VOLUME 9, ISSUE 3 | JANUARY 22, 2013

Orthopedics This Week

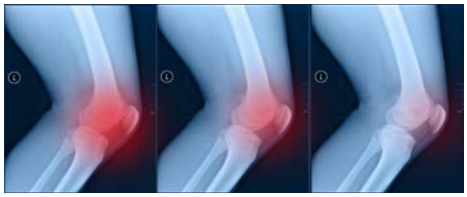
week in review

4 Orthopedic Stem Cell Use Soared in 2012 ♦ Clinic use of stem cell therapies soared in 2012—with approximately 100,000 new patients receiving stem cells in the U.S. last year. Who is using stem cells? For which indications are they using stem cells? What are the outcomes so far? These questions are the curriculum for the February 19th New York Stem Cell Summit. But here is a preview of the answers.

8 Physician-Owned Hospitals TOPS in CMS Quality Survey ♦ Physician-owned hospitals were by far the BEST in a recent CMS Quality Survey. Some famous hospitals landed near the bottom. Which hospitals were deemed the best or the worst in Medicare's $1 billion incentive lottery? Read all the results here.

11 Remarkable New Technique for Eliminating Knee Pain, Escalation in Periprosthetic Fractures! Decrease Disc Degeneration and Regenerate Discs Via External Stimulation? ♦ Dr. Peter Sharkey, M.D. of The Rothman Institute talks about their new technique for one aspect of knee osteoarthritis—Subchondroplasty. Dr. Lisa Cannada describes the major uptick in periprosthetic fractures, and Dr. Todd Albert talks about using external stimulation to address degeneration and regeneration of discs.

14 12 Rounds Over Patella Replacement: Dunbar v. MacDonald ♦ "It's clearly not necessary to resurface the patella," states Michael Dunbar. "Actually," counters Steve MacDonald, "the data is pro-resurfacing. When the patella is resurfaced, patients have improved satisfaction, lower revision rates, less or equal anterior knee pain."



breaking news

18 Hip Revision Risk Factors Identified

AxioMed Spine Raises Another $3.6 Million

Zimmer Spine Is Leaving Austin, Texas

Hulk Hogan Slams Laser Spine Institute for $50 Million

$4.4 Million for **Limb/Prosthetic Project**

Stryker Buys Into China's Spine and Trauma **Markets**

Metal-on-Metal Hips to Require PMA

For all news that is ortho, read on

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Stryker's purchase of the #1 distributor of trauma orthopedic products in China is the kind of strategic use of cash that will drive future shareholder value. For that reason, Stryker is the #1 orthopedic company in the Power Rankings. The company, Trausan, is also MORE profitable than Stryker! China will someday be a larger orthopedic market than the U.S. It already has the largest society of orthopedic surgeons!

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	4	Stryker	23.68%	9.99%	Great opening move for new CEO Lobo. Distribution in the rapidly growing Chinese hospital market is an increasingly rare asset.
2	2	NuVasive	7.08	16.00	Still riding the wave from the early January pre-announcement. NUVA also heads into 2013 with a strong new product pipeline.
3	3	Zimmer	25.45	7.87	Will ZMH also report higher-than-expected sales? Odds are good that Q4 sales were higher than consensus' $1.18B.
4	5	Integra LifeSciences	13.73	11.57	IART has a pattern of beating EPS estimates by double-digit rates. Will it occur again? We think 'yes.'
5	1	Symmetry Medical	5.63	6.81	After a very strong run, SMA is taking a breather. Most buyers are waiting to see what Q4's report looks like.
6	9	Medtronic	28.65	7.61	SYK's purchase of Trausan reminds us that MDT made the first move by buying Kanghui. China really matters and it is a vital aspect of ortho's future.
7	6	Exactech	8.64	4.92	Interestingly enough, EXAC has been one of the most active small ortho companies in China. But, still small.
8	7	ArthroCare	18.04	9.04	It is so interesting to watch buyers soak up ARTC stock in the face of down earnings and flat sales.
9	10	Johnson & Johnson	25.58	3.68	DePuy sales report imminent. Signs point to a modestly upbeat report. As #1 ortho company, DePuy is THE bellwether.
10	NR	Globus Medical	29.39	13.35	Sellers have finally moved on to other stocks. Buyers can now focus on GMED's strong profit margins and top line growth.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	$4.23	$367	32.19%
2	NuVasive	NUVA	$17.62	$767	16.00%
3	Globus Medical	GMED	$12.82	$1,168	13.35%
4	Integra LifeSciences	IART	$42.13	$1,139	11.57%
5	Bacterin Intl Holdings	BONE	$1.42	$60	10.94%
6	Stryker	SYK	$61.55	$23,401	9.99%
7	ArthroCare	ARTC	$36.44	$1,016	9.04%
8	Zimmer Holdings	ZMH	$73.61	$12,771	7.87%
9	Medtronic	MDT	$45.67	$46,189	7.61%
10	Symmetry Medical	SMA	$10.82	$398	6.81%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MAKO Surgical	MAKO	$10.89	$500	-20.45%
2	RTI Biologics Inc	RTIX	$4.09	$229	-7.88%
3	Alphatec Holdings	ATEC	$1.66	$151	-6.74%
4	TiGenix	TIG.BR	$1.23	$123	-5.58%
5	Orthofix	OFIX	$37.00	$715	-5.27%
6	Smith & Nephew	SNN	$55.67	$10,066	0.32%
7	TranS1	TSON	$2.63	$72	1.15%
8	CryoLife	CRY	$6.43	$176	2.23%
9	Wright Medical	WMGI	$21.60	$857	3.50%
10	Johnson & Johnson	JNJ	$73.23	$202,940	3.68%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$37.00	$715	12.29
2	Medtronic	MDT	$45.67	$46,189	13.39
3	Zimmer Holdings	ZMH	$73.61	$12,771	14.21
4	Johnson & Johnson	JNJ	$73.23	$202,940	14.50
5	Stryker	SYK	$61.55	$23,401	15.54

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$21.60	$857	67.50
2	NuVasive	NUVA	$17.62	$767	62.93
3	Symmetry Medical	SMA	$10.82	$398	47.04
4	CryoLife	CRY	$6.43	$176	22.96
5	ArthroCare	ARTC	$36.44	$1,016	21.56

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$37.00	$715	1.07
2	Conmed	CNMD	$28.62	$815	1.33
3	Globus Medical	GMED	$12.82	$1,168	1.35
4	Exactech	EXAC	$17.47	$232	1.47
5	Zimmer Holdings	ZMH	$73.61	$12,771	1.52

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$17.62	$767	7.70
2	Wright Medical	WMGI	$21.60	$857	6.66
3	CryoLife	CRY	$6.43	$176	5.74
4	Symmetry Medical	SMA	$10.82	$398	3.92
5	Smith & Nephew	SNN	$55.67	$10,066	3.05

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.66	$151	0.76
2	Symmetry Medical	SMA	$10.82	$398	1.11
3	Conmed	CNMD	$28.62	$815	1.12
4	Exactech	EXAC	$17.47	$232	1.13
5	Orthofix	OFIX	$37.00	$715	1.23

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.23	$123	107.25
2	MiMedx Group	MDXG	$4.23	$367	47.28
3	MAKO Surgical	MAKO	$10.89	$500	5.92
4	TranS1	TSON	$2.63	$72	3.75
5	Globus Medical	GMED	$12.82	$1,168	3.52

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

Orthopedic Stem Cell Use Soared in 2012

By Robin Young

When 2012 began, an estimated 1 million U.S. patients had been treated with stem cells over the course of the previous 15 years. By the end of 2012, *Orthopedics This Week* estimates that that number of patients treated rose by an astonishing 100,000!

Physician users now number in the thousands. Indeed, it is harder to find physicians who have NOT used stem cells than those that have.

Who is using stem cells? Where are they getting the cells? For which indications are cells being used? What is appearing in peer review literature?

Answering those questions is, in effect, the curriculum for this year's New York Stem Cell Summit – February 19th. (www.stemcellsummit.com/newyork).

Wikimedia Commons and U.S. Navy photo

As we have analysed the remarkable uptake of stem cell treatments in orthopedics, we are left wondering…is this, in effect, the next generation platelet rich plasma (PRP)?

Users

Spine surgeons, ophthalmologists and wound care specialists are currently the most frequent users of stem cell therapies in the United States. Coming up fast, however, are oncologists, cosmetic surgeons and pain management specialists.

Spine surgeons and sports medicine specialists are the two groups we've observed, exhibiting strong adoption patterns and pushing this remarkable uptake in stem cell usage. One common attribute we've noticed is that users of stem cell therapies are also current (and former) users of Infuse and various allograft products.

So, as a foundation for bringing stem cells into their practice, these physicians are almost universally well trained and well experienced in the use of either allograft or recombinant products as adjuncts to surgery which serve to augment the patient's own ability to grow either bone or soft tissue.

To most of these physicians, stem cells appear to represent a new source of growth factors—and in that context are logical extensions of such well characterized materials as demineralized bone matrix and Infuse. But, of course, stem cells are not well characterized. Yet their growth is exploding among spine and sports medicine physicians.

Ironically, insurance companies and the FDA are two of the primary drivers of this trend. Insurance companies or hospitals who have tried to limit the use of Infuse have driven many spine surgeons to look for biologic alternatives.

Seven years ago the first cadaveric-based stem cell products came to market. With zero reported adverse events so far, these allograft-based stem cell products are increasingly considered to be safe and reliable sources of growth factors by the physicians who use them.

The FDA, which continues to make it more difficult for new spine technologies to come to market, has also contrib-

uted to this trend by, in effect, leaving autologous and allograft biologic strategies as increasingly attractive avenues of innovation.

