

Orthopedics This Week

week in review

4 Little Study on the Prairie Stirs Controversy ♦ How did a 10-patient study at the University of Saskatchewan end up in *The New York Times*? And how did the company involved find itself at ground-zero of controversies of industry influence in research and a highly criticized FDA clearance program? We dug in.

8 The March of Robots Into the Spine Surgery Suite ♦ Last quarter Mazor Robotics stunned Wall Street with a 470% sales jump for the June quarter hitting 11.2 million ILS (shekel) up from 2 million ILS million last year. What is going on here? Is there a march of robots into the spine surgery suite?

12 Kick Women Off Soccer Field?... Surgeon Preferences Driving High Costs and more... ♦ No Soccer for Women? ...Surgeon Preferences Driving High Costs...Explosion of Payment Models Coming...QOL Measures in Osteoarthritis and RA and more...

15 Berend, Rosenberg Debate MIS Total Knee Arthroplasty ♦ “MIS is not for all patients. MIS risk factors for failure include infection, fracture, etc.,” asserts Michael Berend. “I agree with most things you said. It’s not that traditional technique doesn’t work...car brakes worked, ABS is better. Maps work, GPS is better,” says Aaron Rosenberg.



breaking news

19 Stem Cell Powered PEEK Implant Coming

Birth Tissue/Ankle Tendon Repair Study Released

NEUROVISION Judge Overturned, Admonished

26-Fold Risk of RA!

Mayo Team Develops Risk Score for Infection

New Rules When Scientists Disagree at FDA

FDA Proposes Postmarket Surveillance Changes

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Buyers unleashed their traders last week as Bernanke announced that the Fed would pump \$40 billion a month into the system indefinitely—or until unemployment improves. The market exploded with buying interest and orthopedic equities were right in the middle of the party. Cheers and pass the bubbly!

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Globus Medical	30.06%	17.96%	The crucial first quarter after going public report is just about 30 days away. After such a hot opening, Wall Street will be watching.
2	7	Smith & Nephew	21.36	5.80	Legion hinged knee (15 years of clinical history) announced. Should deliver a nice bump for Q4.
3	5	Orthofix	16.23	5.24	OFIX nearing a five-year high and this stock is STILL the least expensive ortho stock. At average valuations, OFIX would be 40% higher.
4	2	Medtronic	28.65	6.74	Here's a fun fact. Used pacemakers with 4+ years of battery life being repurposed in patients in other countries. Waste not, want not.
5	4	Symmetry Medical	5.63	12.05	The key valuation measure that makes SMA stand out is Price to Sales. Second lowest in ortho.
6	8	ArthroCare	(0.80)	12.08	Third best performing equity in ortho this past month. Either buyers like ARTC's growth story or it's an emerging strategic play.
7	3	Zimmer	26.37	8.16	Cash was king last week. With the Fed shoveling cash out the door, growth will become the new investor mantra.
8	6	Integra LifeSciences	13.36	2.12	Upcoming 2.3% device tax will hit companies like IART the hardest. Comes off the top, which will really hit op profits.
9	9	Stryker	23.68	3.51	No new CEO. Entering into meeting's season. This time the drama should be in the booth. Clear positive.
10	10	Exactech	7.68	3.97	Wall Street broker Benchmark Co. really likes EXAC's extremity business—reiterates BUY. Buyers still looking for a catalyst however.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Globus Medical	GMED	\$16.81	\$1,521	17.96%
2	TiGenix	TIG.BR	\$0.72	\$66	15.20%
3	ArthroCare	ARTC	\$30.89	\$857	12.08%
4	Symmetry Medical	SMA	\$9.67	\$354	12.05%
5	MAKO Surgical	MAKO	\$17.15	\$732	11.44%
6	CryoLife	CRY	\$5.90	\$162	10.49%
7	Zimmer Holdings	ZMH	\$66.90	\$11,687	8.16%
8	Medtronic	MDT	\$43.05	\$43,917	6.74%
9	NuVasive	NUVA	\$22.23	\$966	6.57%
10	Bacterin Intl Holdings	BONE	\$1.48	\$63	6.47%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Johnson & Johnson	JNJ	\$68.47	\$188,775	0.18%
2	TranS1	TSON	\$2.48	\$68	2.06%
3	Integra LifeSciences	IART	\$40.52	\$1,095	2.12%
4	Alphatec Holdings	ATEC	\$1.75	\$157	2.34%
5	Stryker	SYK	\$56.01	\$21,309	3.51%
6	Exactech	EXAC	\$17.04	\$226	3.97%
7	Wright Medical	WMGI	\$21.45	\$850	3.97%
8	Conmed	CNMD	\$28.34	\$805	4.89%
9	Orthofix	OFIX	\$43.17	\$819	5.24%
10	Smith & Nephew	SNN	\$55.86	\$10,046	5.80%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	\$43.05	\$43,917	12.77
2	Zimmer Holdings	ZMH	\$66.90	\$11,687	13.22
3	Johnson & Johnson	JNJ	\$68.47	\$188,775	13.59
4	Stryker	SYK	\$56.01	\$21,309	14.40
5	Orthofix	OFIX	\$43.17	\$819	14.73

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	\$21.45	\$850	82.50
2	NuVasive	NUVA	\$22.23	\$966	67.36
3	Symmetry Medical	SMA	\$9.67	\$354	56.88
4	RTI Biologics Inc	RTIX	\$4.00	\$224	22.22
5	Exactech	EXAC	\$17.04	\$226	21.04

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	\$43.17	\$819	0.96
2	ArthroCare	ARTC	\$30.89	\$857	1.00
3	Globus Medical	GMED	\$16.81	\$1,521	1.22
4	Zimmer Holdings	ZMH	\$66.90	\$11,687	1.36
5	Stryker	SYK	\$56.01	\$21,309	1.42

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	\$21.45	\$850	9.04
2	NuVasive	NUVA	\$22.23	\$966	7.15
3	CryoLife	CRY	\$5.90	\$162	4.92
4	Symmetry Medical	SMA	\$9.67	\$354	4.74
5	Smith & Nephew	SNN	\$55.86	\$10,046	3.97

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	\$1.75	\$157	0.80
2	Symmetry Medical	SMA	\$9.67	\$354	0.99
3	Exactech	EXAC	\$17.04	\$226	1.10
4	Conmed	CNMD	\$28.34	\$805	1.11
5	RTI Biologics Inc	RTIX	\$4.00	\$224	1.32

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$0.72	\$66	57.72
2	MAKO Surgical	MAKO	\$17.15	\$732	8.66
3	Globus Medical	GMED	\$16.81	\$1,521	4.59
4	TranS1	TSON	\$2.48	\$68	3.53
5	Tornier N.V.	TRNX	\$19.82	\$787	3.01

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

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Little Study on the Prairie Stirs Controversy

By Walter Eisner

A disagreement over a 10-patient study conducted at the University of Saskatchewan four years ago hit the pages of *The New York Times* on September 5, 2012.

At issue was whether or not, Vertos Medical Inc., a small California device company and developer of the “mild” procedure, tried to squelch research and intimidate Daryl Fourney, M.D., the investigator conducting the study by filing a formal complaint against him with his university.

This story begins in November 2007, when the University of

Saskatchewan Investigational Review Board (IRB) approved a 10-patient pilot study of patients who were on a waiting list for laminectomy with fusion surgery. The study would be conducted by Dr. Fourney after he received a grant to fund the work (not from Vertos). The IRB reviewed the proposed study protocols, including a six-month end point, and approved the study plan. Dr. Fourney agreed to abide by those protocols.

“mild” Procedure

Vertos’ “mild” procedure treats lumbar spinal stenosis by removing portions of the lamina and ligamentum flavum to restore space in the spine. According to published studies, the procedure provides an early option after failed injection, but before more invasive surgery.

The first University of Saskatchewan patient was treated in September 2008 and the final and tenth patient was treated by July 2009. In May 2011, according to the company, Dr. Fourney submitted a draft of his results from the study to Vertos and it included 18-month follow-up data. A month later, the company sent Dr. Fourney a letter taking issue with his decision to include 18-month data. They copied the University.

Dr. Fourney did not want to limit his study report to a six-month follow-up, which was the study protocol, and which was Vertos’s request. Negotiations between the company and Dr. Fourney ensued. But no compromise was reached. Eventually, Dr. Fourney’s study result report was published in the

Vertos
MEDICAL



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Royal University Hospital, University of Saskatchewan/Wikimedia Commons and Drm310

journal *Neurosurgery* but not, according to the company, as a clinical study. Instead, it was published as a ‘case series’ report which is Level 4 evidence.

So why did this little study on the prairies of Saskatchewan end up in *The New York Times*?

New York Times reporter Barry Meier wrote that that the disagreement over the study, “provides a glimpse into the sometimes contentious world of medical testing and the federal rules that allow device makers to market new products with little or no data about their long-term effectiveness or safety.”

The “mild” procedure has been cleared by the FDA through the 501(k) clearance process.

Carragee

Meier backed up this narrative by bringing in Eugene Carragee, M.D., the editor of *The Spine Journal*, the official journal of the North American Spine Society.

Dr. Carragee reportedly said it was, “not surprising to see device producers like Vertos laud studies that supported their product and denounce ones that did not.” But the intensity of the complaints by Vertos about Dr. Fourny reminded him, stated the article, “of a time not that long ago when a manufacturer could prevent a study with negative results from being published.”

Dr. Carragee, according to Meier, said that what he found most striking about the episode was how Vertos and its allies were attacking Dr. Fourny about the quality of his research when the research being used to promote the company’s procedure was also limited and of questionable value.

Meier reports that Dr. Carragee said: “The thing that gets me about this is the double standard. The positive findings are pushed far beyond their scientific merit and the limitations of it are being ignored...Either this company has a poor or odd understanding of what the ethical responsibilities of a researcher are or this was a naked attempt at intimidation.”

Jim Corbett, the CEO of Vertos said regarding Dr. Carragee: “I don’t know what he knows. I can only say what I think is that it’s neither of those. It was a very basic disagreement over the conduct of the scientific elements of a pilot study. It was our first step to understand how to design a better study.

“I have no idea how Dr. Carragee could have any direct knowledge of the scope or intensity of our concerns. He could have learned something from the *Times* reporter and he could have learned something from Dr. Fourny.”

Corbett said inclusion of information after the end point of the protocol would have meant reaching a conclusion without adequate data. “Dr. Fourny simply said that the patients needed surgery, but never explained why or provided data to demonstrate why. It would not be a good study.”

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“mild” Tool Kit/Vertos Medical Inc.

“If the pain and disability scores had gotten worse and he presented that data saying look the pain scores improved at six months, but got worse in a year, I had to do surgery, that would be a wholly rational conclusion,” added Corbett

Meier writes that the company filed a “complaint” with the University of Saskatchewan. “In that complaint, Vertos accused Dr. Fourney of scientific misconduct and violating ‘research ethics’ by failing, among other things, to follow the study’s original protocol and by independently deciding to follow his patients for added time without seeking agreement from Vertos.”

