest.

—WE (June 14, 2012)

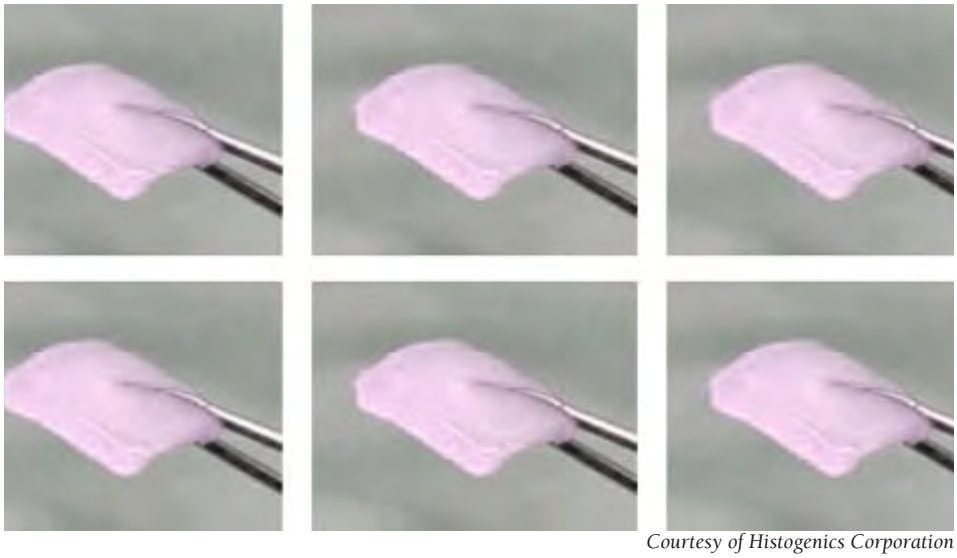
large joints

NeoCart Tissue Implant Superior to Microfracture

The regenerative medicine company Histogenics Corporation received encouraging news in an article in the *Journal of Bone and Joint Surgery* reporting the two-year results of a Phase 2 clinical trial of its product NeoCart Autologous Cartilage Tissue Implant (ACTI). The implant is designed for patients with grade II chondral injury to the femur (the cartilage in the knee).

NeoCart is an autologous bioengineered neocartilage grown outside the body using the patient's own cells for the repair of full thickness cartilage lesions. The current standard of care for this problem is microfracture surgery which works by creating tiny fractures in the underlying bone. While this treatment is widely recommended as a primary treatment for chondral injury to the femur, outcome measures have been reported to plateau between 12 to 24 months.

The results of the two-year Histogenics study, as reported in the June 6 news release, are that NeoCart has a comparable safety profile to microfracture surgery, significantly improves pain and function within six months of treatment, provides significantly greater improvements in a greater proportion of patients than microfracture, and is associated with greater clinical efficacy



Courtesy of Histogenics Corporation

two years after treatment than does microfracture.

Dennis Crawford, M.D., Ph.D., Assistant Professor, Orthopedics, Oregon Health Science University and the lead author of the paper, said, "Preliminary findings strongly suggest that autologous cartilage tissue implant using NeoCart significantly improved knee pain and function within six months and provided significantly greater improvements, in a greater proportion of patients, than microfracture. This includes, importantly, greater clinical efficacy two years after treatment in contrast to those treated with microfracture surgery."

He went on to say, "There is a clinical need for a primary surgical treatment option for cartilage repair that improves on the historical outcomes of microfracture and the results detailed in our recent analysis and publication strongly suggest that NeoCart may meet this need as a first-line therapeutic alternative to microfracture procedures."

Histogenics officials report that a multicenter randomized Phase 3 study of NeoCart is presently underway comparing that treatment of articular cartilage defects of the knee with microfracture surgery.

Histogenics is a regenerative medicine company that combines cell therapy and tissue engineering technologies to develop innovative products for tissue repair and regeneration. In May 2011, Histogenics acquired the Israeli cell-therapy company Prochon Bio-Tech. Histogenics' products focus on the treatment of active patients suffering from articular cartilage derived pain and immobility.