Neurosurgeon "Ty" Thaiyananthan, M.D., (UCSF medical school-trained, Yale residency and founder of the BASIC spine network of clinics in and around Los Angeles) speaks for most spine surgeons when he says: "I really think that spine surgery will be focused on regenerative medicine in the future. We will be looking into stem cells to fix problems that typically require big surgeries. I think that spine surgeons in the future will do more procedures through a needle instead of using the scalpel."

In his practice Dr. "Ty" openly advertises his stem cell therapies for spine patients as part of an overall treatment plan which includes such traditional spine surgeries as fusion, micro-discectomies and scoliosis treatment.

At the New York Stem Cell Summit the co-founder of Rocky Mountain Associates—one of the leading independent spine treatment clinics in the United States—and inventor of Medtronic's Maverick motion preserving disc replacement, Kenneth Pettine, M.D., will present his experience with stem cell treatments for spine patients. Dr. Pettine has treated, we estimate, around 100 patients with stem cells and is seeing remarkable results.

Down the road from Dr. Pettine's clinic is one of the world's most famous sports medicine clinics—the Steadman Clinic in Vail, Colorado. Richard Steadman, M.D., is the legendary founder of this clinic which treats Olympic athletes as well as the famous and not-so-famous weekend warriors. After extensive testing in animal models, he is launching a stem cell practice for his orthopedic patients.

These are not trivial decisions by these leading physicians and clearly points to a powerful and growing trend.

In our opinion, the percentage of spine surgeons who are now incorporating stem cell treatments in their practice is probably between 30-40% of all spine and neurosurgeons.

By way of precedent and comparison, the percentage of ophthalmologists who use stem cells is close to 100%.

The Ophthalmology Precedent – a Model for Orthopedics?

Limbal stem cell transplants were the first autologous stem cell transplant used in the 1970s. In this procedure stem cells are taken from the healthy eye of the patient or a live donor (usually a sibling or a parent). During this outpatient procedure stem cells are harvested from the healthy eye or the

donor's eye and then transplanted to the affected eye.

Sound familiar? This is almost exactly the procedure for autologous stem cell treatment by spine or sports medicine physicians who are currently using autologous stem cell systems.

If the transplant is successful, the stem cells will produce a new layer of epithelial cells in the patient's eye. The success rate of growing the new cells from transplanted stem cells varies from 25% to 70%, depending on the underlying condition of the eye.

A stem cell transplant alone can make a patient's vision considerably better. There are about 40,000 cornea transplants performed each year. Stem cell transplants have been a routine part of modern ocular surgery for more than two decades. Tens of thousands of patients have had stem cells harvested from one eye and then transplanted in the other eye.

According to the literature if a surgeon attempts a cornea transplant WITHOUT stem cells, the cornea transplant nearly always fails.

We estimate that **there have been more than 500,000 autologous limbal stem cell transplants** since this technique first gained popularity in the 1980s.

As we observe the uptake of stem cell therapies in orthopedics, frankly we are reminded of the experience in ophthalmology. If the orthopedic use follows this market model, within a few years, virtually all spine surgery and most sports medicine and trauma treatments will employ stem cells.

Where Are Physicians Getting Stem Cells?

There are three sources of stem cells: from the patient (autologous), from cadavers (allograft) or from living donors (allograft).

At this year's Stem Cell Summit, several companies will be demonstrating their systems for concentrating stem cells from the patient and a number of presenters will be describing allograft stem cell products.

Without doubt, the most successful stem cell product is cadaveric derived stem cells within a bone matrix. These products, which are distributed by Orthofix International, N.V. and NuVasive, Inc., have been terrific for both physicians and patients with both superior safety profiles and efficacy as compared to alternative allograft adjuncts to spine surgery.

Amniotic Tissue

But coming on strong are autologous systems—which are, in effect, upgraded versions of PRP systems with a focus on concentrating stem cells—and living donor stem cell products. Perhaps the most interesting of the living donor

products are the amniotic tissue-based products.

One clinic, the BASIC spine clinic with offices in the greater Los Angeles area, has made amniotic stem cell therapies a center piece of their practice and has branded the tissue "inSRT".

Here is a quote from the BASIC spine clinic web site:

> *"During the stem cell retrieval process, the embryonic and mesenchymal stem cells are taken directly from the amniotic fluid, placenta, and umbilical cord of a healthy, living, consenting donor immediately after the birthing process. inSRT is processed in accordance with protocols and procedures that have been developed to meet or exceed all applicable industry standards for the use of human cellular and tissue-based produces. Unlike other stem cell injections and therapies, inSRT has no negative affect on life or the birthing process. We believe the use of live and healthy donors provides a better approach to regenerative medicine. Injections are done in-office and recovery time is a minimal.*
>
> *Both FDA registered tissue banks work closely to adhere to all regulations and industry standards regarding HCT/P recovery, processing, storage, labeling, packaging, and distribution. Each lot of processed human tissue must be determined suitable according to FDA regulations by a Medical Director. inSRT is derived from live, healthy donors during childbirth and provides viable human tissue for clinical use."*

The founder of the BASIC spine clinic is G. "Ty" Thaiyananthan, M.D., who is originally from Oklahoma. He earned his Bachelor of Science degrees (Biomedical Engineering and Electrical and Computer Engineering) from Johns Hopkins University. Dr. Ty's medical degree is from the University of California, San Francisco and he completed his general surgery internship and neurosurgery residency at Yale New Haven Hospital where he was also named Chief Resident of Neurological Surgery. Dr. Ty completed his minimally invasive and complex spine surgery fellowship at Cedars-Sinai Medical Center's Institute for Spinal Disorders.

The New York Stem Cell Summit February 19th

This will likely be the most significant New York Stem Cell Summit in eight years since it will be capturing and describing a true treatment revolution *as it is occurring*. The speakers this year and the manner in which this meeting has been organized will teach attendees about the specific technologies, the indications where stem cells are achieving their strongest uptake and the outcomes observed so far. With just three weeks remaining before the meeting, it is time for all interested physicians to sign up before space is gone. ♦

Physician-Owned Hospitals TOPS in CMS Quality Survey

By Walter Eisner

Treasure Valley Hospital, Boise, Idaho/RRY Publications LLC

The Centers for Medicare and Medicaid Services (CMS) is the single largest payer of health care services in the country. As part of the Affordable Care Act (ACA), the government wants to exercise CMS' power to reward and penalize the best and "least best" hospitals through the Hospital Value-Based Purchasing (VBP) Program.

On December 20, 2012, CMS came out with its first scorecard for almost 3,000 hospitals across the country.

Winners

The Physicians Hospitals of America (PHA) trade association was quick to point out that the big winners were physician-owned hospitals (POH) which scored nine out of the top ten hospitals. Ironically, the ACA (aka Obamacare) bans POH hospitals from expanding Medicare beds. Of the 3,000 hospitals participating in the program, less than 200 are physician owned, but those hospitals received 48 out of the top 100 ratings.

Paul Kerens, PHA's president, said PHOs continue to provide the best quality within the new system of value-based purchasing. "These numbers do not surprise me; POH's have always welcomed standards and competition and continue to consistently show they are top-rated. This is just one more way our communities can see that we provide the best care in America."

Top Ten

Here are the top ten and their percentage bonuses:

1. Treasure Valley Hospital, Boise Idaho (0.83)
2. Lincoln Surgical Hospital, Lincoln, Nebraska (0.78)
3. Baylor Medical Center at Trophy Club, Trophy Club, Texas (0.78)
4. Tops Surgical Specialty Hospital, Houston, Texas (0.75)
5. Marlboro Park Hospital, Bennettsville, South Carolina (0.74)
6. Baylor Medical Center at Uptown, Dallas, Texas (0.74)
7. Minden Medical Center, Minden, Louisiana (0.73)
8. Irving Coppell Surgical Hospital LLC, Irving, Texas (0.73)
9. Surgical Hospital at Southwoods, Youngstown, Ohio (0.73)
10. Indiana Orthopaedic Hospital LLC, Indianapolis, Indiana; Baylor Heart and Vascular Hospital, Dallas, Texas; and Midwest Sur-

gical Hospital, Omaha, Nebraska (0.72)

Bottom Ten

The bottom ten? Read 'em and weep:

1. Eastern Niagara Hospital, Lockport, New York, (-0.74)
2. Pacifica Hospital of the Valley, Sun Valley, California (-0.75)
3. Wiregrass Medical Center, Geneva, Alabama (-0.75)
4. East Texas Medical Center Crockett, Crocket, Texas (-0.77)
5. Memorial Hospital Sweetwater County, Rock Springs, West Virginia (-0.77)
6. St. Joseph's Hospital, Philadelphia, Pennsylvania (-0.78)
7. Medical Center of Southeastern Oklahoma, Durant, Oklahoma (-0.80)
8. Greater El Monte Community Hospital, South El Monte, California (-0.83)
9. St. Anthony's Hospital, Houston, Texas (-0.89)
10. Auburn Community Hospital, Auburn, New York (-0.90)

Lessons From the Extremes

Nicholas Genna, CEO of Treasure Valley Hospital in Idaho, credited close attention to patients, including a low nurse-to-patient ratio and handwritten thank-you notes to patients, along with the fact that the doctors own the hospital. "People answer the phone with a smile on their face," he told *Kaiser News*.

Thomas Filiak, the chief operating officer at Auburn Community Hospital in New York, told *Kaiser News* that executives have begun a number of initiatives to lower noise near patient hallways, including putting new wheels on squeaky food carts. "They sounded like Mack trucks going through the hallway," he said.

Only 39% of Auburn patients reported their rooms were always quiet, below the national average of 60%, according to Hospital Compare. Filiak said the hospital has been improving the quality of the food, which a private survey company found was affecting patient satisfaction, and trying to improve by focusing teams of workers on the problems. Auburn's low scores included its rate of giving the right antibiotic to surgery patients, which did not occur 11% of the time.