“We did not file a complaint against Dr. Fourney,” said Corbett. “We sent the letter [noted earlier]. That’s it. Filing a complaint is a very different thing.”

The company said the letter stated the following:

“Dr. Fourney, we have had this discussion on this population of patients three times in the past year. The various elements

described in your manuscript provide, at a bare minimum, ‘perceived’ scientific misconduct. This is evidenced by the multiple issues we have raised previously to you, and in this letter.”

Corbett said Dr. Fourney never responded directly to him about the letter. “I did hear from the University. They said they appreciate my communication. They later wrote that they looked into it and have resolved it.”

Corbett also told *OTW* that the *Times* “distorted and omitted” important facts about the “proven” “mild” back-pain relief procedure.

“The article highlighted an extremely limited and scientifically flawed study (only 10 patients), while failing to even mention that its conclusions are contradicted by a vast body of FDA-registered research (on clinicaltrials.gov)—including more than 400 patients tracked in eight published studies. The long-term research performed by Dr. Fourney was not registered with the FDA as is the proper scientific protocol. His study also didn’t provide any data that would

lead to his long-term conclusions. This boils down to a sincere disagreement on the science.”

We ask again, why was this such a big deal worth coverage in *The New York Times*?

We have reported in the past on stories in the *Times* and *The Wall Street Journal* which weave a narrative of industry misbehavior and greed at the expense of patients. Clearly, the relationship between industry and surgeons has undergone a significant change since the deferred prosecution agreements with major hip and knee makers and the passage of the Sunshine law contained in the healthcare law, also known as “Obamacare.”

Accusations against the company for trying to intimidate Dr. Fourney through an official complaint and associating the company and Dr. Fourney’s disagreement to the larger issue of surgeon industry relationships and a controversial FDA clearance process, did not serve to inform surgeons, industry and the public about science.

It’s hard to imagine that Dr. Fourney would be easily intimidated. He’s a well-known clinician and researcher.



Daryl Fourney, M.D./University of Saskatchewan

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Spine recently named him and Scott Boden, M.D., reviewers of the year for completing the best reviews for the journal in 2011.

Dr. Fourney has served as president of the Canadian Spine Society and is a member of *Spine's* associate editorial board. This past year, he served as the annual meeting chair for the American Association of Neurological Surgeons and Congress of Neurological Surgeons Joint Section on Disorders of the Spine and Peripheral Nerves. He is currently the director of the neurosurgery residency program at the University of Saskatchewan and authored more than 60 published peer-reviewed articles during his career.

If a journalist wants to weave a narrative which rests on the premise that indus-

try is behaving badly, he must offer evidence with the same rigor and accuracy that is expected in medical technology reporting.

The *Times* story offered no evidence that the “mild” procedure was improperly cleared by the FDA, nor did the story offer credible evidence that this company filed a “complaint” against Dr. Fourney or tried to squash evidence.

Are there lessons here for industry? We asked Corbett.

“I’ve been a CEO for 26 years and have been involved in all levels of trials, studies and device development. This was a very unique case and I can’t draw any lesson yet,” said Corbett. He also told *OTW* that he did not expect this situation to have any impact on the com-

pany’s regulatory or coverage status. He said the majority of the U.S. is now covered, with more decisions to come.

He added, “Thankfully, Medicare contractors are required to use peer-reviewed literature to make their decisions. *The New York Times* is not one of them.”

Are there lessons for researchers?

We wanted to ask Dr. Fourney. Unfortunately, he was unavailable in time for this story’s deadline, but a University of Saskatchewan official told us that Dr. Fourney will be available to discuss the details of this study in the near future and respond to this story. We’ll report back on his side of the story and what lessons may be learned by researchers as the surgeon/industry relationship continues to evolve. ♦

The March of Robots Into the Spine Surgery Suite

By Robin Young

Last quarter Mazor Robotics Ltd stunned Wall Street by posting a 470% sales jump for the June quarter hitting 11.2 million ILS (Israeli Shekel, about one-fourth the U.S. \$) for the trailing 90 days, up from just under 2 million ILS for the same period a year earlier. Mazor effectively booked more revenue in the first six months of this year than they did for all of 2011.

That 470% top line growth rate compares very well with the other orthopedic surgical robotic company, MAKO Surgical Corp., which reported sales

of \$23.7 million, up 27%, for the same June quarter.

What is going on here... is there a march of robots into the spine surgery suite?

The Robot

Mazor's robot has no arms, articulating joints or force feedback server motors. It has, instead, a frame which attaches to the patient's spine, a few million lines of software code and a Pepsi can sized 6 degrees-of-freedom robotic guidance system which hovers directly over the

prone patient's back and guides each implant to its exact, precise and unerringly correct location. (See images on next page)

The software? That you'll have to imagine. But here is a picture of what it does. (See next page) That operating room monitor on the left has a virtual 3D environment which is used by the surgeon to create a preoperative blueprint of the ideal surgery for that specific patient. During surgery the software automatically synchronizes two fluoroscopy images with the CT based sur-



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gical blueprint (independent of anatomy). With that in place, the controller is able to guide instruments and implants into place to within 1.5 mm accuracy.

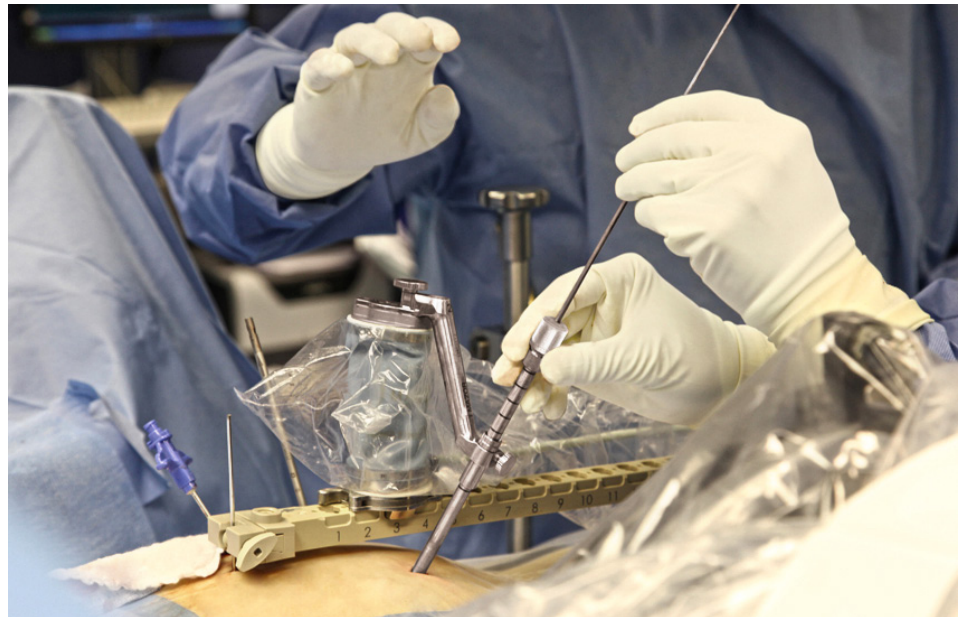
So, a robot? Mazor's system—which is branded Renaissance™—is in reality a robotic surgical guidance system specifically designed for spine and neuro surgery.

Israeli Technology

Mazor, which is based in Israel, is part of the now well documented tradition of advanced Israeli engineering technology and talent.

Israel has more engineers and scientists per capita than any other country. Here a sample of the kinds of technologies that have emerged from Israeli engineers:

- A camera the size of a pill which is literally swallowed by the patient. As the camera travels through the digestive tract, it captures images of the bowel unreachable by endoscopes, so physicians can more accurately diagnose diseases.
- The first fully computerized radiation-free diagnostic scanning device for breast cancer.
- Voicemail, SMS, and other cellular services.
- ICQ--AOL Instant Messenger. Developed in 1996 by a team of four young Israelis.
- The first high resolution camera that fits on a single electronic chip for use in cellular phones.
- The world's first cell phone.
- Microsoft's Windows XP operating system.
- Internet and network security technology such as Firewall.
- The first and most powerful portable storage device on the market.



Robotic controller/Mazor Robotics Ltd.

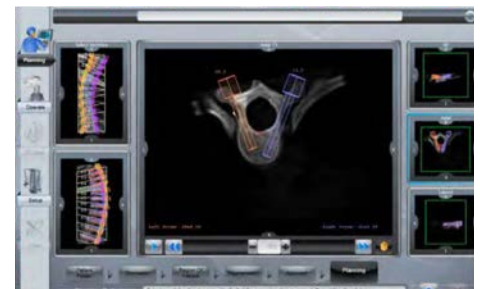


One of the 3 frame options/Mazor Robotics Ltd.

And now, a surgical guidance device roughly the size of a can of soda pop.

Mazor Robotics was founded in 2001 by Professor Moshe Shoham, head of the robotics lab at Israel's famed technical university Technion, and Eli Zehavi, the former Director of engineering at Elscint.

The company's guiding principal has been to take the best of Israeli engineering talent and create a compact,



Mazor Robotics Ltd.

affordable and unerringly precise surgical guidance device for spine and neuro surgeons. Such a lofty goal has been extraordinarily difficult to achieve

but after 10 years, Mazor has the product ready for prime time—as the recent rush of orders clearly indicates.

98% Less Radiation Exposure

As early as 2007, data was emerging that using the Mazor system, then called the SpineAssist, could improve spine surgery for both the surgeon and the patient. As reported in an April 2007 study, 15 surgeons reported that when they used Mazor's SpineAssist that their *radiation exposure fell 98% even though they were performing minimally invasive spine surgery.*

For the patient, this earlier version of Mazor's Renaissance system also improved implant placement precision 2.5 times over freehand placement. The study, which was conducted at the Cleveland Clinic, Texas Back Institute, Johns Hopkins University and UCLA Medical Center tested the use of Mazor's system for implanting 217 screws using minimally invasive techniques versus conventional techniques. One group of surgeons worked with the guidance of the SpineAssist system, while another group performed the same procedures freehand.

Radiation exposure dosimeters indicated that surgeons operating conventionally were exposed to radiation levels an average of 51 times greater than the surgeons using SpineAssist. At the same time, with SpineAssist's guidance, placements deviated by an average of only 1.1 mm from surgical plan site. Placements made using freehand techniques deviated an average of 2.8 mm, which is 2.5 times higher than with SpineAssist's guidance.

More recently, January 2011, another study (Devito, DP, Kaplan, L, Dietl R, Silberstein, et al. *Clinical acceptance and accuracy assessment of spinal*

implants guided with SpineAssist surgical robot: retrospective study. **Spine.** 2010;35(24):2109-2115. doi:10.1097/BRS.0b013e3181d323ab.) reviewed the use of SpineAssist to position tools and guide 3,271 pedicle screws in 14 hospitals for 635 cases using intraoperative fluoroscopy and 139 patients using postoperative CT scans.