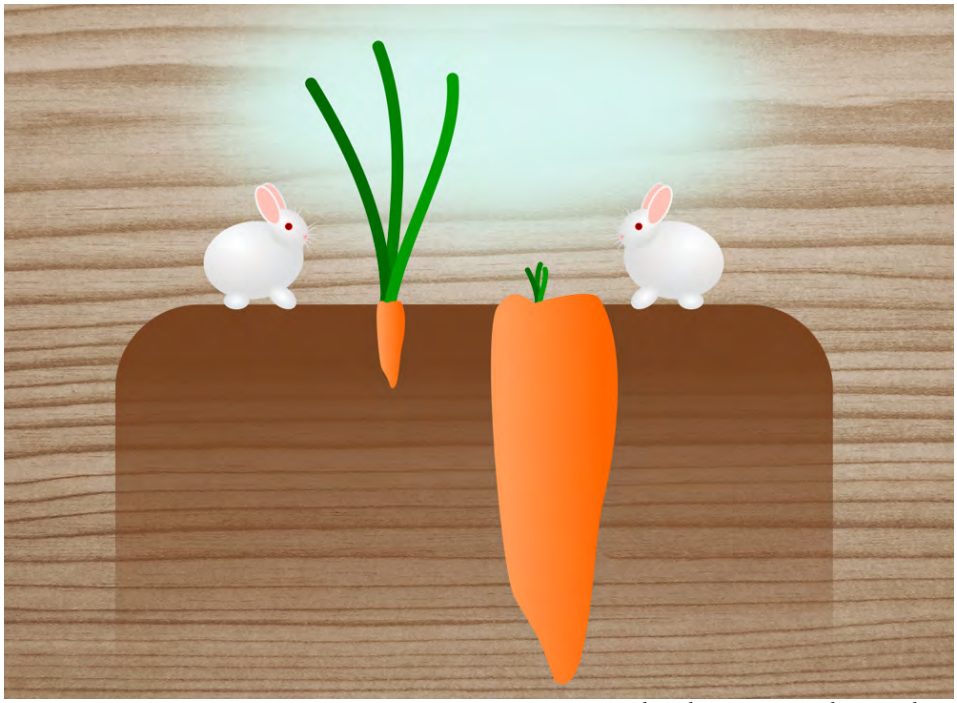
—BY (June 11, 2012)

Patients Wildly Overestimate Surgeon Payment

What do patients believe their surgeons are being paid to implant their new joints—and how accurate are their perceptions? To find out, Denver orthopedic surgeon Jared Foran and some colleagues devised a study that asked 1,200 patients what they thought their orthopedic surgeons should make for a hip or knee replacement and what they thought Medicare paid them for the service. Foran, the co-author, reported their results in the paper, "Patient Perception of Physician Reimbursement in Elective Total Hip and Knee Arthroplasty," published in the june issue of *The Journal of Arthroplasty*.

On average, the patients thought that surgeons should receive $18,501 for a total hip replacement and $16,822 for a total knee replacement. Patients estimated the Medicare reimbursement to be $11,151 for a total hip replacement and $8,902 for a total knee replacement. The reality? Surgeons get paid on average $1,375 for a total hip and $1,450 for a total knee .According to Foran, between 1998 and 2007, the average Medicare reimbursement decreased 21% for a total hip arthroplasty (THA) and 20% for a total knee arthroplasty (TKA).

The majority of the patients believed that the average national Medicare reimbursement ($1,375 and $1,450) for a THA and TKA was too low. Of the patients, 68.5% believed that $1,375 for a THA was "somewhat lower" or "much lower" than what a surgeon should earn. Similarly, 67.2% of patients believed that $1,450 for a TKA was also "much lower" or "somewhat lower" than what a surgeon should earn. Patients with higher education levels tended to perceive the value of a TKA as being higher than those with lower education levels and patients with a history of knee



Wikimedia Commons and Nevit Dilman

arthroplasty saw the value of the operation as being higher than did those who had not had experience with the surgery.