"We know we started off at the bottom, but we are going to work our way to much more acceptable scores," Filiak said. The penalty will cost Auburn an estimated $100,000, he said, which the hospital's $85 million budget can absorb without having to take drastic measures like layoffs.

Regional Winners and Loser

CMS also tracked results on a regional basis.

The Ft. Wayne, Indiana, region did best. Most bonuses went to hospitals in Maine, Nebraska, South Dakota, Utah, and South Carolina. The most penalized states and district are the District of Columbia, Connecticut, New York, Wyoming and Delaware.

Here are the best and worst of 212 market areas:

Top Ten Markets (by highest bonuses)

1. Ft. Wayne, Indiana
2. Greenville, South Carolina
3. Newport News, Virginia
4. Boise, Idaho
5. Florence, South Carolina
6. Bangor, Maine
7. Grand Rapids, Michigan
8. Jackson, Tennessee
9. Portland, Maine
10. Charleston, South Carolina

Lowest Ten Markets (by highest penalties)

1. Washington, D.C.
2. Buffalo, New York
3. Bronx, New York
4. Bakersfield, California
5. Syracuse, New York
6. Altoona, Pennsylvania
7. Hartford, Connecticut
8. Corpus Christi, Texas
9. Saginaw, Michigan
10. Springfield, Missouri

Auburn Community Hospital

Big Names Shut Out

The hospitals that scored best are not the ones with the big reputations. New York-Presbyterian in Manhattan and Massachusetts General Hospital in Boston, for example, both dominant hospitals in their cities, will have their payments reduced. Other leading names in the hospital industry, including the Cleveland Clinic and Intermountain Medical Center in Utah, will receive bonuses, although not the largest in their regions.

Kaiser News reported that results for hospitals within the same system often varied. For instance, in Rochester, Minnesota, the Mayo Clinic's Methodist Hospital will be getting a bonus. But Mayo's flagship St. Mary's Hospital, also in Rochester, will be losing money. Michael Rock, M.D., an orthopedic surgeon at the Mayo Clinic, said that Medicare's scoring system tends to favor hospitals with patients like those at Methodist, which primarily does elective surgeries, over hospitals with lots of trauma and emergency cases, which St. Mary's handles.

Michael Henderson, M.D., chief of quality at the Cleveland Clinic told *Kaiser News*, "To me, it's the tip of the iceberg for where we are going, "We've been working on this for two or three years, and it really made us strive for excellent performance."

Quality Over Quantity

CMS is changing the way it pays hospitals by rewarding hospitals for the quality of care they provide to Medicare patients, not just the quantity of procedures they perform. Hospitals are rewarded based on how closely they follow best clinical practices and how well hospitals enhance patients' experiences of care.

Measures

The first are 12 "measures of timely and effective care" also known as "process" measures. The measures include clinical areas of acute myocardial infarction, heart failure, pneumonia, infections and surgeries.

The second set of eight measures is culled from surveys of patients who had recently left the hospital. These are frequently called "patient experience" or "patient satisfaction" measures. For these measures, Medicare only looked at the percent of patients who said they "always" had a favorable experience in these areas

For 2012 the process measures accounted for 70% of a hospital's score and the patient satisfaction measures accounted for 30%. Medicare looked at both how a hospital did compared to its peers and how much it improved its own performance over time, and whichever score was higher was the one used to calculate its payment factor. Hospitals stood to lose or gain up to 1% of their regular Medicare reimbursements in the first year of the program. The amount of money at stake increases incrementally over the next four years to reach 2% of payments.

Incentive Funding Source

To pay for the program CMS reduced payments to all hospitals by 1%, estimated at $964 million. It then calculated a score on how much money each hospital deserved to get back based on the quality of its care. While every hospital is getting something back, almost half aren't recouping the 1% they forfeited and thus are net losers.

The incentive payments come from the regular fees Medicare pays hospitals through its Diagnosis-Related Group (DRG) system. Hospitals participating in the program have their base operating DRG payments for each patient discharge across all hospitals reduced by a small percentage each year. The base operating DRG percent reduction is 1.0% for fiscal year (FY) 2013, 1.25% for FY 2014, 1.5% for FY 2015, 1.75% for FY 2016, and 2.0% for FY 2017 and subsequent years.

Overall, 1,557 hospitals received bonus and 1,427 received penalties.

Does It Matter?

Will these carrots and sticks work? Does more money translate into better care?

Interestingly, the RAND Corporation, which helped CMS design the purchasing program, just analyzed results from 61 studies comparing spending with outcomes.

What was the RAND Corporation's conclusion? "Results are all over the map," and, "It's totally unclear what the real relationship is." Of the 61 studies, 21 showed a positive connection between spending and outcomes, 18 found worse outcomes and the remaining 22 studies showed no difference.

Raj Behal, M.D., senior patient safety officer at Rush University Medical Center in Chicago, which is getting a bonus, said the prospect of the financial incentives has not had a huge effect. "I wouldn't say we've changed our course radically. All of these things were already on our radar," he said. "These are nuts and bolts measures. All of us should be doing these things right. But is that enough?" ♦

Remarkable New Technique for Eliminating Knee Pain, Escalation in Periprosthetic Fractures!

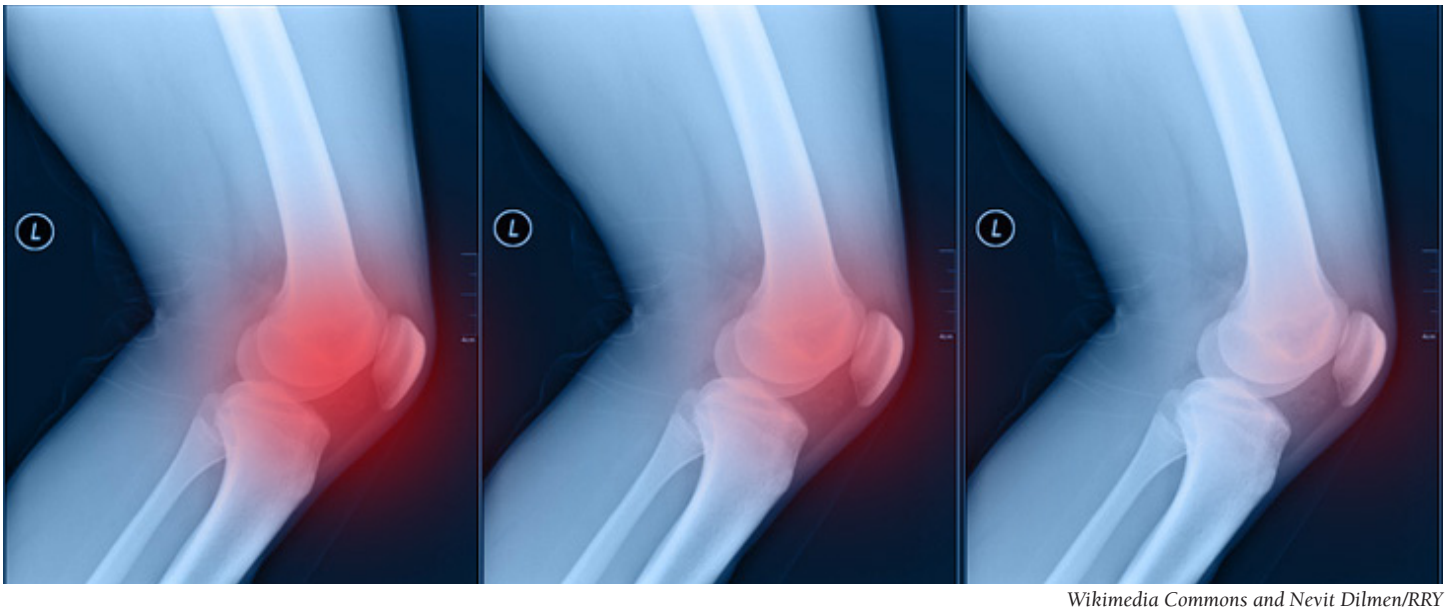
By Elizabeth Hofheinz, M.P.H., M.Ed.

More Elderly Pushing Up Rates of Periprosthetic Fractures! Lisa Cannada, M.D. is an associate professor of orthopaedic traumatology at Saint Louis University School of Medicine in Missouri. She is also an orthopaedic traumatologist at Saint Louis University Hospital and Mercy Medical Center in St. Louis. She tells *OTW*, "Periprosthetic fractures are on the rise…and it's not the total joint surgeons who are having to deal with them anymore. A patient comes into the hospital with a fracture so the case goes to the surgeon on call. These fractures occur in patients with poor bone quality. Periprosthetic plates can be thicker and surgeons may place all locking screws, making the construct too stiff to promote healing. You may have skin issues with thicker periprosthetic plates in thin skin. Some of the distal femur fracture plates are not as thick as the specific distal femur periprosthetic plates. In addition, they have variable screw trajectories with up to 30 degrees of freedom. In that way, the screw placement can avoid the hardware that is already in place."

"We are seeing this significant rise in these fractures because the geriatric population is increasing. In addition, we are seeing more inter prosthetic fractures. My advice to surgeons taking care of periprosthetic fractures: control the stiffness of the plate with liberal use of non locking screws in the diaphysis in order to maximize healing. It may be challenging to choose the plate length. What is key is to always think ahead for next surgery. If fixing a distal femur periprosthetic fracture and the patient had plans for a total hip in the near future, consider using a longer plate so there will not be a stress riser once the total hip is placed."

"Anyone taking call these days needs to know how to handle these fractures. The good news is that I do see the appropriate training occurring as more and more research on the issue is presented. I hope that everyone eventually learn that every screw in a locking plate does not have to be a locking screw."