The investigators in the more recent study reported that SpineAssist's screw placements were clinically acceptable in 98% of the cases when intraoperatively assessed by fluoroscopic images. Measurements derived from postoperative CT scans demonstrated that 98.3% of the screws fell within the safe zone, where 89.3% were completely within the pedicle and 9% breached the pedicle by up to 2 mm. The remaining 1.4% of the screws breached between 2 and 4 mm, while only 2 screws (0.3%) deviated by more than 4 mm from the pedicle wall. Neurologic deficits were observed in four cases yet, following revisions, no permanent nerve damage was encountered, in contrast to the 0.6% to 5% of permanent neurologic damage reported in the literature.

Comparative Advantage

Renaissance currently costs close to \$1 million in the USA, not including disposables, which run about \$1,500 per case. On average, hospitals charge between \$40,000 and \$80,000 for a lumbar spine fusion surgery. So one Renaissance costs about as much as 15 or 20 lumbar fusion surgeries.

Renaissance may be the least expensive surgical assist "robot" on the market yet it is addressing a comparatively high priced set of procedures. Furthermore, the types of surgeries that Mazor is migrating to (complex surgeries and neuro surgery) are procedures that routinely cost more than \$100,000 per case

and have a much higher potential for error or poor outcome than, say, knee or hip reconstruction.


The other major orthopedic robot company, MAKO, offers hospitals a surgical assist system which costs just under \$1 million and is most often used for knee reconstruction surgery, a procedure that most hospitals charge about \$25,000 – \$45,000 for. So one MAKO RIO costs about as much as 30 to 40 knee recon surgeries.

MAKO's RIO generates approximately \$5,000 per procedure in disposables and implants. Mazor's Renaissance generates about \$1,500 per case currently. While Mazor had announced in 2011 that its Emerald pedicle screw system was cleared by the FDA, it has not yet started to market it. The potential synergy with implants is clear: it could further increase surgical efficiency and flow, and the potential per-case revenues for Mazor should rise substantially.

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MAKO and Mazor's system have several similarities. Both employ computer technology to improve pre-surgery planning and, in collaboration with the surgeon, perform a more accurate and precise surgery to, in turn, improve patient outcomes.

Both systems start with an accurate CT model of the patient's anatomy and both use those pre-operative images to create a three-dimensional dataset which works as an exact geometrical map of normal and pathological tissues and structures.

Both systems analyze and process the image data. Using each system's virtual 3D anatomical model, users can refine their diagnosis and simulate the upcoming surgery. When all surgical planning is done, the robot then uses that data to program pre-planned actions during actual surgery.

During surgery, both the RIO and Renaissance use these programmed images and surgeon generated datasets to direct the actual surgery.

But after this the two systems diverge. MAKO's system is a shared-control system and its key feature is the Haptic control which gives the surgeon tactile feedback. Mazor's uses its controller to guide the instruments and implants. It is not, in fact, a shared control system. It's a semi-active robot that allows surgeons to maintain full control while being guided to the entry point and trajectory that they planned.

Neurosurgery

Historically, surgical robots have found greatest acceptance in the most technically challenging procedures like neurosurgery (first used in the 1980s), oral and maxillofacial surgery (extremely tight tolerances), laparoscopic abdomi-

nal or gynecological surgery and cardiac surgery.

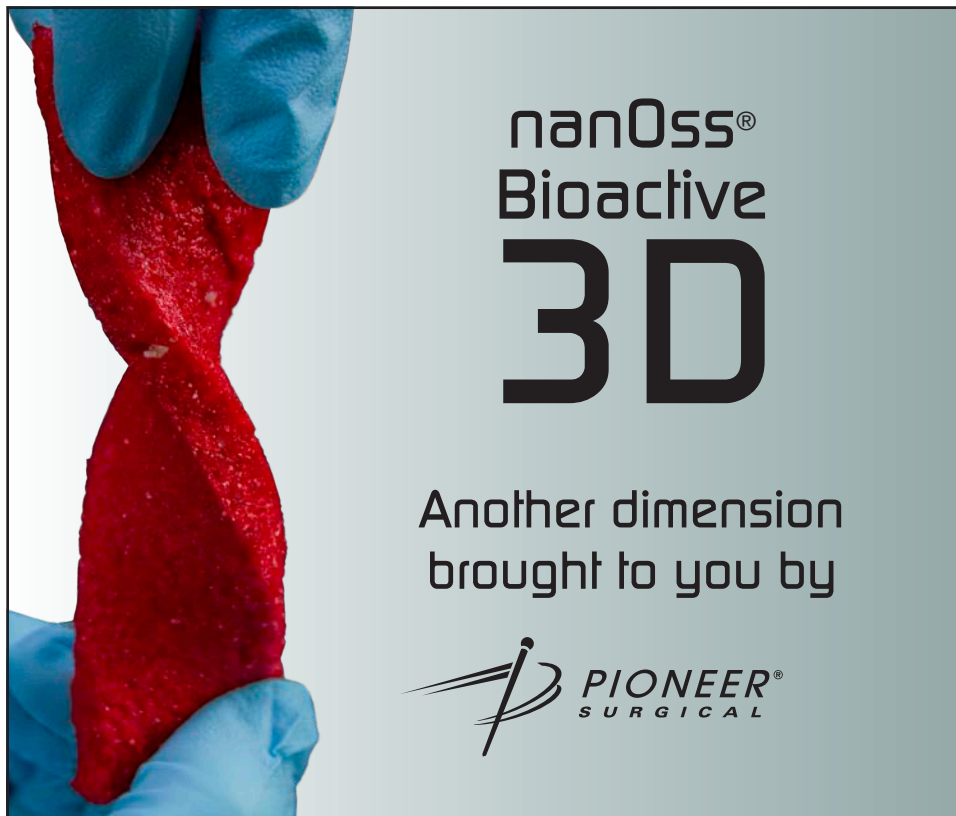
The great innovation of Mazor's system is that it is also tackling the most technically challenging cases like complex spine or brain surgery, but it is doing so with a distinctly more elegant, compact and much less expensive system.

By definition, complex surgeries have a greater risk of misplaced implants and surgeon error. A 2007 meta-analysis of pedicle screw placements (Pedicle Screw Placement Accuracy: a Meta-Analysis Kosmopoulos V, Schizas C.; Spine 2007 Feb 1;32(3):E111-20) reported 10% misplacements when pedicle screws are implanted freehand. Another study (Trends, Major Medical Complications, and Charges Associated With Surgery for Lumbar Spinal Stenosis in Older Adults. JAMA April 2010) reported that major medical complications were reported in 5.2% of complex fusion procedures.

Accepting the maxim that the cost of precision, i.e., the purchase price and ongoing maintenance of a surgical assist device, must be less than the cost of imprecision, the fact that Mazor is targeting big ticket, complex surgeries which have comparatively high rates of complications and less than satisfactory outcomes is just plain smart.

In the same press release where Mazor's CEO Ori Hadomi announced that his sales had jumped 470% to more than 11 million ILS for the June quarter, he also informed his lucky shareholders that his little Pepsi can of a surgical guidance device had now been used to place more than 20,000 implants worldwide.

No doubt Mazor's booth at this coming NASS will be one of the most crowded of the show. It will be fascinating. ♦



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Kick Women Off Soccer Field?...Surgeon Preferences Driving High Costs and More...

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



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No Soccer for Women?...Surgeon Preferences Driving High Costs... Explosion of Payment Models Coming ...QOL Measures in Osteoarthritis and RA

Women...Off the Soccer Field! A veteran sports medicine specialist has seen so many injured female soccer players that he is wondering, "Should females be playing soccer?" He tells *OTW*, "Look, my daughter is a talented, devoted soccer player, and I've always cheered her on. But I have to wonder what's going on with so many female soccer players

being injured...it's at unprecedented levels. There's still a lot we don't understand about the mechanism of injury in the knee, and particularly the ACL. And there is more pressure on our treatment protocols—anything less than perfect is unacceptable. No one wants to have a young mother pushing a stroller and limping."

"These are largely noncontact injuries; a typical patient is a 17-year-old girl who is accelerating on the field and pivoting vigorously...then her knee gives out. If you study the average woman athlete

compared to the average male of the same age doing the same sport, you find that in a simple horizontal leap test, the male's trunk stays centered on his lower body when he lands, while with females as the lower body stops the moving trunk keeps moving, thus putting a lot of torque on the knee. Unfortunately, no one can even say that working on trunk strength has changed much of anything for these athletes. I think we are in denial as to what all of this means. Are we sacrificing our daughters' future for the glory of sport? I think we need to all take a deep breath and have an hon-

est dialogue about the risks involved here. If a young boy is considering playing football, the family has a discussion about that...not the case if a young girl wants to play soccer. I think a change is coming, however.”

Surgeon Preferences Driving High Costs

Kevin Bozic, M.D., M.B.A. has just published some enlightening work on the cost of hip and knee replacement. Discussing his study, “Variability in Costs Associated with Total Hip and Knee Replacement Implants,” Dr. Bozic tells *OTW*, “There are a number of policies aimed at controlling costs associated with hip and knee replacements, and several that are specifically focused minimizing non valued added costs. For example, you have the same procedure performed at three different hospitals by three different surgeons; you have roughly the same patient population and the same outcome—but there is a threefold difference in cost. What

we found was that the implants are the major driver of the variability in cost...with little evidence that the implant is the primary driver of outcome.”

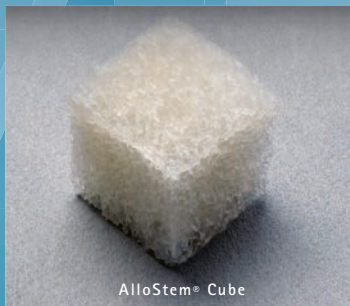
“Our goal was to understand what factors drive this variability. First, we found a significant variability in cost of implants, even after controlling for things like patient age (you might think that a younger person would have a more expensive implant, but that was not the case), hospital size (you may think that a larger hospital would have better pricing, but that wasn’t the case), procedure volume (discounts for volume—not the case). And interestingly, hospitals that had fewer vendors (a common strategy employed by hospital purchasing groups to control implant costs) didn’t have better pricing than hospitals that didn’t. Indeed, we found that very little of the variability can be explained by patient, hospital, or market factors. We concluded that a

majority of the variability was the result of surgeon preferences...and that ultimately hospitals, surgeons, and device companies must be aligned around the delivery of high value care which would produce the best outcomes at the lowest cost.”