So what did the patients think the surgeons should be paid? The patients surveyed felt that surgeons deserved to be paid, on average, $14,358 for performing a THA, a figure which is over ten times the average national Medicare reimbursement. They believed, on average, that surgeons should be paid $13,322 for performing a TKA, which is over nine times the average national Medicare reimbursement.

Some patients expressed concern that the current reimbursement rates might decrease access to care—either by physicians refusing to accept Medicare or through a decrease in qualified persons willing to enter the field.

That appears not to be the case. From 1992 to 2007, according to the paper, there was a 44% decrease in the consumer price index-adjusted Medicare reimbursement rate for hip and knee arthroplasties. Over the period between 2000 and 2004, the number of THA and TKA procedures increased by 37% and 53%, respectively.

Medicare is the major source of payment for hip and knee arthroplasties. In 2004 it paid for 55.4% of hip and 59.3% of knee replacements. A 2009 survey of the American Orthopaedic Association found that only 3% of orthopedic surgeons had opted out of Medicare. An additional 4% were nonparticipating providers.

The authors of the paper report that many patients feared that orthopedic surgeons might opt out of the Medicare system. If that should happen, the authors write, "it is likely that less qualified surgeons will be faced with the responsibility of treating an increasing number of complex primary and revision total joint arthroplasty patients. The effect of this will have on the quality of joint arthroplasties in the United States and in the long term financial impact on the health care system remains to be seen."

—BY (June 11, 2012)

trauma

Brain Injuries From Sports Going Up

Fatalities in football are down, but traumatic brains injuries from sports are up, according to Alice G. Walton, Ph.D. writing June 4 in the online journal *TheDoctorWillSeeYouNow.com*. She reported that young football players are suffering more serious head injuries than before.

The good news is that neurological injuries resulting in death have been decreasing. During the 1960s, 128 football related deaths were reported. During the 2000s the number of football related deaths fell to just 32. But serious brain injuries rose to 14 in 2011 and individuals with spinal cord injury with incomplete recovery numbered 8 for the same year. In 2008 there were 14, in 2009 there were 9, and in 2010 there were 7. The rate of "catastrophic" injuries is still very low, with about 0.19 occurring for every 100,000 cases. The rate of injury with incomplete neurological recovery is about 0.4 in 100,000, according to Walton.

A study conducted by researchers Frederick O. Mueller, Ph.D of the University of North Carolina and Robert Cant, M.D. of Emerson Hospital in Concord, Massachusetts, attributed the fact that, while injury rates are going up, the death rate is lower, to "kids getting better medical care on the field," he said in a news release; "they're not dying, but they're having permanent brain damage."

The bounty issue that was in NFL news toward the end of the past season did not help matters any. "That's probably the worst thing that's happened in football in a long time," said Mueller. "High school kids see professional players on TV using their heads as battering weapons and announcers saying, 'that's a great hit.' Kids think maybe that's what they should be doing."

—BY (June 12, 2012)

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reimbursement

AAOS: Cracking the Codes

AAOS, Wikimedia Commons and Tomwsulcer/Medical Files

Getting paid correctly for surgical work performed in the office and the hospital is of great concern to orthopedic surgeons. Incorrect coding can result in payment delays, reductions, denials, or worse, fraud charges.

Surgeons need to know the codes because they are the legal party signing off on reimbursement requests. Delegating this responsibility to others who do not share liability is playing with fire.

If you are a member of the American Academy of Orthopaedic Surgeons (AAOS), there is a new tool to help you keep coding policies and reimbursement straight. The Academy has a new webpage dedicated to helping you meet your legal obligations and help you assure your practice is getting appropriate reimbursements.

The site allows you to browse through coding frequently asked questions, review previously published articles on coding issues, find information on various payment policies, and check for upcoming AAOS-sponsored coding courses.

In conjunction with the new coding webpage, AAOS is introducing a new coding inquiry service. AAOS members—as well as practice executives who are members of the American Association of Orthopaedic Executives (AAOE)—can request coding guidance on a fee-for-service basis. All inquiries will be reviewed by AAOS staff, members of the AAOS Coding, Coverage, and Reimbursement Committee, and outside coding experts. Written responses will be provided.