Remarkable New Technique for Eliminating Knee Pain Peter Sharkey, M.D. is an orthopedic surgeon at The Rothman Institute in Philadelphia and a professor at Thomas Jefferson University Hospitals. He told *OTW* about a procedure developed by him and his colleagues at the Rothman Institute. "It's called Subchondroplasty®* and it provides a minimally invasive option for addressing one aspect of knee osteoarthritis. It turns out that the number one predictor of pain in patients with knee arthritis is something called a bone mar-



Wikimedia Commons and Nevit Dilmen/RRY

row lesion (BML), and it can only be seen on MRI. Once you develop BMLs, which can usually be found underneath a cartilage lesion, then two things are predictable. First, you will have pain. Second, your odds of going on to have a total knee surgery have increased… likely as high as 9x! The reason is because BMLs represent the healing response surrounding an insufficiency fracture within the subchondral bone. There is pain because the bone starts to collapse and eventually you will probably go on to a total knee replacement. With the Subchondroplasty® procedure we drill a small hole into the bone and fill in the defect with calcium phosphate which helps the body heal the fracture. The bone substitute we are using is injectable into cancellous bone and is resorbable so you can still have a knee replacement in the future if it is required."

"The purpose of Subchondroplasty® is to fill the defect and heal the insufficiency fracture. Patients typically notice a change within one week, but the bone substitute material continues being resorbed over one to two years. And although we have not proven it yet, we believe that this will slow the cartilage changes and delay the inevitable total knee surgery. We are getting about 80% good results at two years, and have just published articles in the *American Journal of Orthopedics and Techniques in Knee Surgery;* we have several additional publications coming out in the next couple months. Over 1,200 of these procedures have been performed in the past two years."

"The purpose of the procedure is to correct the pain within two to three days. And although we have not proven it yet, we believe that this will stop the attrition of the subchondral bone and delay the inevitable total knee surgery. We are getting about 80% good results at two years, and have just published an article in the *American Journal of Orthopedics;* we have several additional publications coming out in next couple months. And I'm proud to say that we have performed nearly 2,000 of these procedures."

*Dr. Sharkey indicates that he is financially invested in Subchondroplasty®.

Is an Explosion of Infection Testing Coming? Todd Albert, M.D. is a spine surgeon and is president of the Rothman Institute in Philadelphia. He is also chair of the Department of Orthopaedic Surgery at Thomas Jefferson University. He tells *OTW*, "Some of the exciting work we are doing here is on the diagnosis of infection. There is sometimes pain or [joint] loosening and the surgeon can't diagnosis the bug in order to treat it appropriately. One of our surgeons, Dr. Javad Parvizi, has recently published on multimodality polychromal testing using a machine called the IBIS. It can identify the bug, and is taking polychromal testing to new level. If all continues to go well with testing, we will see an explosion of this testing in practice within two years. It will be such that not doing it will be harmful to patients."

"This work is critical because there is a great swath of patients getting their joints revised where we think it's loosening…but it's actually an undiagnosed infection. There may be ways—even in the early stages after replacements—to make a diagnosis of early infection and treat patients, thus avoiding revision."

"Yes, there is a price prohibition until the testing becomes more widely used. But pharmaceutical companies will help drive costs down because they will create new machines due to the huge diagnostic opportunities."

And From the Rothman Spine Lab… Dr. Albert tells *OTW*, "We are focusing on identifying what causes pain and degeneration at a molecular level and how we can regenerate discs with pulsed electromagnetic fields. We have some very preliminary positive results indicating that we may be able to decrease the degeneration of discs and/or regenerate discs with external stimulation. And if the results pan out clinically some companies are looking at doing trials. This could eventually mean a noninvasive way to significantly decrease pain."

"As of now the trial is planned, but not yet operationalized. We will take patients who come to physiatrist offices—those who have a one or two level degenerative disc on an MRI—and use stimulators. It would be a true randomized double blinded trial because the participant won't know if they have a dummy brace or a real stimulator. Then we can measure back pain scores and do health outcomes assessments in two groups and see if the discs look like they have regenerated. Since back pain is the second leading cause of missed work in the U.S., our work in this area could be of great interest and help to many parties."

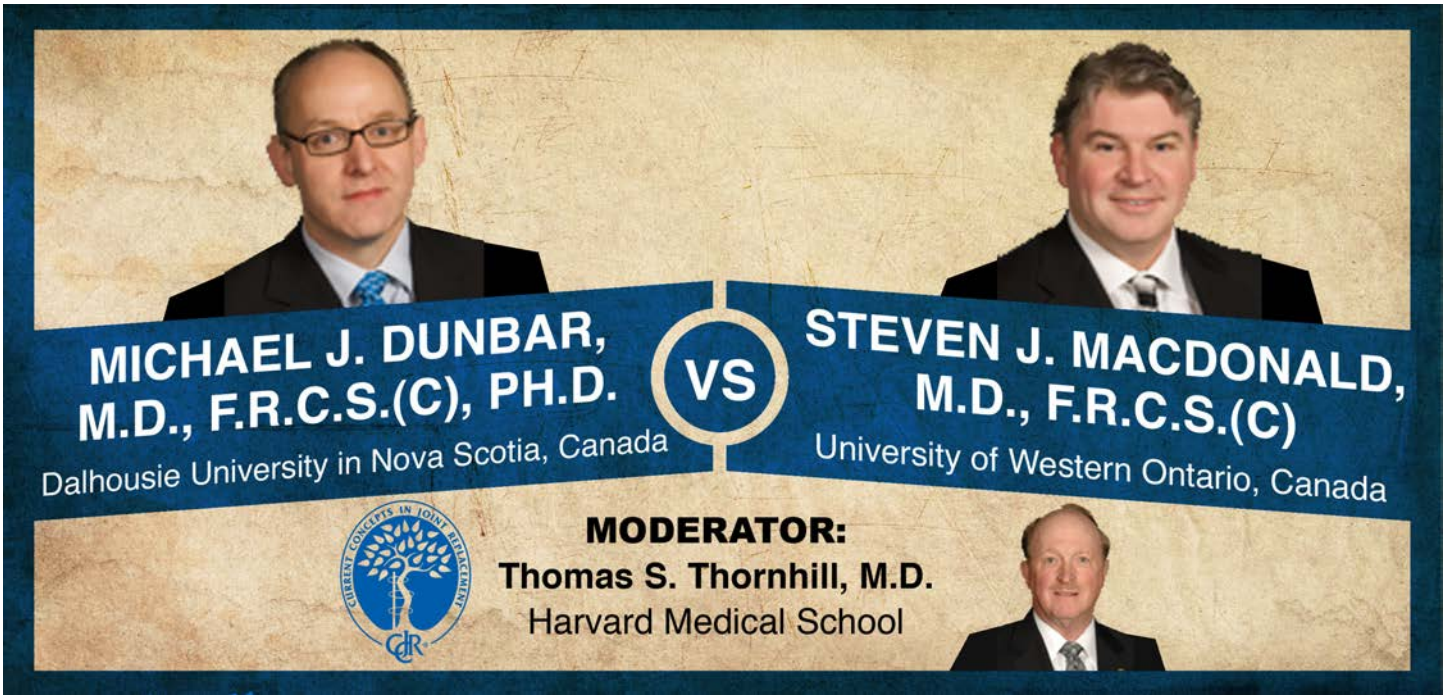
Face It: You Need a Team David L. Helfet, M.D. is professor of orthopedic surgery at Weill Cornell Medical College and director of the orthopaedic trauma service at both Hospital for Special Surgery and New York-Presbyterian Hospital. Dr. Helfet, a former president of the OTA (Orthopaedic Trauma Association), tells *OTW*, "In the modern arena of orthopedic trauma it is no longer just the doctor, the injury and the

patient…it's also the hospital system, funding, and the patient's social situation, family, other underlying problems (medical or not). Twenty-five years ago we trauma surgeons could focus on what we thought was the right thing, do it and no one questioned us. You could focus on the patient's acute problem—not the spectrum of the patient and problems. These days, orthopedics is increasingly a collaborative effort; we need to work with the hospital, our colleagues in medicine, surgery, metabolic bone, the implant manufacturer etc. Having access to the right team is essential to allow you to do the work you do best. With increasing numbers, longevity and an active life style the elderly are becoming the largest piece of orthopedics—with a whole new set of additional problems, co-morbidities, osteoporosis etc.—and all have to be managed and/or treated."

"Fortunately for traumatologists, this isn't such a difficult new trend. We have always worked as a team, so this is a natural evolution for us. My advice to my non-trauma colleagues is to spend time looking at the advantages of working as a team. Surgeons in private and solo practice, used to working on their own, may be more resistant, but I do think they are realizing that it's increasingly hard to work alone—especially with all of the patient, system, insurance, hospital, government regulations these days. We all want to be independent and have egos…but we have to get past that. Once you experience the benefits of working with knowledgeable others you relax. And it helps enormously if you are at an institution that understands and supports you and appreciates how valuable you are, especially doing what you do best!" ♦

12 Rounds Over Patella Replacement: Dunbar v. MacDonald

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



Current Concepts in Joint Replacement/RRY Photo Creation

"It's clearly not necessary to resurface the patella," states Michael Dunbar. "Actually," counters Steve MacDonald, "the data is pro-resurfacing. When the patella is resurfaced, patients have improved satisfaction, lower revision rates, less or equal anterior knee pain."

This week's Orthopaedic Crossfire® debate is "Rethinking Patella Replacement: It Really Isn't Necessary." For the proposition was Michael J. Dunbar, M.D., F.R.C.S.(C), Ph.D. from Dalhousie University in Nova Scotia, Canada. Against the proposition was Steven J. MacDonald, M.D., F.R.C.S.(C) of the University of Western Ontario, Canada. Moderating was Thomas S. Thornhill, M.D. from Harvard Medical School.

Dr. Dunbar: "The fact is that there are multiple randomized controlled trials looking at the issue, all of which show no difference in the outcome. So you'd say there is no advantage to resurfacing the patella, so subsequently you'd default to 'it's not necessary.' But this is a power issue and so we need to look at bigger data sets."