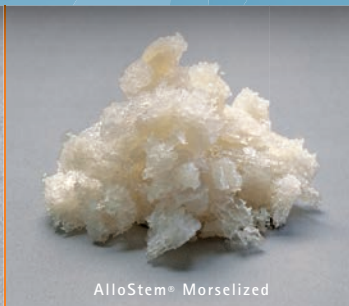
QOL Measures in Osteoarthritis and RA

Michael Carter, M.D. is a transitional resident at Indiana University in Indianapolis, and will be starting a residency in radiology at the University of Michigan in July 2013. His recent study, “Total Shoulder Arthroplasty on Generic and Shoulder-specific Health-related Quality of Life Measures,” has shed light on the physical and mental outcomes of total shoulder arthroplasty. Dr. Carter tells *OTW*, “Quality of life measures are huge in osteoarthritis and autoimmune diseases like rheumatoid arthritis...they are the way you determine if a treatment is working. Using these measures helps orthopedic sur-

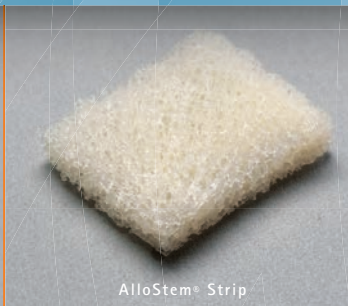
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geons keep track of patient outcomes. The use of global measures, such as the SF-36, helps to show effectiveness, which is increasingly important to patients and payers of health care.”

“We did a full systematic review of all the measures people are using...what scales, what results were obtained when using certain scales. We looked at over 40 different outcome measures. When looking at outcome scales and analyzing the data we found the most dramatic effect of total shoulder arthroplasty was for pain relief; improvement in activities of daily living were also significant. We did not have sufficient data to establish the effect on mental status, however. In the future we would like to pursue other studies with other global measures that address quality of life.”

Steven Teitelbaum, M.D. Wins Mentorship Award The 2012 Gideon A. Rodan Excellence in Mentorship Award has gone to Steven Teitelbaum, M.D. of the Washington University School of Medicine. The Gideon A. Rodan Excellence in Mentorship Award is given in recognition of outstanding support provided by a senior scientist who has helped promote the independent careers of young investigators in bone and mineral metabolism. Dr. Teitelbaum is the Wilma and Roswell Messing Professor of Pathology and Immunology and Medicine at Washington University School of Medicine where he is a member of the Division of Bone and Mineral Diseases. Dr. Teitelbaum served as President of the American Society for Bone and Mineral Research and of the Federation of American Societies of Experimental Biology. He participated in efforts which led to the doubling of the National Institutes of Health (NIH) budget and liberalizing stem cell research in the state of Missouri. Dr. Teitelbaum has trained more than 70 graduate students and post-

doctoral fellows, many of whom have become leaders in bone and mineral research and hold distinguished academic and industrial positions. His research focuses on the osteoclast.

Explosion of Payment Models Coming Chad Mather, M.D. is an attending orthopedic surgeon at Duke University and is a former American Academy of Orthopaedic Surgeons Washington Health Policy Fellow. He tells *OTW*, “The November election does create uncertainty in the health care landscape. As such, many providers are trying to place their efforts in areas that are unlikely to change. One of those areas is in payment reform. When I was on Capitol Hill recently, it was clear that there is bipartisan support for dramatic changes to traditional fee-for-service reimbursement. But there is also strong support for intimate physician involvement in development of new models.

And we are already seeing this—not only from government payers, but also private insurers. It may be a fee for service type system, with value based payment adjustments. It will also involve episodic payments which involve a greater shift in financial risk to the provider from the insurer. We probably can't do away with fee for service completely, as a recent *Health Affairs* article has suggested, but the variety and scope of payment models will explode over the next four years no matter which party is in power. Many providers are intrigued by this because a shifted financial risk can be positive—if we can figure out how to deliver quality care at a lower cost. You can prepare now by examining your own delivery landscape and look for opportunities to coordinate care and cut waste—unfortunately there isn't a one-size-fits-all strategy as each individual system and episode poses different challenges and opportunities. My prediction for November? I like to follow historic trends and the approval rating of the incumbent: above 50% will mean reelection and below that we might see a new administration.”

Blue Belt Technologies Wins Innovation Award Blue Belt Technologies, Inc., whose U.S. headquarters is in Pittsburgh, Pennsylvania, has won the 2012 Global Orthopedic Surgery Technology Innovation Award from Frost & Sullivan. The company has developed the Navio PFS System, the next generation of “smart” instruments providing precise robotic control to physicians. Blue Belt is specifically targeting unicompartmental knee surgery as their first application for the Navio PFS System. The following criteria were used to benchmark Blue Belt Technologies' performance against key competitors: Uniqueness of Technology, Impact on New Products/Applications, Impact on Functionality, Impact on Customer Value, and Relevance of Innovation to Industry. ♦



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Berend, Rosenberg Debate MIS Total Knee Arthroplasty

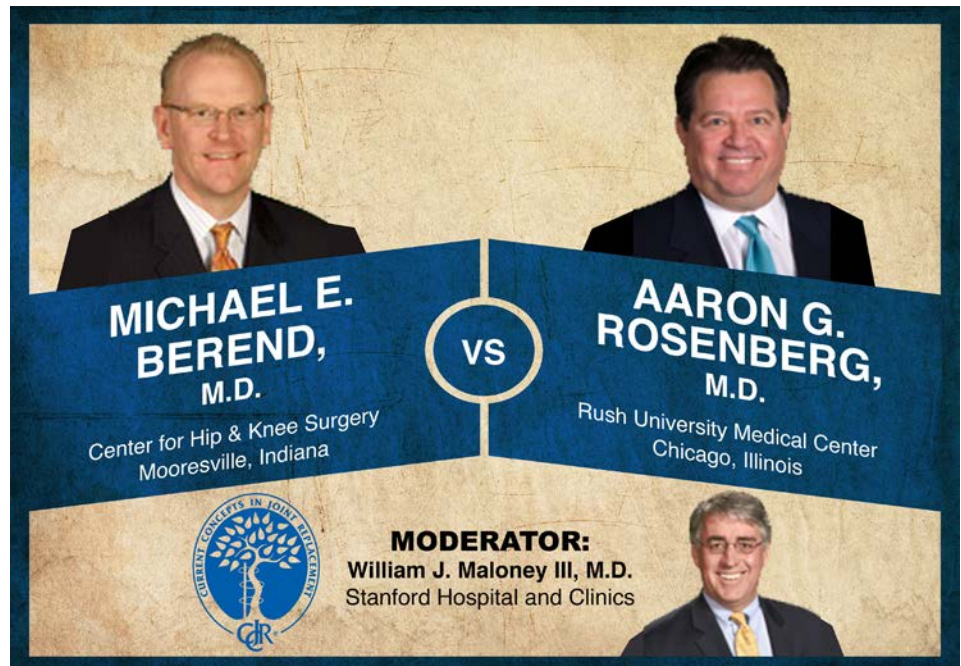
By Elizabeth Hofheinz, M.P.H., M.Ed.

“**M**IS is not for all patients. MIS risk factors for failure are multifactorial (infection, fracture, poly resin, etc.), asserts Michael Berend. “Michael, I agree with most things you said. It’s not that traditional technique doesn’t work...car brakes worked but ABS is better. Maps work, GPS is better,” says Aaron Rosenberg.

This week’s Orthopaedic Crossfire® debate is “MIS: A Risk Factor of Early TKA Failure.” For the proposition was Michael E. Berend, M.D. from the Center for Hip & Knee Surgery in Mooresville, Indiana. Against the proposition was Aaron G. Rosenberg, M.D. of Rush University Medical Center; moderating was William J. Maloney III, M.D. from Stanford Hospital and Clinics.

Dr. Berend: “There are emerging studies that are prospective and randomized and well designed. For example, Karpman and Smith (*J Arthroplasty* 2009) compared three different approaches to total knee replacement (TKA) and remarkably at two weeks the patients had improved scores.”

“I was early to minimally invasive surgery (MIS), and in 1999 performed a total knee through a two inch incision. I cut no tendons or muscles; the patient was at work in four hours, left the recovery room with 0-145 degrees range of motion (ROM). So we’ve changed our vernacular from inches to centimeters, from years to weeks; and perhaps we’re training folks—us and our patients—to ask the wrong questions. Perhaps we should redefine MIS to ‘must insist



Current Concepts in Joint Replacement/RRY Photo Creation

on seeing’ and ‘must insist on doing a reproducible and quality job.’”

“There’s not much minimally invasive about a total knee replacement, regardless of incision or approach. There’s the same biologic response, the same amount of bone removal, same or similar implants, same postoperative rehab. Perhaps it’s less predictable, and I think an important message is new anesthesia protocols.”

“Reasons for TKA revision: infection, instability, aseptic/wear, patellofemoral—these things may be made worse by an MIS approach. Another prospective, randomized study showed no improvement clinically, no difference in X-rays, the 12 week outcomes were

the same...however, in the MIS group 10% of the patients had wound healing problems, and I think this puts patients at risk for perioperative infection.”

“MIS risk factor for failure is multifactorial (infection, fracture, poly resin, etc.). Robert Barrack and others have recently suggested that MIS is a risk factor for early revision in TKA, and if you look at the combined increased risk of infection, increased operative time, possible risk of malalignment, and ligament imbalance, I think it is a significant question for us all. He reported a multicenter study of early revision in 237 knees—MIS versus standard approaches—and the most important consideration was those knees that had an MIS total knee had early revision at

14 months compared to 80 months in the standard total knee. Importantly, the indication for revision was loosening and instability.”

“Steve Incavo has also reported early revision for malrotation, with symptoms of pain, instability and poor ROM... and 81% of these knees were revised at less than two years. So assessing rotation is critical. Doug Dennis and David Dalury looked at 30 MIS knees and 30 standard knees, and unfortunately 13% had greater than 4 degrees of malalignment. We and others have shown the catastrophic effects of malalignment on tibial loosening, at least with a flat on flat articulation. If you combine that with a large body mass index (BMI) patient, there’s a precipitous drop in survivorship in patients with varus malalignment and a high BMI.”

“Do we have the time to invest in MIS? Yasutaka Tashiro reported clinical measurements, radiographic measurements, and operative time. At one to two weeks the MIS patients were better, had no change in coronal alignment; they noted a medial shift in the implant, which may have implications for patellofemoral tracking and long term loading of the implants. They found it took nearly an hour longer to perform MIS; and we’ve learned from HSS [Hospital for Special Surgery] that TKA infection rates are higher in patients that had a total knee that took more than 33 minutes longer than standard techniques.”

“It’s not for everyone. It’s not a ‘name that tune’ of a picture of how small the incision is, or redefining the quadriceps mechanism, but let’s take the good and leave the bad and develop a multidisciplinary

approach of education, anesthesia protocols, proper instrumentation, careful patient selection and careful surgery.”

Dr. Rosenberg: “Michael, I agree with most things you said. It’s not that the traditional technique doesn’t work...car brakes worked but ABS is better. Maps work, GPS is better. It’s clearly harder: component placement can be compromised, you lose visual cues, you may be unable to protect vital structures, and you do place more stress on the soft tissues if you’re stretching the skin excessively. There’s no free lunch...there are risks with MIS and they can contribute to a higher complication rate, including soft tissue damage, malalignment, imbalance, and retained bone cement. We’ve also seen compromised fixation with the introduction/re-introduction of cementless components or the use of MIS-friendly type components that haven’t had significant vetting.”