You can direct specific CPT and/or ICD-9 coding questions to AAOS staff in the "Submit a Coding Question" section of the website (Member Log In Required). In addition, you can view the most frequently asked questions which are organized by anatomical site. AAOS staff works directly with the Academy's Coding Coverage and Reimbursement Committee which reviews member's request for coding guidance. You can also browse through the Coding Articles Archive relating to coding that have been extracted from issues of *AAOS Now*.

For more information, visit www.aaos.org/coding.

—*WE (June 14, 2012)*

spine

Porous Metal Key to Spine Implant

Zimmer Holdings, Inc., a Warsaw, Indiana, firm deeply invested in musculoskeletal health, has introduced a new porous interbody implant, its TM Ardis Interbody System, at the 2012 Spine Week meeting in Amsterdam, The Netherlands. The implant, which is for the lumbar spine, uses the firm's Trabecular Metal (TM) Technology now in use across the company's portfolio including products for the cervical spine.

Trabecular Metal Material is a highly porous substance that resembles the structure, function and physiology of trabecular bone. Because of its porous qualities, it supports bone in-growth between the implant and the bone, enabling biologic fixation. Zimmer officials say that no other porous metal material is supported by the amount of peer-reviewed, published clinical data as Trabecular Metal Technology.

Courtesy of Zimmer Spine

"The Ardis System is the latest innovation from Zimmer Spine, and we are excited to make this unique implant available to European surgeons and their patients," said Steve Healy in a May 29 news release, President, Zimmer Spine. "This system, which incorporates Trabecular Metal Technology, is truly differentiated and we are confident it will offer clinical advantages in the treatment of degenerative disc disease." The TM Ardis Interbody System is now being released commercially across Europe.

Zimmer officials designed the TM Ardis implant with a large surface area available for biologic fixation. They believe that the Trabecular Metal Material of the implant can more evenly distribute the load and decrease the risk of stress shielding. The implant also features an updated, anatomical shape which allows the implant to be inserted into the disc space more easily. Company officials say that the TM Ardis Interbody System has one of the most extensive size offerings on the market to allow the implant to more closely match a variety of patient anatomies.

Zimmer officials offer the Ardis Interbody System for use as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. They add that patients with previous non-fusion spinal surgery at involved levels also may be treated with the device. Surgeons implant the device, singly or in pairs with supplemental fixation, using a posterior or transforaminal approach.

—BY (June 13, 2012)

Runners Live Longer Than Walkers

It is official. Runners live longer than non-runners. The study, conducted by researchers at the University of South Carolina and the Ochsner Health System of New Orleans, analyzed the link between running and cardiovascular-related deaths in 53,000 adults. They presented the results of their study at the American College of Sports Medicine meeting in San Francisco.

As reported on June 4 by Mary Brophy Marcus, *Health Day* reporter, the participants ranged between the ages of 20 and 100 and had undergone a medical exam between 1971 and 2003. None had heart disease, cancer or diabetes at the start of the study.

The researchers collected their information from questionnaires sent to the participants, on which they reported their leisure-time activities, including their running habits. About 27% reported that they ran.

Using data from the National Death Index the researchers found that the runners had about a 20% lower mortality rate than did the non-runners, said lead researcher Dr. Chip Lavie, medical director of cardiac rehabilitation and prevention at John Ochsner Heart and Vascular Institute, in New Orleans.

The study did not report a complete home-run for the runners. Running lowered the risk for mortality when a runner did not exceed more than 20 miles a week, log more than five to seven miles per hour, or run more than two to five times a week, the authors reported.

"Although higher doses [of running] are not associated with worse outcomes when compared with non-runners, those with higher doses of distance, frequency and speed seemed to lose the survival advantage gained at lower doses of running," Lavie noted.

A second study, reported on by Marcus and published in the June issue of the *Mayo Clinic Proceedings*, reviewed the scientific literature on the effect of extreme endurance training— such as that performed by marathoners, triathletes and professional cyclists—and found it can lead to long-term heart damage.

"There's probably nothing better a person can do for himself for his long-term health than daily exercise," said Dr. James O'Keefe, lead author of the second study and a professor of medicine at the University of Missouri and Saint Luke's Hospital in Kansas City, Mo. "But if you train more than the cardiovascu-

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lar system is designed to handle, you can tax your heart and do damage."