"There are a couple of meta-analyses that I'm sure Steve will bring up to counter the point. One is by Parvizi and one is by Calvisi and they came to the same conclusion. All patients improved, whether their patella was resurfaced or not. That speaks to the standard effect size. But in these studies the investigators identified the fact that there is more anterior knee pain in the un-resurfaced group, decreased satisfaction rates, and increased revision rate."

"In our study based on the Swedish registry, we looked at satisfaction as an outcome. When we looked at every patient in the country—about 30,000 people. With that huge power we found a subtle difference in terms of satisfaction rates for the patella resurfaced group. But what Steve probably doesn't know is that when we looked at what satisfaction means—we correlated sat-

isfaction with every questionnaire we looked at—we found that what patients were really talking about was reduced pain. So I'd submit to you that anterior knee pain and satisfaction are the same thing."

"So let's look at it a little differently. If we look at longitudinal outcomes and how patients proportionately reported whether they were satisfied or not with time—and this is working backwards by the cohort—we have un-resurfaced groups that remain the same over time. However, what we like to say from the Swedish registry is that the beneficial effect of early satisfaction is not persistent and it changes with time the further you go out. So the satisfaction that's obtained is subtle and it's short-lived."

"What about the increased revision rate? We heard it from Mike and Bill who both articulated the fact that if you have two patients, one with an un-resurfaced patella and one with resurfaced and they're both complaining about the same anterior knee pain, there's a selection bias…you're much more likely to do a revision. These revisions come early and they're about flipping the patella and putting a button on. The fact is that when you do that, the satisfaction rates are abysmal."

"From the Swedish registry data we saw that the incidence of resurfacing the patella changed over time. In 1985 it was about 80% and now it's down to 5%. So I have the nation of Sweden behind me saying, 'It's not necessary to resurface the patella.'"

"The interesting question is, 'Why did this happen?' If you look at the revision rates now for resurfaced versus un-resurfaced from 1985-1994 it turns out that the revision risk ratio is flipped… so there was a higher revision rate for the resurfaced group. What happened? There was a transition between the universal to an anatomic femoral component, and when you look at the satisfaction rates (subtle, but because of the power, statistically significant), there was an advantage for the un-resurfaced group in the anatomic component. That wasn't the case in the resurfaced [group]. So it looks like a lot of the resurfacing was being done to accommodate a universal component, and when we all switched to an anatomic type component that was no longer necessary."

"In talking to Otto Robertsson—who runs the knee registry—about why this has changed so radically in Sweden, it's because of the type of revisions and the ratio of revisions that are required. When you resurface the patella your revisions are early and are for simple

problems like a tracking issue. If you don't resurface the patella you do much more complicated revisions later on at a higher ratio for fracture, wear, and loosening."

"In another meta-analysis looking at the outcome of periprosthetic fracture we find that they almost always occur—99%—in the resurfaced group. If you don't resurface the patella you're not going to have a periprosthetic fracture. There is a 92% failure rate with ORIF [open reduction internal fixation], 29% complication rate, and 19% incidence of infection."

"Based on all of the above, it's clearly not necessary to resurface the patella."

Dr. MacDonald: "My opponent is a good critical thinker…most of the time. Evidence of his good thinking: he published a paper about 10 years ago with 27,000 total knees, increased satisfaction rate—in which group??—those resurfaced!"

"So how do you measure success? Patient satisfaction and implant longevity, failure rates, and revision rates. And we should avoid only un-blinded, small series…that's the advantage of the registries. There are multiple small series, randomized trials; reasonably well powered…they either show that resurfacing is equal or superior. None show that the un-resurfaced group is better."

"There are multiple systematic reviews. I quote the conclusions: 'Patellar resurfacing is the best management; patellar resurfacing reduces the risk of anterior knee pain and patella-related knee pain; patellar resurfacing reduces the risk of reoperation; the literature favors resurfacing the patella routinely; lower risk of reoperation and anterior knee pain with resurfacing.' There isn't a systematic review that says the opposite."

"The advantage of resurfacing is availability for osteoarthritic patients, rheumatoid patients, so regardless of the cohort the satisfaction rate across the board, across the diagnosis, is higher if you resurface the patella. Survivorship: the Swedish registry says there's a 1.27x higher revision rate if you leave it un-resurfaced. These are quotes from the registry from a few months ago: '…the curves have turned to the advantage of the patellar button' and '…previous findings show that patients who have had resurfacing are more often satisfied with their knee' and '…this speaks for a more LIBERAL use of the patellar button.' So the Swedish registry doesn't back up not doing it, it backs up the premise that perhaps we should be doing it more liberally."

"Data from the Australian registry mirrors it almost exactly. There's a 1% difference in revision rate. It holds true for both PS [posterior stabilized] and CR [cruciate retaining]. The argument often put forth is, 'You're only revising it because you can…it's just like for unis.' Actually, if you look at unis (registry data) it isn't just because we can, it's because they're having problems. What doesn't work: going back and trying to resurface it if you've done the wrong thing in the first place, i.e., leave it un-resurfaced, to go back later and resurface it…that's about a 50% success rate."

"We're not that good at revising people for pain, so it's the same for a total knee and it's the same for an un-resurfaced patella. It's not an indictment of the original procedure; it's an indictment of our ability to revise people for pain. The trend in Australia is rapidly changing: 41.5% were resurfaced in 2005 and four years later it was 47%."

"The weakest argument I've seen is, 'Don't resurface to preserve bone stock

and prevent fractures'. Give me a break. There's no evidence that that's true and there's a great publication about a year ago looking at a series of fractured, unresurfaced patelli."

"Patients have improved satisfaction, lower revision rates, less or equal anterior knee pain…and this theoretical late revision rate does not sway me and the data is certainly pro-resurfacing."

Moderator Thornhill: "Thirty second rebuttal?"

Dr. Dunbar: "I think the strongest argument was the one you said was the weakest, which is the fact that the resurfacing does not lead to increased incidence of complications. That has been published and it's a germane fact given that we're operating on younger, heavier patients. If we're expecting these implants to last 30 years I'm going to want some bone back there to resurface. You must have seen difficult revisions with the patella gone with osteolysis that failed. I think that's the strongest argument to go forward."

Dr. MacDonald: "Then I guess we should do bipolars for arthritic hips because we're going to preserve the acetabulum. The point is, you do today what's going to give the patient the best satisfaction rate…and I haven't seen any data at all to suggest the 50 year old cohort presents at 20 years if you resurface or not resurface with increasing patella problems."

Dr. Dunbar: "How would you rebut the risk ratios from Otto Robertsson? The number one reason for re-revision in Sweden long term is becoming the patellofemoral mechanism. The rest of us are about 10 years out of shift with that country. If you look at what has happened with the UK it's the same curve…it's only 5% now."

Dr. MacDonald: "Otto Robertsson—he's the one who authored the registry data—is saying, 'We should be looking at this again and resurfacing at a greater degree.'"

Moderator Thornhill: "Mike, do you resurface the patella in patients with rheumatoid arthritis who have an active synovitis?"

Dr. Dunbar: "Yes. I do a lot of patella resurfacing, but I'm rethinking this. Somebody has to square the circle. Why is that entire nation [Sweden] that's extremely evidence based that arguably has the largest revision burden in the reporting world on knee replacements, has gone that way? I think that in the younger patient that this is something we need to consider. I think you need to play the Jedi mind trick on these patients. You have got to tell them, 'You are going to have a bit more anterior knee pain, but that's a good thing because I'm going to save that bone for you in the future.' If you warn them and their expectations are met they're going to have a better outcome."

Moderator Thornhill: "Steve, what percentage of patients do you resurface?"

Dr. MacDonald: "Close to 80%."

Moderator Thornhill: "When you resurface the patella do you like to put the largest button you can, do you like it central, medial?"

Dr. MacDonald: "I do an inlay not an onlay. And I put it central."

Dr. Dunbar: "I do what he does."

Moderator Thornhill: "Do you think that the desire to do uncemented components is going to drive to more patellar unresurfacing?"

Dr. MacDonald: "I do because it will be a time issue. If you do an uncemented tibia and then an uncemented femur… to mix a batch of glue and fiddle around with the patella…"

Dr. Dunbar: "I agree, expect that we're going to see a problem with that in the future and we'll have fixation issues, etc."

Moderator Thornhill: "Thank you, gentlemen." ♦

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

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company

Stryker Buys Into China's Spine and Trauma Markets

Stryker Corporation has struck into the middle trauma and spine markets of the Middle Kingdom by offering to acquire Chinese-based Trauson Holdings Company Limited for approximately $685 million.

Trauson is a leading manufacturer of instruments and implants for trauma and spine, and the market leader in trauma for the middle market. Founded in China in 1986 by Chairman Fuqing Qian, Trauson had sales in 2011 approximating $60 million, up 32% year-over-year. Trauson reported revenue in the first half of 2012 equivalent to $33 million, up 28% year-over-year from the prior year period.

Stryker and Trauson have maintained a relationship under an OEM (original equipment manufacturer) agreement for instrumentation sets since 2007. With this acquisition, Stryker will expand its presence in a key emerging market with a product portfolio and pipeline that is targeted at the large and fast growing value segment of the Chinese orthopedic market.

Access to 3,000 Hospitals

The company has over 100 products marketed under its leading brands (Trauson and Orthomed), has an extensive distribution network covering 30 provinces and autonomous regions throughout China, and serves as a supplier of orthopedic products to over 3,000 hospitals.

"The acquisition of Trauson is a critical step toward broadening our presence in China and developing a value segment platform for the emerging markets through a well-established brand," said Kevin A. Lobo, Stryker's president and CEO, in a January 17 press release. "The acquisition of a leading player in the Chinese trauma and spine market underscores our commitment to strengthening our presence globally. With its research and development expertise, manufacturing capabilities and strength of its distribution network, Trauson is a compelling opportunity for Stryker to drive growth in China and other emerging markets for years to come."