“But there are benefits. In a comparison of 24 MIS and 25 standard cases looking at extensor torque and time to rehabilitation guidelines. Neither group had significant malalignments or complications. The MIS group had lower average pain scores at one and two weeks; they also had earlier straight leg raising, earlier 90 degrees of flexion, and earlier use of a single cane and higher extensor torque (again, early).”

“In a mini-subvastus approach researchers compared 150 MIS cases to 150 traditional cases. There was no increase in number or severity of complications, and no increase in OR time. Length of stay was reduced with a more rapid quad recovery; fewer of the MIS patients required skilled nursing facilities or rehab facilities. At two years the MIS group had greater flexion.”



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“The most recent systematic review that I could find included all prospective studies—28 of them. They found that patients undergoing MIS TKA tend to have decreased postop pain, faster recovery of quadriceps function and ROM, reduced blood loss, and shorter stay. But the benefits must be balanced against increased tourniquet time, and a higher degree of component malalignment.”

“There was a lot of talk in the early days about how important it was to change the surgical technique to make it truly MIS, but more recent studies like the one by Dalury showed that it didn't matter whether they everted the patella or translated the tibia anteriorly; patients seem to prefer in these bilateral knees the traditional technique at six and twelve weeks. The economics have been shown nicely in a study by Thomas Coon...MIS patients had shorter LOS [length of stay] and the average cost of surgery was 26% less.”

“Factors influencing the recovery curve: pain management, the preoperative functional level, as well as their motivation. But surgical technique is part of it. It's hard to know how much, but a study by Doug Nuelle is an interesting one. It was done in a private practice, comparing the same surgical technique in 50 hips and 50 knees...compared standard protocols to MIS pathways with anesthesia and postoperative management, and they measured the time to various postoperative landmarks. Using the same technique, the protocols and anesthesia pathways demonstrated a marked difference between the standard and the number of hours it took to achieve those landmarks.”

“It's reasonable to proceed in shrinking your incision, doing surgery that is less

disruptive of the soft tissues, but not throwing the baby out with the bathwater and ignoring the important principles we've learned about TKA.”

Moderator Maloney: “Mike, comments?”

Dr. Berend: “The contributions you all have made in terms of anesthesia, preoperative education, programming the patient that only the special people get to go home on day two...those are important things. I agree with the rational approach. I don't think all of us should feel the same pressure to do the smallest incision. I also think length of stay has far more to do with the entire program, with nursing, therapy, anesthesia, than it does with the incision. On manipulation rates, ours is around 1.8% with huge shark bite incisions.”

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Dr. Rosenberg: “Those things are true. My position has been to assess what the additional risks are when I make any change in how I do something. We all learned from the early MIS days that focusing on the length of the incision was a mistake...that you should focus on the amount of tension in the tissues. There are going to be wide differences in that depending on the size of the patient, the amount and stiffness of the subcutaneous fat. To get a good feel for those things it takes time and experience.”

Moderator Maloney: “So does the incision length make any difference as it relates to the outcome?”

Dr. Rosenberg: “Within reasonable limits.”

Moderator Maloney: “What about the length of the arthrotomy?”

Dr. Rosenberg: “I think the type of arthrotomy, as opposed to the length, doesn't make any difference as far as the studies that have been done have been prospective and randomized.”

Moderator Maloney: “Mike, do you agree?”

Dr. Berend: “I agree. I think getting the adequate exposure to use the instruments you're comfortable with, put the implant in properly and balance it well is the critical take home message.”

Moderator Maloney: “Aaron, what's the most important factor for a good long term outcome in terms of knee arthroplasty?”

Dr. Rosenberg: “Good surgical technique, good patient selection, education,...”

Moderator Maloney: “In a patient with end stage arthritis and they hurt a lot...”

Dr. Rosenberg: “If they’re depressed and dysfunctional they’re not going to do well.”

Moderator Maloney: “Mike, your take on the most important factor?”

Dr. Berend: “I think the biggest shift in the last 10 years has been to do less of an operation in 40% of the patients, so to recognize unicompartmental knee disease has been the true minimally invasive procedures...to do more unis and less total knees.”

Moderator Maloney: “Aaron, what did we do wrong with MIS as far as education?”

Dr. Rosenberg: “I don’t have a good answer because the genie is out of the bottle, and that is, trying to fight the Internet is difficult. But the same thing is true across the board in the distribution of information. People have always promoted snake oil...and our patients are going to be following this information. Also, there’s a difference between a shorter incision—not the smallest, necessarily—and standard incisions, but I think we’ve all sort of adopted.”

Moderator Maloney: “Bob Booth said it best: if you’re a size 16 you’re going to get a size 16 incision; if you’re a size 6 you’ll get a size 6 incision. Thank you, gentlemen.” ♦

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company

NEUROVISION Judge Overturned, Admonished

NuVasive, Inc. is getting a new trial. Neurovision Medical Products' \$60 million court victory over NuVasive over the use of the "NEUROVISION" trademark has been overturned and sent back for another trial.

On September 10, the U.S. Court of Appeals for the Ninth Circuit sent the judge who oversaw the jury trial a stinging rebuke by basically firing him from the case and pointing out shoddy and lazy legal work.

After a five-day jury trial last January, the jury, based on the judge's instructions, found that NuVasive committed fraud in procuring the NEUROVISION trademark registration, that Neurovision Medical had prior rights to the NEUROVISION mark and that NuVasive willfully infringed on Neurovision Medical's rights.

NuVasive had serious problems with, among other things, the judge's instructions to the jury and appealed.

The appeals court didn't hold back by practically accusing the district judge of rubber stamping Neurovision Medical's allegations. The appeals court noted that each of the orders strongly favoring the company was prepared by Neurovision Medical's lawyers, and that the district court engaged in the "regrettable practice" of signing each one without altering a single line.



Pima County Public Defender/Ninth Circuit Court of Appeals

"The district court abused its discretion by excluding relevant evidence based on its legally erroneous determination...," stated the appeals court opinion. Furthermore, the appeals court said another judge should hear the new trial because the district court judge "ignored our precedent, persistently cut off or excluded relevant testimony, and repeatedly [incorrectly] instructed the jury."

Ouch. But wait, there was more.

"In light of the district court's adherence to a view of trademark law that is at odds with clear Ninth Circuit precedent, there is reason to believe that the district judge may have substantial difficulty in putting out of his...mind previously expressed views or findings determined to be erroneous."

Specifically, the appeals court said the district court erroneously instructed

the jury as to the elements required to prove fraud on the United States Patent and Trademark Office. The district court also erred by instructing the jury to determine only whether NuVasive omitted knowledge of Neurovision Medical's prior use of the NEUROVISION mark.

The appeals court concluded that the district court failed to properly instruct the jury as to the showing required to challenge an "incontestable" mark and that Neurovision Medical may not challenge NuVasive's use of the NEUROVISION mark unless it can prove that its own use of the mark was "maintained without interruption."

In a regulatory filing, NuVasive stated it expects the new proceedings to begin in the coming months.

—WE (September 11, 2012)

legal

New Rules When Scientists Disagree at FDA

What happens when you go to the FDA with an application and the scientists within the agency disagree about the science behind your device or procedure?

These disagreements lie at the heart of the lawsuit by the FDA 9 whistleblowers over exposure to radiation. Internal disagreements and the ensuing public prosecution by *The Wall Street Journal* of Regen Biologics, Inc. and their appeals process brought down the company's application and, according to some, hastened the departure from the agency of Dan Schultz, M.D., the former Director of the Center for Devices and Radiological Health (CDRH).

ReGen eventually filed for bankruptcy. Internal scientific disagreements within the agency have serious consequences when promoting public health and bringing new technologies to patients.

The FDA is trying to do something about it.

On September 4, 2012, the FDA announced the implementation a new "Standard Operating Procedure (SOP) for Resolution of Internal Differences of Opinion in Regulatory Decision-Making."

This document sets forth the general policy for the CDRH for resolving internal differences of professional opinion and provides an approach for documentation of associated scientific, clinical



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and regulatory findings, perspectives and opinions.

As background for developing the SOP the agency stated:

When any regulatory decision or action is considered, CDRH should reach an institutional position after all appropriate scientific and regulatory recommendations and perspectives are obtained, documented, and considered. This process is often complex and may involve multiple staff members and disciplines and may cross organizational boundaries. In most cases, alignment on a decision is achieved through discussion during progress toward a decision. Open and respectful discussions enhance the quality of Center decisions and it is incumbent on all Center employees to maintain an atmosphere of inclusion, professionalism, and mutual respect. In situations where differences of opinion arise during the decision-making process and are resolved through discussion, it is important that the official administrative file captures

these differences and the resolution thereof.

Given the complex, multi-layered nature of decision-making and the diversity of expertise of CDRH staff, it is expected that differences of professional opinion will arise in the normal course of business. These differences may be scientific, clinical, or regulatory in nature, or some combination of the three.

When differences of professional opinion arise between peers or between an individual and their next-level manager or supervisor and cannot be resolved through discussion, and the parties are unable to align with a decision, then the procedures set forth in this policy can be invoked.

If you have business with the FDA, you'll want to read this nine-page document. (Click here http://ryortho.com/FDA_Internal_Opinion_Resolution.pdf)

—WE (August 30, 2011)

FDA Proposes Postmarket Surveillance Changes

The FDA is proposing four changes to its postmarket medical device surveillance system.

A September 6 report from the agency says, while the U.S. has a robust system, there are things the FDA can do to strengthen the system.

Here are the four recommendations:

- Establish a unique device identification (UDI) system and promote its incorporation into electronic health information. The FDA issued a proposed rule for a UDI system in July and is currently accepting comments. A final rule is expected in November.
- Promote the development of national and international device registries for selected products. This system would maintain records on a specific disease or condition and of patients who had been exposed to a specific medical device, biological or drug product.
- Modernize adverse event reporting and analysis. The FDA proposes to improve its ability to report adverse events through the use of digital records and a mobile app.
- Develop and use new methods for evidence generation, synthesis and appraisal. The FDA proposes to be forward looking in its development of “innovative methodological approaches for evidence generation, synthesis and appraisal” of devices.

Two large healthcare purchasers praised the UDI proposal.



FDA Strengthening Postmarket Surveillance Report

Joe Pleasant, chief information officer of Charlotte, North Carolina-based Premier Inc. healthcare alliance told *Healthcare Finance News* in July that the FDA's UDI rule will result in supply chain efficiencies for providers. “If (providers) can depend upon the coding on the package, they can begin to eliminate internal barcoding and labeling and the costs associated with them,” he said.

Irving, Texas-based supply contracting firm Novation's Senior Vice President of Information and Data Services, Dan Sweeney, told *Healthcare Finance News* that the UDI system is also likely to improve patient safety. “It's extraordinarily difficult today to communicate to a patient that they may have been exposed to a recalled product,” he said, adding that new levels of information management would positively impact

patient safety after a procedure has been done.