He pointed out that the certain cardiovascular biomarkers become elevated during extreme training in some athletes. "Even though they go back to normal within a week, over months and years, the elevations may lead to heart damage and increased susceptibility to certain types of arrhythmias," O'Keefe said.

—BY (June 13, 2012)

Robotic Spine Surgery Performed In Florida

Besides having an M.D. after his name, Nizam Razack has a JD making him one of a very few board certified neurosurgeons in the U.S. who are also licensed to practice law. Razack has now become the first in Florida to perform surgery with the Renaissance robotic guidance system for spine procedures made by Mazor Robotics Ltd.

"It is always both exciting and a little nerve racking to be the first to do anything when it comes to patient care. You always want things to go smoothly and safely for the patient so a good clinical outcome is achieved," Razack said.

Celebration Health Hospital, of Celebration, Florida, a part of the Florida Hospital System, has purchased a Renaissance system, described by Mazor Robotics as the next generation surgical guidance system for spine procedures.

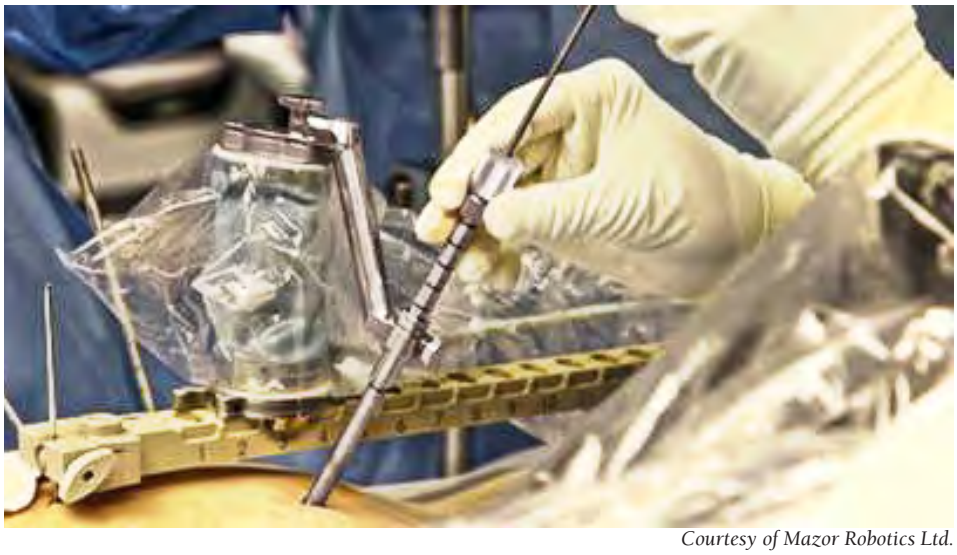
"Mazor aims to work closely with early adopters of Renaissance within large hospital networks to broaden the system's potential exposure to a large number of surgeons," said Ori Hadomi, CEO of Mazor Robotics. "With a state-of-the-art training facility, its large affiliate hospital network and global reputation, we are confident that Celebration Health will be a strong partner for training surgeons to perform robotic spine procedures and an excellent reference point for other hospitals considering the distinguishing features of surgical robotics."

Razack added, "Like any new emerging technology, robotic spine technology has a steep learning curve that requires hours in the lab to achieve clinical competency."

According to Mazor officials the Renaissance system is appropriate for a wide range of clinical applications including open, MIS and percutaneous posterior thoracolumbar approaches, complex spinal deformities, screw placement and osteotomies.

Razack is the founder and president of the Spine and Brain Neurosurgery Center. He currently serves as the Chairman of the Department of Neurological Surgery for Orlando Health, is an assistant clinical professor in the department of neurosurgery for the University of Central Florida College of Medicine and a former Assistant Professor of Neurological Surgery, Orthopedics and Rehabilitation from the University of Miami. He is a Fellow of the American College of Surgeons and of the American Association of Neurological Surgery, and a member of the Florida Medical Association.

—BY (June 11, 2012)



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