Piper Jaffray analyst Matt Miksic said Piper views the China middle market for medical devices as an attractive opportunity, and recognizes that the acquisition "nicely complements Stryker's existing geographic footprint."

—*WE (January 17, 2013)*

Shanghai/Wikimedia and Trabajo propio

Zimmer Spine Is Leaving Austin, Texas

The *Austin American-Statesman* reported on January 10 that Zimmer Spine is closing its Austin, Texas facility.

Zimmer Holdings, Inc. acquired Austin-based Abbott Spine in 2008 for $360 million. About 100 people are currently employed at the facility. An undisclosed number of workers from Austin will be given the opportunity to relocate to the Twin Cities in Minnesota, where Zimmer Spine is headquartered. Zimmer owns a 51,000-square-foot building in Minnesota, which it acquired when it bought out the Swiss company that had previously acquired Spine-Tech, Inc. in 2003.

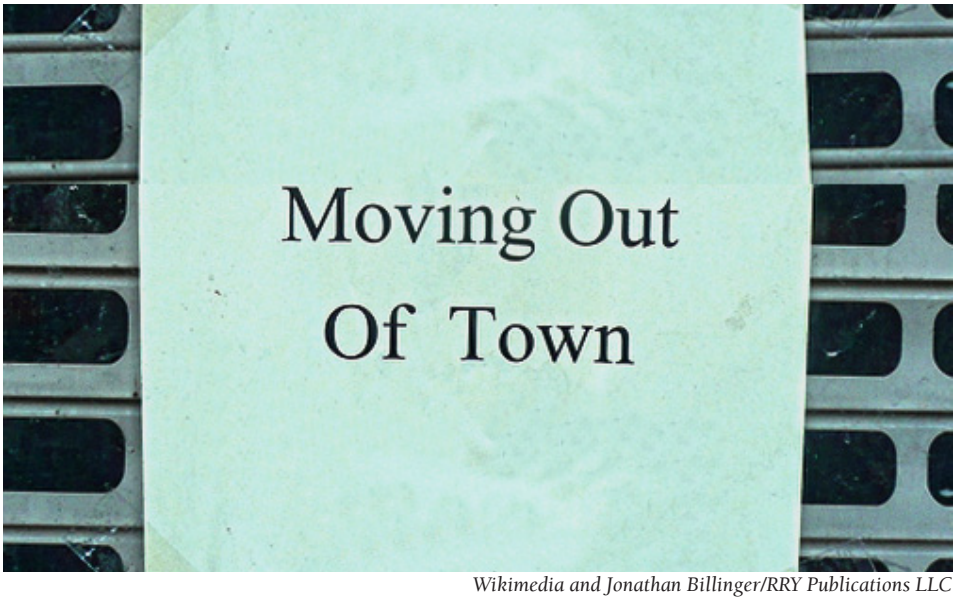
The consolidation is expected to be completed by this coming July. The company issued a statement that said the changes were being made to "streamline its business," by consolidating operations in Minneapolis and Memphis, Tennessee.

Zimmer Spine has been losing market share over the last couple of years, including reporting a 10% decline in sales for the third quarter of 2012. Sales declined each quarter this past year.

When Zimmer acquired Abbott Spine in 2008, Zimmer President and CEO David Dvorak said, "This acquisition is another significant step in executing our strategies to position Zimmer for sustained growth in the future. We are excited to be adding a number of innovative products that round out the Zimmer Spine portfolio and help us build toward critical mass in this important business segment. In addition to bringing great products and a promising pipeline, the Abbott Spine acquisition will add to our research and development capabilities in the spinal category and will strengthen our sales coverage."

Among the key products acquired in the deal were the InCompass Pedicle Screw System; the Pathfinder Minimally Invasive Pedicle Screw system; the Wallis Interspinous Stabilizer System (available outside the U.S.); the Ant-Cer Dynamic Cervical Plate; and the Universal Clamp.

—*WE (January 15, 2013)*



Wikimedia and Jonathan Billinger/RRY Publications LLC

AxioMed Spine Raises Another $3.6 Million

AxioMed Spine Corporation has raised $3.6 million in new financing from current and new investors.

AxioMed Spine HQ/AxioMed Spine Corporation

The Garfield Heights, Ohio, company formed in 2001 is developing products, according to a January 10 press release, "to restore spinal function in patients with degenerative spine disease by advancing the standard of care beyond fusion and first generation total disc replacement." With this round of financing, the company has raised over $37 million.

To date, the company's leading products are the Freedom Lumbar and Cervical Discs. The devices have received CE Mark approval for distribution in the European Union. The company is pursuing U.S. regulatory approval for the technology. The cervical disc is a viscoelastic one-piece total disc replacement featuring a polymer core. The lumbar disc received a CE Mark in 2009 while the cervical disc received its CE Mark in 2012.

Viscoelastic Technology

The company notes on its web site that the first discs to be approved in the U.S. are first generation designs based upon ball-and-socket articulating bearings, modeled after hip and knee replacement

prostheses. While offering some advantages over fusion, such as preservation of motion and reduced complications, they have significant shortcomings and cannot replicate the native function of the natural disc, specifically:

- three dimensional motion
- dynamic stiffness
- load sharing capability
- proper maintenance of the lordotic curve.

AxioMed's viscoelastic technology, according to the company, provides three-dimensional motion that biomechanical testing has shown functions within the natural biomechanics of the spine.

Patrick McBrayer, the company's president and CEO, is the former head of Osteotech, Inc.

—WE (January 14, 2013)

Former DePuy Exec Jonathan Howe Joins Biomedical Structures

Biomedical Structures LLC (BMS) is a developer of biomedical textiles for medical devices. The firm, located in Warwick, Rhode Island, has expertise in knitting, braiding, weaving and has a broad offering of biocompatible absorbable and non-absorbable materials in devices, drug delivery and surgical systems such as bifurcated stent grafts, heart valve solutions, and tapered tendon and ligament repair structures.

BMS is now, through the construction of a 10,000 square foot addition, tripling the firm's cleanroom space. The expansion will provide space for the engineering center to expand product development and increase ultrasonic and roll-to-roll triple cleaning capabilities. According to company officials, there will be more weaving capacity which will be able to handle rising demand for synthetic tendons, orthopedic tissue repair, and other woven textile structures.

To manage this expanded capacity BMS has named medical device industry veteran Jonathan Howe to take on the duties of vice president of research and development. Howe brings more than 15 years of spine, sports medicine, and interventional cardiovascular product experience to BMS. Howe's main job will be to meet the precise performance requirements of these device textiles.

Prior to joining BMS, Howe was the director of research and development at DePuy Spine, where he activated, developed and led a global product portfolio designed to grow DePuy Spine's market share, including the invention of lumbar spine and cervical interbody devices.

Howe also served as the director of new product development for DePuy Mitek, a soft tissue repair/sports medicine device company, and was a product development engineer at Cordis, where he specialized in cardiovascular and neurovascular implants. Howe holds numerous patents and has launched dozens of products and product development programs. He received his BS in Biomedical Engineering from Rensselaer Polytechnic Institute and his MS in Mechanical Engineering and MBA from Massachusetts Institute of Technology.

"BMS is thrilled to welcome Jonathan Howe to our R&D team," said BMS CEO Dean Tulumaris. "We are experiencing a tremendous demand for our biomedical textiles for increasingly sophisticated solutions across the orthopedic and cardiovascular markets. Jonathan's track record of device development and innovative engineering approach are a great fit for our customers' needs as they continue to evolve."

Howe responded saying, "Biomedical textiles can provide the perfect solution for many medical device engineering challenges. A cutting-edge medical textile developer like BMS is in the middle of a perfect storm of opportunity as device engineers look to improve performance and move toward more lifelike solutions for patients. I'm excited to join the BMS team with the chance to truly innovate on established designs."

—BY (January 14, 2013)

Jonathan Howe

legal

Hulk Hogan Slams Laser Spine Institute for $50 Million

Hulk Hogan/Wikimedia

Hulk Hogan is smacking down the Florida-based Laser Spine Institute.

The Hulkster is suing the institute for persuading him to have half a dozen of "unnecessary and ineffective" spinal operations. After all the procedures, his back problems worsened, according to his lawsuit filed on January 14 in Florida state court in Clearwater.

Bloomberg News reported on January 14 that Hogan, whose real name is Terry G. Bollea, said in his lawsuit that he became aware that the surgeries, "may have been unnecessary or performed negligently after reading a 2011 *Bloomberg News* report that detailed complaints that the care offered at the center is expensive and ineffective."

According to his complaint, Hogan says he underwent six procedures over 19 months, getting short-term relief of two to three weeks after each one. The relief was the result of doctors using a laser to burn nerves that eventually regenerate.

Hogan alleges, according to the story, that he was unaware that the institute doctor who urged him to have surgery there also had a substantial ownership interest in the center. He said his health insurer was billed "multiple six figure sums" for the procedures.

Hogan was scheduled to have an anterior inter-body fusion at a local hospital when a friend told him he should consider the Laser Spine Institute, according to the lawsuit. Hogan says he stopped in at the institute without an appointment and met with James St. Louis, the founder of the institute and a neighbor of Hogan's in Belleair, Florida, near St. Petersburg. He said St. Louis talked him out of getting surgery at the hospital and persuaded him to undergo less invasive measures at the institute's outpatient center.

The Laser Spine Institute falls into a gray area of spine surgery that has sparked scope of practice fights between traditional spine surgeons and interventionalists and pain management physicians. The institute maintains a high public profile through extensive advertising but has scarcely been seen or heard from the podium at spine conferences or published results. The North American Spine Society (NASS) logo is prominently displayed on the institute's web site. A NASS spokeswoman told us that the institute was not authorized to use the society's logo and that there was no relationship between the organizations.

One of Hogan's complaints reported by *Bloomberg News* was that his name was used without his permission and that in March 2011 his lawyer ordered the spine center to stop using his likeness.