The FDA is making available for public comment a preliminary report entitled “Strengthening Our National System for Medical Device Postmarket Surveillance.” This report, in addition to providing an overview of FDA's medical device postmarket authorities and the current U.S. medical device postmarket surveillance system, proposes the four specific actions, using existing resources and under current authorities, to strengthen the medical device postmarket surveillance system in the U.S.

To read the entire report, click here: http://ryortho.com/FDA_Post_Market_Report_Sep2012.pdf

—WE (September 16, 2012)

biologics

Birth Tissue/Ankle Tendon Repair Study Released

AFCell Medical announced last week results of a retrospective study of the use of an amnion based allograft membrane to prevent post-operative adhesions between the tendon, peritendinous structures and overlying skin. Of the 14 study patients, 86% were clear of adhesions anywhere around the surgery site and 93% were adhesion free at the tendon repair site 1.7 years post-surgery, on average, and of those patients with signs of adhesions the effects were rated mild or moderate.

“It was a very positive result to find that amniotic membrane reduced adhesions following tendon surgery. This study confirmed my clinical experience over the past three years in reducing the adhesions and pain after tendon repair.” – Dr. Richard Jay, Professor of Foot and Ankle Orthopedics, Temple University, Chief, Foot and Ankle Surgery, South Jersey Healthcare Hospital.

“Our data showed that less than 20% of the patient’s operated on with an AmnioClear overlay get adhesions on the surrounding tissues. Normally this is a very large problem in a variety of different surgical arenas tendons being one of them.” – Dr. Adam Landsman, Assistant Professor of Surgery, Harvard Medical School, Chief Division of Podiatric Surgery, Cambridge HealthAlliance.

The amnion based allograft material used in the study was AmnioClear, AFCell’s proprietary amnion based allograft. AmnioClear is the only dry, shelf stable amnion based allograft



AFCell Medical

processed under patent protected techniques. AmnioClear’s processor is the leading tissue bank and supplier of allografts in the world, the Musculo-skeletal Transplant Foundation.

About the Study

The 14 patient retrospective study was conducted by Dr. Richard Jay, Professor of Foot and Ankle Orthopedics, Temple University and Dr. Adam Landsman, Assistant Professor of Surgery, Harvard Medical School. All patients in the study had been treated with AmnioClear during surgery to repair peroneal or posterior tibial tendons.

Post-operatively, each patient in the study was asked to return to the clinic for further evaluation to determine whether or not there were any adhesions between the tendon repair site, and the surrounding tissues, including the overlying skin.

The assessment included a subjective assessment of the motility of the overlying skin at the incision site, and manual measurements of range of motion,

to determine if any restrictions related to the surgical site could be identified. Each subject also was asked to complete a questionnaire to rate their pain and function on the day of examination and was asked to compare this to their symptoms prior to surgery. Pain and function were assessed with the Bristol Foot Score (BFS) and the Foot Function Index (FFI), both validated scoring systems that have been used to assess both pain and functional capacity.

In addition, under the direction of a physician with experience in ultrasound imaging, each repair site was assessed dynamically to determine the relative thickness of the repair site, as compared to the adjacent tendon, and was also compared to the contralateral limb. The time after surgery ranged from 4 months to 3.5 years, with an average follow-up time of 1.72 years after surgery.

Results

Twelve (86%) of the patients in the study did not develop adhesions in or around the surgical site and only one

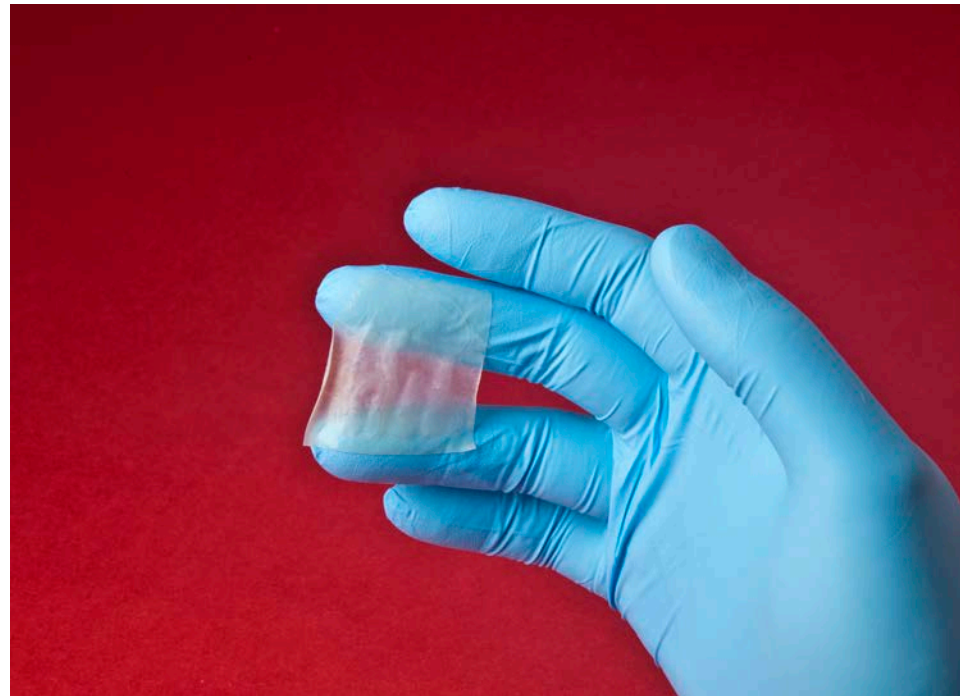
patient developed an adhesion at the tendon repair site. Two patients developed adhesions in the skin (14%) and one of those patients also developed an adhesion at the tendon repair site (7%). Of the two cases where adhesions were observed in the skin, both were rated as mild to moderate, and the case in which a tendon adhesion appears to have occurred was more complex, and was rated as moderate. None of the adhesions caused severe limitation in motion, and none were associated with pain upon range of motion.

Statistical analysis was performed to determine if these changes were statistically significant. Prior to surgery, the average FFI was 123.2 (SD=22.3), as compared to 91.0 (SD=40.7). The difference was strongly significant with $p=0.003$. The average BFS prior to surgery was 55.4 (SD=13.8), and the BFS after surgery was 45.4 (SD=16.2). This difference was also statistically significant with $p=0.012$.

Discussion

This retrospective study regarding the use of amniotic membranes as transplants to restore natural sheathing or covering between the tendon, peritendinous structures, and overlying skin in order to help prevent post-operative adhesions at the surgery site generated data which is generally consistent with prior animal studies of amniotic membranes as transplants to help prevent post-operative adhesions.

In the canine laminectomy model (Tao, Fan: Implantation of amniotic membrane to reduce postlaminectomy epidural adhesions; *European Spine Journal*: 2009, Published online) cross-linked amnion membranes (CAM) were used to help prevent post-operative



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adhesions. In that study, animals treated with amnion were observed to have a much weaker or nearly absent epidural adhesion. The white, slightly vascularized membrane was found between the dura mater and surrounding tissues to reduce scar intrusion. Furthermore, the CAM layer seldom adhered to the dura mater and was easily removed. Only a layer of fibrous tissue could be found between the CAM layer and dura mater in three samples [out of 24 total]. Of those animals with adhesions, the adhesions were mild and histologies of those adhesions showed that they were highly disorganized.

Amniotic membrane tissues are comprised of collagen type III, I, IV, V and VI and contain native and endogenous proteins and peptides. The structure and function of amniotic tissues is nearly identical to that of fascia tissues—which serve to cover, protect and lubricate underlying structures of the body including, but not limited to, the

fetus, muscles, tendons, nerves, bone and major organs.

The hypothesis of this study is that transplanting an amnion covering—specifically, AmnioClear—to restore the natural sheathing or covering over damaged or denuded structures will contribute to the prevention of such post-operative complications as scarring or adhesions.

About AmnioClear

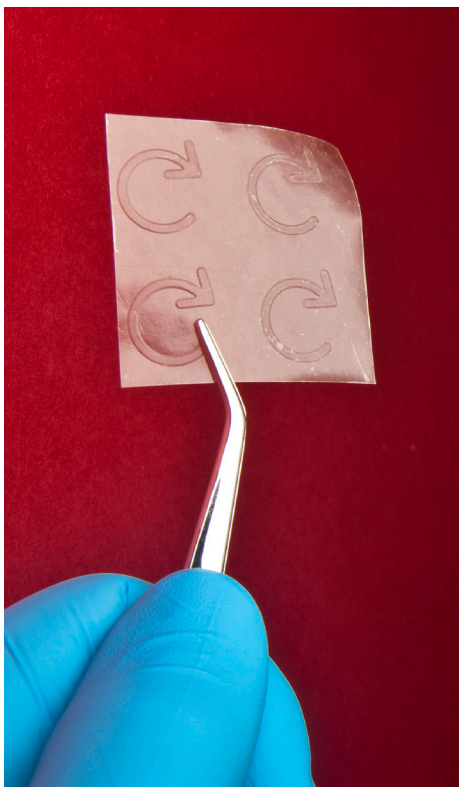
AmnioClear is a wound covering made of donated amniotic membrane derived from the largest continuous sheet of human fascia membrane available for transplant—the inner lining of the placenta. This membrane is comprised of native human amnion and chorion consisting of collagen types I, III, IV, V and VI, laminin, fibronectin, nidogen, proteoglycans and endogenous proteins and peptides. The allograft is minimally processed to remove cells

from the membrane while retaining the structural properties of the extracellular matrix. The resulting decellularized and dehydrated allograft is aseptically packaged in hermetically sealed foil and Tyvek pouches and stored at ambient temperature until ready for transplantation.

About AFCCell Medical

AFCCell Medical is the leading supplier of birth tissue products for use in the clinical setting. Its processing partner is the Musculoskeletal Transplant Foundation which is the leading tissue bank and supplier of allograft tissues to hospitals and clinics in the North America and Europe. The company is located in Parsippany, New Jersey and is supplying AmnioClear® to more than 100 hospitals in the United States.

—RRY (September 12, 2012)



AFCCell Medical

Stem Cell Powered PEEK Implant Coming

Researchers from Scotland's University of Glasgow Colleges of Science and Engineering and Medical, Veterinary and Life Sciences have come up with a stem cell powered implant that, they firmly believe, will revolutionize orthopedic surgery.

The researchers are trying to reduce the rate of implant loosening. Polyethylene, stainless steel, titanium or ceramic implants being synthetic materials can fail to integrate with surrounding tissues and loosen. If they do, then the patient becomes an excellent candidate for revision surgery after about 15 or 20 years of use.

The team from the University has found a reliable method to encourage bone cell growth around an implant made of PEEK-OPTIMA, from Invibio Biomaterial Solutions.