The institute declined to discuss Hogan's allegations, telling *Bloomberg News* in an email that the institute, "cares about its patients and their outcomes, and is proud to have helped thousands of patients achieve a better quality of life."

Hogan seeks $50 million for lost work opportunities while he was a patient of the institute.

—WE (January 16, 2013)

large joints

Metal-on-Metal Hips to Require PMA

The FDA has decided that makers of metal-on-metal total hip replacement systems should be ordered to submit premarket approval (PMA) applications.

On January 17, 2013, the FDA issued the proposed order along with a series of recommendations to orthopedic surgeons and patients thinking about getting a metal-on-metal hip or dealing with already implanted devices.

Orthopedic surgeons should take extra care in patient selection before using metal-on-metal hips and inform patients of the risks before using the implants. Surgeons should also evaluate current asymptomatic patients every six months and be aware of certain patients who are at risk for increased device wear.

The new recommendations follow last June's unprecedented meeting of the FDA's orthopedic advisory panel, warnings of implant failures from overseas, product recalls and thousands of lawsuits pending against the makers of the hips.

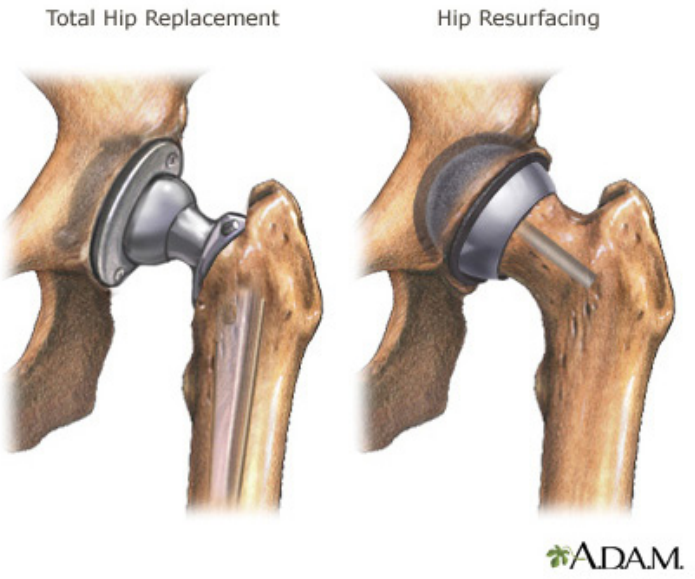
Recommendations for Orthopedic Surgeons--According to the FDA Recommendations:

Before Surgery

- Select a metal-on-metal hip implant for your patient only after determining that the benefit-risk profile of using a metal-on-metal hip implant outweighs that of using an alternative hip system (metal-on-polyethylene, ceramic-on-polyethylene, ceramic-on-ceramic or ceramic-on-metal). Factors to consider include the patient's age, sex, weight, diagnosis, and activity level.
  - o Note that a 2012 FDA advisory panel of experts identified young males with larger femoral heads as the best candidates for hip resurfacing systems.
- Inform patients about the benefits and risks of metal-on-metal hip implants, including the risk that the hip implant may need to be replaced. Also discuss the patient's expectations and review the potential complications of surgery with a metal-on-metal hip implant.
- Pay close attention to patient populations for which metal-on-metal hip systems are contraindicated. Be aware of the risk factors that may predispose a device to excess wear and early failure.

Patient Follow-Up

- Follow-up of asymptomatic patients with metal-on-metal hip implants, including physical examinations and routine radiographs, should occur periodically (typically every 1 to 2 years). If the hip is functioning properly, the FDA does not believe there is a clear need to routinely perform additional soft tissue imaging or assess metal ion levels in the blood.
- Be aware that there are certain patients who are at risk for increased device wear and/or adverse local tissue reactions (ALTR) and should be followed more closely. They may include:
  - o Patients with bilateral implants
  - o Patients with resurfacing sys-



Metal-on-Metal Hip Implants/fda.gov

tems with small femoral heads (44mm or smaller)
  - o Female patients
  - o Patients receiving high doses of corticosteroids
  - o Patients with evidence of renal insufficiency
  - o Patients with suppressed immune systems
  - o Patients with suboptimal alignment of device components
  - o Patients with suspected metal sensitivity (e.g. cobalt, chromium, nickel)
  - o Patients who are severely overweight
  - o Patients with high levels of physical activity.
- Pay close attention to signs and symptoms that may be associated with metal-on-metal hip implants. Please see the website for a list of common ALTRs and systemic symptoms/complications.
- Conduct a thorough evaluation if a patient with a metal-on-metal hip experiences local symptoms such as pain or swelling at or near the hip, a change in walking ability or a noise from the hip joint more than three months after metal-on-metal hip implant surgery.
- Follow symptomatic patients with metal-on-metal hip implants at least every 6 months.

You've got until April 18, 2013 to comment on the proposed order to require PMAs by April 18, 2013. Click here to read the proposed order and submit comments: http://www.gpo.gov/fdsys/pkg/FR-2013-01-18/html/2013-01006.htm

—WE (January 18, 2013)

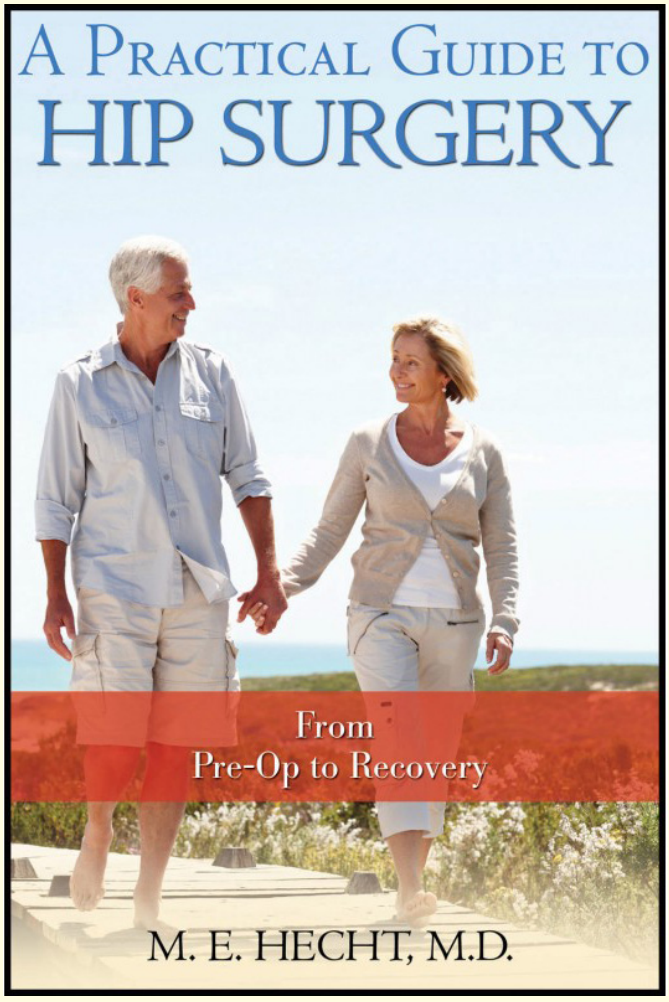
New, Updated Guide to Hip Replacement Announced

Responding to the importance of "patients being part of the solution," M.E. Hecht, M.D., an orthopedic surgeon, has written a guide for patients about to undergo hip replacement surgery. Titled *A Practical Guide to Hip Surgery,* the book provides readers with all the details before undergoing hip replacement or hip resurfacing surgery, directly from an orthopedic surgeon. Hecht has performed countless hip surgeries and has undergone a double hip replacement herself.

Besides informing patients and walking them through the process of total hip replacement or hip resurfacing from diagnosis to recovery, the book is written to be of help to the many orthopedic surgeons who simply don't have the time to explain in-depth the entire surgical process and how to be prepared. The publisher says that the book is meant to augment the materials (pamphlets, booklets, visual presentations) currently available in offices today.

Dr. Hecht besides being an orthopedic surgeon, writes both fiction and non fiction. She has written for *Vogue Magazine*, *The Wall Street Journal, American Medical News, Medical Tribune, Nations Business* and other publications. She is the Assistant Chief of Orthopedics at Elmhurst Hospital, an affiliate of Mount Sinai School of Medicine, New York. The book is published by Sunrise River Press headquartered in North Branch Minnesota. The publisher can be reached at 1-800-895-4585.

—BY (January 14, 2013)



Courtesy of Sunrise River Press

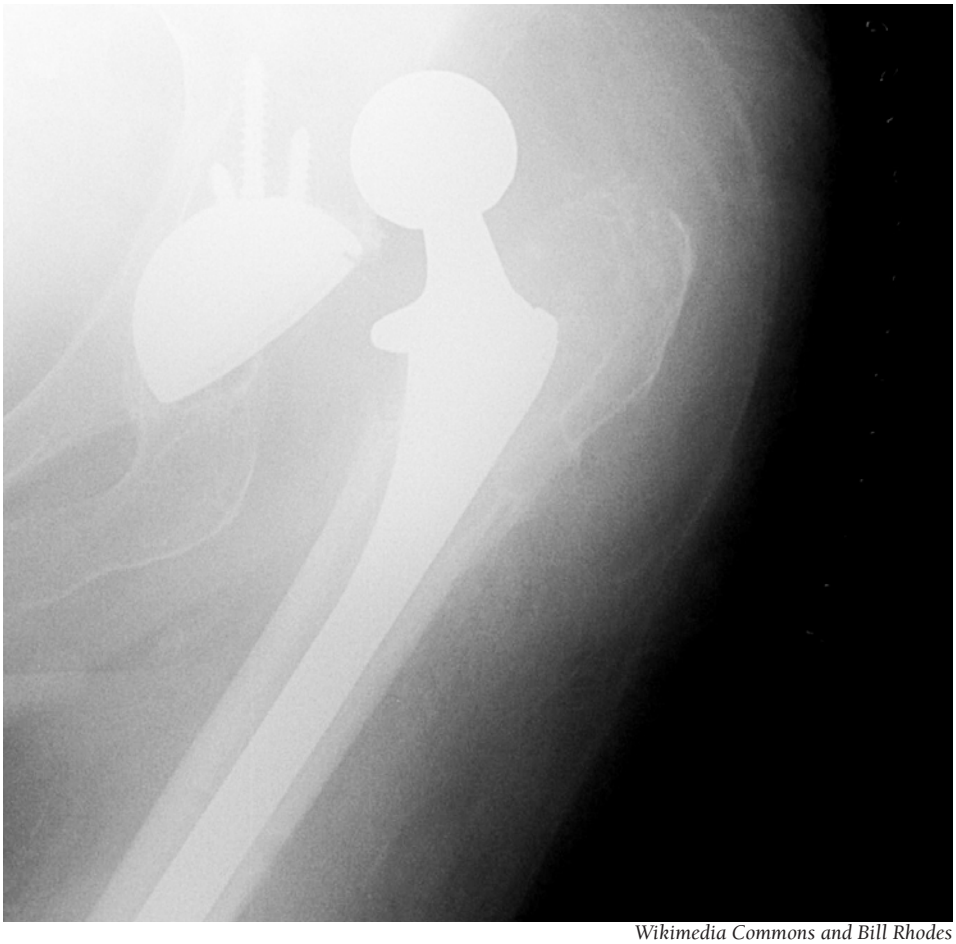
Hip Revision Risk Factors Identified

Which patients are most at risk for having to have a hip replacement procedure? A study conducted at Brigham and Women's Hospital and the Harvard Medical School found that "younger, taller and heavier patients, and those receiving a cemented femoral component, had greater likelihood of undergoing a revision total hip replacement over a 12-year follow-up period."

Researchers examined data on patients who had a hip replaced between July 1995 and June 1996, each of whom was matched with a control patient. They looked at 719 pairs of patients, as well as their hospital records, in order to observe any potential risk factors. They found that patients who were aged 75 or under at the time of their initial surgery were more likely to need revision surgery than those who were older. Taller patients were also more likely to need revision surgery, as were those with a high body weight.

Investigators published their findings, believed to be the first such U.S. study to look for risk factors for hip replacement revision surgery, in the journal *Arthritis Care & Research*. They recommended that, "Effects of age and body size on revision risk should be addressed by clinicians with patients considering primary total hip replacement."

—*BY (January 14, 2013)*



Wikimedia Commons and Bill Rhodes

extremities

$4.4 Million for Limb/ Prosthetic Project

Using advanced composite materials and technology, researchers are moving ahead to a next generation of prosthetic limbs for military-veteran amputee patients. Florida State University's High Performance Materials Institute (HPMI) is leading a major partnership that involves a two-year, $4.4 million contract with the U.S. Department of Veterans Affairs (VA).

Wikimedia Commons, DVIDSHUB

The VA Innovation Initiative (VAi2) project is aimed at addressing the shortcomings of current prosthetic socket systems through the development, testing and delivery of "Socket Optimized for Comfort with Advanced Technology" (SOCAT) prototypes.

"Despite the advances made in prosthetics over the years, the socket continues to be a major source of discomfort for our amputees due to issues arising from poor fit, elevated temperatures and moisture accumulation," said Changchun "Chad" Zeng, an assistant professor at the Florida A&M University-Florida State University College of Engineering and principal investigator

on the project, in the January 16, 2013 news release. "These adverse conditions effectively limit the basic activities of amputees and can greatly diminish their quality of life. This award gives us the opportunity to tackle those problems so our veteran amputees can live better, more fulfilling lives."

The project will result in prototypes that will feature a unique combination of advanced composite materials and technology, some of which are cornerstone research and development initiatives of HPMI. These components, such as auxetic materials, which have the unique property of getting fatter when stretched, and carbon nanotube buckypaper, will be used to enable an intelligent prosthetic socket system that monitors the socket environment. According to the news release, the system automatically adjusts to provide new, unmatched levels of comfort. In addition, vital information on the socket environment, such as pressure, temperature and moisture, will be recorded by the system and wirelessly transmitted to orthotic and prosthetic practitioners to facilitate better patient care.

The SOCAT research team being led by HPMI consists of Advanced Materials Professional Services, the Georgia Institute of Technology, Prosthetic and Orthotic Associates, Quantum Motion Medical and St. Petersburg College.

"This transformative project will leverage the latest advances in innovative materials and advanced manufacturing technologies to build the next-generation prosthetic socket system with significantly improved comfort," said Ben Wang, executive director of the Georgia Tech Manufacturing Institute and a key researcher on the project. "These advanced materials can improve the fit, pressure points, humidity and temperature of the prosthesis so that the patient can wear it longer and much more comfortably."

The first phase of the two-year contract will focus on developing and testing the specific technologies for individual socket components. The second phase will involve the refinement of each system/material and the complete production of the prototypes.

—EH (January 16, 2012)

people

Shane Nho, M.D.:Team Doc for Roosevelt University

Chicago's Roosevelt University Athletic Program has announced the selection of Shane Nho, M.D., sports medicine specialist with Midwest Orthopaedics at Rush, as their new medical provider.

As the new head team physician, Dr. Nho will work to prevent injuries and, when injuries do occur, he will oversee the athletes' safe return to play. Dr. Nho was previously a member of the Northwestern Men's Ice Hockey Team, and currently serves as the head team physician for the Chicago Steel Hockey and Morton High School, Cicero.

Dr. Nho told *OTW*, "My priority as team physician of Roosevelt University is to be sure that we provide the best possible care for the student athletes. We have a team of physicians that can take care of the athletes from head to toe to provide the same expert level of care that we provide to our professional athletes. Communication is critical with all members of the health care team, and the athletic trainers, Michael Hanna and Laujwinae Preacely, have an open door policy when it comes to the care of the athletes. We want to see them, treat them, and allow them to back to the playing field when medically safe to return."

—EH (January 17, 2012)

Midwest Orthopaedics at Rush

Benjamin A. Alman, M.D. to Lead Duke Orthopedics

Benjamin A. Alman, M.D., A.J. Latner Professor and Chair of Orthopaedics at the University of Toronto, is set to become the new chair of the Department of Orthopaedic Surgery at Duke University School of Medicine.

Dr. Alman, who will assume this new role in June 2013, currently serves as a senior scientist in the Research Institute's Developmental and Stem Cell Biology Program at The Hospital for Sick Children in Toronto, where he has been on faculty for the past 16 years. He is also vice chair of research in the Department of Surgery and interim director of the Toronto Musculoskeletal Centre at the University of Toronto.

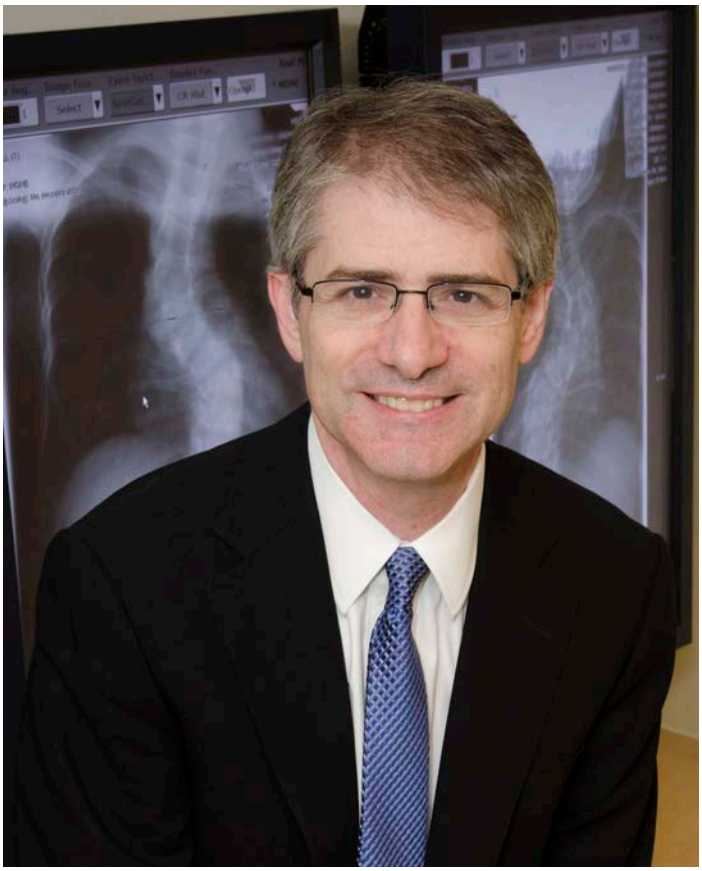
In the January 9, 2013 news release, Nancy Andrews, M.D., Ph.D., dean of the Duke School of Medicine, stated that Dr. Alman is "the ideal leader for our orthopaedic surgery department, one of the country's most esteemed programs. In his new role, he will lead a respected team of more than 60 clinical and research faculty and 55 residents and fellows committed to advancing scientific discovery and enhancing patient care."

His clinical practice focuses on the care of children with syndromes, spinal deformity, neuromuscular disorders, and tumors involving the bones, joints and soft tissues. He also runs an active basic science research program, studying the role of developmental signaling pathways in musculoskeletal tumors and reparative processes.

That research has brought Dr. Alman numerous awards, including the J. Edouard Sampson Award for outstanding research, the Arthur H. Heune Award for outstanding contributions in pediatric orthopaedics, and most recently the Lodwick Award for the best publication in the musculoskeletal field and the Charles Tator Surgeon-Scientist Mentoring Award.

Dr. David Attarian will serve as interim chair of the department until June.

—EH (January 17, 2012)



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