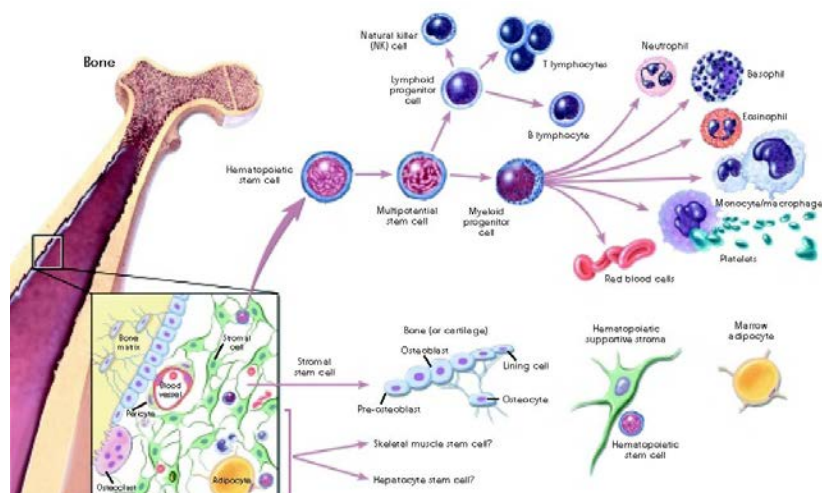
Matthew Dalby, M.D. of the University's Institute of Molecular, Cell and Systems Biology, explained: "Last year, we developed a plastic surface which allowed a level of control over stem cell differentiation which was previously impossible.

The surface is covered in tiny pits 120 nanometers across. When stem cells are placed onto the surface, they grow and spread across the pits in a way which ensures they differentiate into therapeutically useful cells.

"By covering the PEEK implant in this surface, we can ensure that the mesenchymal stem cells differentiate into the bone cells. This will help the implant site repair itself much more effectively than has ever been possible before and could well mean that implants will last for the rest of patient's life," said Dr. Dalby in an August 30 press release.

Nikolaj Gadegaard, M.D., senior lecturer in Biomedical Engineering at the University, explained, "Another benefit of PEEK is that it matches the mechanical properties of our own bodies much better than do traditional materials. While bone has a certain amount of flex to it, the use of inflexible titanium in implants results in loss of bone density because the bone is not exercised. The flexibility of PEEK is similar to that of bone, and will allow the implant to flex in a natural manner, significantly helping the process of bone regeneration."

The stem cells the researchers are using are derived from the patient's own bone



Wikimedia Commons and US Government

marrow—which is a rich source of mesenchymal stem cells. These cells have the potential to ‘differentiate’ into other types of cells such as bone which can improve the process of healing. However, stem cells can also differentiate into cells which have no use in therapy. Artificially controlling the final outcome to ensure that the desired type of cells is created is very difficult.

When traditional implants are fixed into bone marrow, the marrow’s stem cells do not receive messages from the body to differentiate into bone cells, which would help create a stronger bond between the implant and the bone. Instead, the cells usually differentiate into a buildup of soft tissue which, combined with the natural loss of bone density which occurs as people age, weakens the bond between the implant and the body.

The partnership between academics and surgeons is a result of the Glasgow Orthopaedic Research Initiative (GLORI). GLORI, formed in 2009, to foster collaboration between scientists and clinicians to turn novel materials research into the next generation of orthopedic care. “It’s an extremely exciting project to be working on, with implications for improving a wide range of joint replacements and other orthopaedic surgeries. We’re keen to see a prototype ready for use in hip replacement surgery within a decade,” said one of the researchers.”

The research has been funded by the Biotechnology and Biological Sciences Research Council (BBSRC), the Medical Research Council (MRC), the Engineering and Physical Sciences Research Council (EPSRC), the Scottish Government’s Chief Scientist Office and the European FP7 project NaPANIL.

—BY (September 11, 2012)

large joints

26-Fold Risk of RA!

Researchers in Denmark have found that individuals with raised levels of an antibody known as rheumatoid factor in their blood have up to a 26-fold greater long-term risk of developing rheumatoid arthritis (RA). The study, just published on *bmj.com*, indicates that even those people without typical arthritic symptoms like pain and swelling in the joints should get an early referral for examination after a positive rheumatoid factor test.

The team measured rheumatoid factor levels in 9,712 Danish individuals aged 20 to 100 years without RA at the start of the study and followed them for up to 28 years. Raised rheumatoid factor levels of 25-50 IU/mL, 50.1-100 IU/mL and more than 100 IU/mL were compared with normal levels (less than 25 IU/mL). During the study period, 183 individuals developed rheumatoid arthritis.

After taking account of several other possible risk factors, a doubling of rheumatoid factor level was associated with a 3.3-fold increased risk of developing rheumatoid arthritis. The highest rheumatoid factor level (100 IU/mL or more) was associated with a 26-fold increased risk of developing the condition.

In the September 6, 2012 news release the authors stress that their study can-

not prove that rheumatoid factor plays a causal role in the development of rheumatoid arthritis, but they conclude that the findings “may lead to revision of guidelines for early referral to a rheumatologist and early arthritis clinics based on a positive rheumatoid factor test—even in the absence of the typical arthritic joint symptoms.”

Dr. Nordestgaard told *OTW*, “If a patient without a diagnosis of rheumatoid arthritis is found to have elevated rheumatoid factor, he/she should be referred to a rheumatologist and early arthritis clinic. This is because a rheumatoid factor level above 100 versus below 25 IU/mL is associated with a 26-fold increased risk of developing rheumatoid arthritis, and because early treatment may prevent the disease from getting into the very severe stages. The highest risk was found in women who



Borge G. Nordestgaard, M.D., DMSc

smoked and had a rheumatoid factor level above 100 IU/mL, where 1 in 3 women will develop rheumatoid arthritis over 10 years.”

—EH (September 14, 2012)

Joint Replacement Patients Risk Heart Attack

A new study coming out of Utrecht University of the Netherlands has found that, “Total hip replacement patients 60 and older were 25 times more likely to have a heart attack within the first two weeks after surgery. Those with total knee replacements had a slightly greater risk. But after six weeks, the risk returned to baseline.”

The lead study author, Arief Lalmohamed, said, “We learned from this study that we need to focus more on preventing cardiac outcomes following this major surgery.”

According to the report in *Arthritis Today Magazine* the study was compiled from information gained from

more than 95,000 Danish patients who underwent total hip replacement or total knee replacement surgeries between 1998 and 2007.

The article stated, “The average age of the hip patients was 72, while the average age of the knee patients was 67. The researchers found that during the two weeks immediately following each surgery, heart attack risk rose sharply—25-fold for hip patients and 31-fold for knee patients, compared with similar people in the Danish registries who did not have these surgeries.”

Researchers found that after two weeks, heart attack

risk dropped dramatically. Nevertheless, the overall risk of heart attack after hip replacement surgery remained elevated for six weeks. Researchers also found that the association between hip and knee replacement surgeries and heart attack was strongest in those 80 years or older.

—BY (September 10, 2012)



12-Lead EKG ST elevation tracing color coded. Source: Wikimedia Commons

Mayo Team Develops Risk Score for Infection

A team from Mayo Clinic has delved into the topic of rheumatoid arthritis (RA), the related higher risk of death, and the infections that are often behind the problem. The researchers have found that a risk score can be developed to predict a patient’s chances of having serious infections. The score uses information about how rheumatoid arthritis is affecting a patient, plus factors including age, corticosteroid use and the presence of other illnesses. The findings are published online in the American College of Rheumatology journal *Arthritis & Rheumatism*.

Using the National Institutes of Health-funded Rochester Epidemiology Project, researchers studied medical records



Wikimedia Commons and Hellerhoff

of 584 rheumatoid arthritis patients diagnosed between 1955 and 1994 and followed up on until January 2000. Of those, nearly half had more than one

serious infection requiring hospitalization and/or intravenous antibiotic; those 252 collectively racked up 646 infections.

The Mayo team developed an infection risk score based on those and other rheumatoid arthritis patients they studied. Factors in the calculation include age; previous serious infections; corticosteroid use; a low white blood cell count; elevated results in a blood test used to detect signs of inflammation, called an erythrocyte sedimentation rate; signs of rheumatoid arthritis outside joints; and the presence of other serious conditions such as heart disease, heart failure, diabetes, lung disease, vascular disease and alcoholism. They confirmed the usefulness of the risk score in a second group of patients with rheumatoid arthritis from the same population.

“Using a risk score in this way can alert physicians that their patient is at high risk for infection and needs more frequent follow-ups, measures for infec-

tion prevention and possible changes in treatments,” says senior author Eric Matteson, M.D., chair of the Division of Rheumatology at Mayo Clinic, in the September 5, 2012 news release. “Rheumatoid arthritis patients are at higher risk of infection, and that risk is clearly not just because of the arthritis drugs.”

The future? The researchers conclude that further work is needed to determine the level of infection risk at which patients get the most benefit from medications to prevent infection and how infection risk might affect use of a category of rheumatoid arthritis drugs called disease-modifying antirheumatic drugs, or DMARDs, such as biologics.

—EH (September 11, 2012)

Canadian Joint Replacement Wait Time Lengthens

Despite the best efforts of hospitals and doctors the wait times for hip replacement surgery in eastern Ontario has gotten longer instead of shorter—according to a report in the *Ottawa Citizen*. Patients in eastern Ontario have the longest wait time of anyone in the province. Those desiring knee replacements are ranked 10th among 14 health regions in waiting time.



Wikimedia Commons and Boilly

From the time a hip replacement is ordered to the time surgery is scheduled, 9 out of 10 eastern Ontarians wait up to 343 days, according the September 3 article by Pauline Tam in the *Ottawa Citizen*. Of the three regional hospitals performing this surgery, the longest wait is at The Ottawa Hospital (421 days), followed by the Cornwall Community Hospital (303) and Queensway Carleton Hospital (218). The wait for a knee replacement is now 281 days.

Two of the hospitals, which perform the bulk of the region's 3,350 joint replacements annually, attribute the longer delays to a higher volume of surgeries as a result of an aging population. One

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hospital, which in 2008 performed 450 replacement surgeries a year, now does over 1,200 annually.

Ottawa Hospital's head of orthopedic surgery, Geoffrey Dervin, M.D., said the improvements being made to shorten wait times cannot keep up with the number of seniors needing joint replacements. "With the demographic shift and the increasing demand, it has just pretty much kept us at a plateau," he said.

Health officials in the province disagree and say that it is the unequal caseloads among surgeons causing the problem. Some surgeons have waits of no more than 3 months, while patients of other doctors wait more than 18 months for their surgery.

"If you are an average 70-year-old patient who needs a generic hip or knee replacement and you don't need anything fancy, like a partial knee-replacement or a hip-resurfacing, you really should be able to get it done within six months," said Dervin.

Hospitals would like to put their patients on a hospital-wide waiting list and assign them to the first surgeon available to do the procedure. That has not been popular with patients who want to go to a surgeon about whom they have heard good things. Dervin indicated, "It's consumer choice. Once they're on someone's list and they've met the surgeon, they seem reluctant to get off the list." The *Ottawa Citizen* writer notes that surgeons themselves are sensitive to the issue because any changes to the referral system can affect their surgical volumes, and thus their livelihoods.

—BY (September 11, 2012)

reimbursement

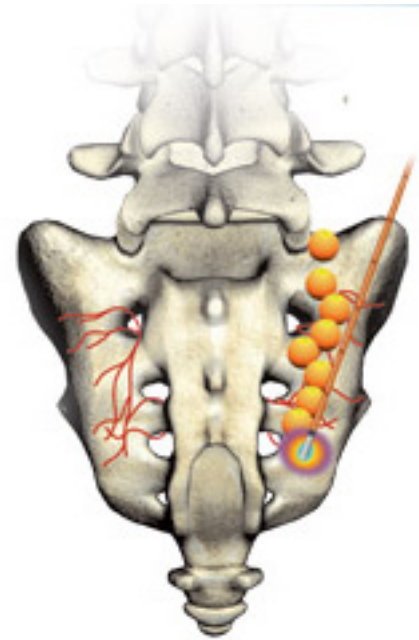
Cooled Radiofrequency Procedure Coverage in NJ

Horizon Healthcare Services, Inc., New Jersey's largest and oldest health insurer, has agreed to provide reimbursement for Kimberly-Clark's SInergy Cooled Radiofrequency System. The policy covers sacroiliac joint denervation for patients diagnosed with chronic sacroiliac joint (SIJ) pain. The procedure temporarily destroys the nerve endings to the sacroiliac joint.

A Kimberly-Clark press release stated that approximately four out of five adults in the U.S. will experience chronic axial low back pain, and SIJ pain accounts for between 18% and 30% of that. This number, claims the company, converts to Americans spending at least \$50 billion each year on low back pain, making it the most common cause of job-related disability and a leading contributor to missed work.

The procedure is a minimally-invasive treatment intended to target and treat the pain-generating nerves in the lower back and buttock region that may be responsible for SIJ pain. The treatment can significantly reduce low back pain, according to the company.

Additionally, the company says results of a study published in the March edition of *Pain Medicine* showed that slightly more than half of patients treated with the procedure demonstrated significant improvements in pain, disability and quality of life outcomes. The durability of the relief was also maintained at the nine-month follow-up.



Kimberly-Clark/SInergy Cooled Radiofrequency System

The *Pain Medicine* study compared lateral branch neurotomy using cooled radiofrequency to a sham intervention. Lateral branch neurotomy involved the use of cooled radiofrequency electrodes to ablate the S1–S3 lateral branches and the L5 dorsal ramus. The sham procedure was identical to the active treatment, except that radiofrequency energy was not delivered.

Study authors, Nilesh Patel M.D., Andrew Gross M.D., Lora Brown M.D. and Gennady Gekht M.D., reported statistically significant changes in pain, physical function, disability, and quality of life were found at three-month follow-up, with all changes favoring the lateral branch neurotomy group. At three-month follow-up, 47% of treated patients and 12% of sham subjects achieved treatment success. At six and nine months, respectively, 38% and 59% of treated subjects achieved treatment success.

—WE (September 16, 2012)

spine

Alphatec Spine Launches Spinous Process Device

Alphatec Spine, Inc. is launching its BridgePoint Spinous Process Fixation System, a device designed to enable spine surgeons to immobilize and stabilize spinal segments without the need for pedicle screw and rod constructs.

Company officials say that this minimally invasive surgery (MIS) system is intended to be an adjunct to fusion of the thoracic and lumbar spine to treat disorders resulting from degenerative disc disease, spondylolisthesis, tumor and trauma.

In describing the process they say that BridgePoint is designed to be implanted through a relatively small posterior incision of approximately 5cm in length, which should result in less injury to muscle and tissue and less blood loss than occurs when pedicle screw and rod systems are implanted through a non-MIS approach.

Officials explain that the BridgePoint System incorporates telescoping plates that allow surgeons to compress or distract the spinous processes before immobilizing the spinal segment. The device's large contact area provides a strong anchor point to each spinous process, facilitating compression or distraction and optimal stability during the fusion process.

BridgePoint can be used as an adjunct to interbody fusion or posterior fusion with decompression treatment. The large bone graft window allows surgeons to pack additional bone graft between the spinous processes.

BridgePoint conducted its first implantation case in August 2012 at Cheyenne Regional Medical Center in Cheyenne, Wyoming. The surgeon was Steven Beer, a board certified neurological surgeon. "I recently had a patient with degenerative disc disease and spinal stenosis, and BridgePoint offered a way for me to treat her less invasively," said Beer in a August 23 press release.

—BY (September 10, 2012)



Courtesy of Alphatec Spine

people

Firefighter's Trauma Illuminates Importance of Diagnosis

Anthony Ramos, a firefighter in Rockledge, Florida, was performing routine physical training with his squad and took his turn practicing with the hoseline. While handling with the firehose—and with water blasting at approximately 150 pounds per square inch—he heard a loud ripping sound.

Ramos was mistakenly diagnosed with a shoulder injury and even cleared to go back to work at the fire station after a few months. Things didn't feel right, however, so Ramos did some research and found Matthew Stiebel, M.D., an orthopedic surgeon at Jupiter Medical Center specializing in sports medicine—and he had performed more than 40 pectoralis major repairs.

"I wanted to hug Dr. Stiebel for finally confirming that something was still wrong with my chest (and not my shoulder). You know when your tire on your car is flat. I knew something wasn't right. I was so fortunate to find Dr. Stiebel in South Florida. The next closest doctor I found was in Puerto Rico!" said Ramos in the August 24, 2012 news release.

Dr. Stiebel explained, "I make a trough or a cavity in the proximal humerus and drill holes in the lateral side of it. Then, I pull the muscle into the trough I've created, pull the sutures out of the holes I make in the bone and tie them over a bone bridge. The trick is to mobilize the muscle and free it away from all the adhesions to make sure the nerves around it are okay. To get a good repair



Anthony Ramos, Firefighter; Courtesy: Jupiter Medical Center

the muscle has to go to the bone. You can't repair the muscle back to the tendon."

Ramos told *OTW*, "As for my impression of orthopedic surgeons prior to my injury, quite frankly I had heard horror stories from other co-workers and friends, but I knew I had to do my own research and form my own opinion. As for 'going under the knife' I was a little reluctant at first, but I knew that surgery was my only option at this point. Going through this experience, and working in the medical field myself, I have learned that there are two ways to retrieve information verbally from patients, hearing and listening. Key word: 'LISTEN' to your patients! Dr. Stiebel is a doctor that listens."

Dr. Stiebel commented to *OTW*, "As these are somewhat rare injuries, Mr. Ramos was misdiagnosed. Also, most of the time these injuries occur with weight lifting/bench press. In this case it happened via work."

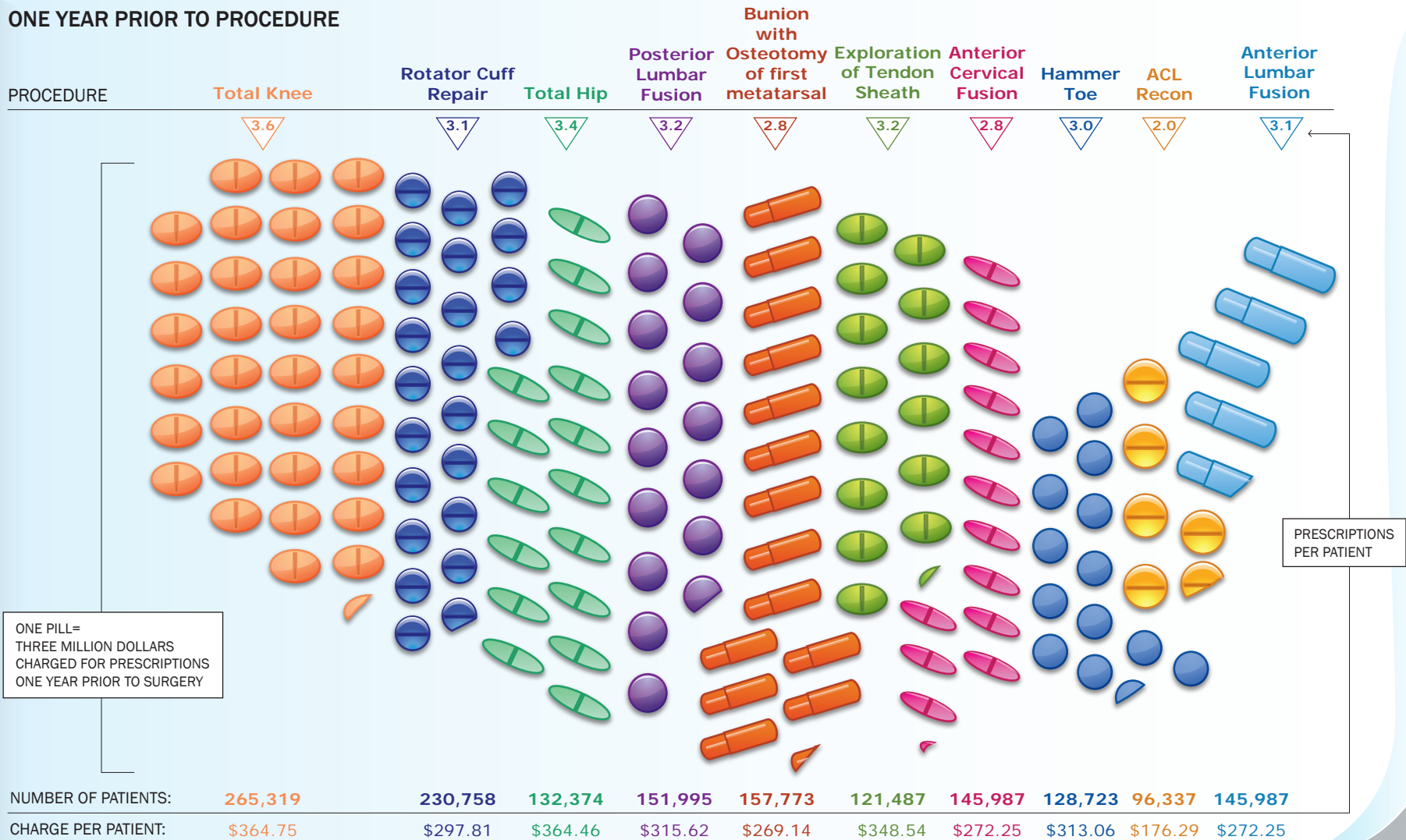
Asked if there was anything else he would like the orthopedic community to know about this situation/surgery, Dr. Stiebel told *OTW*, "To the surgeons who don't do a lot of pec repairs, please let them know that a repair back to the humeral tendon stump usually fails, and that the tendon must be re-attached to the bone—usually via a trough. Too big a trough, however, can result in late humerus fractures."

—EH (September 13, 2012)

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