VOLUME 6, ISSUE 13 | APRIL 27, 2010

Orthopedics This Week

week in review

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Spine Procedure U.S. Market Reports	Code
Spine Fusion	
Anterior Cervical Fusion	81.02
Posterior Cervical Fusion	81.03
Anterior Dorsal and Dorsolumbar Fusion	81.04
Posterior Dorsal and Dorsolumbar Fusion	81.05
Anterior Lumbar Fusion	81.06
Lateral Lumbar Fusion	81.07
Posterior Lumbar Fusion	81.08
Refusion	
Posterior Lumbar Refusion	81.38
Other Spine Procedures	
Discectomy	80.51
Decompression	03.09

Large Joint Reconstruction Market Reports	Code
Total Hip Replacement	81.51
Total Knee Replacement	81.54
Revision of Hip Replacement	81.53
Revision of Knee Replacement	81.55
Excision of Semilunar Cartilage	80.6
Cruciate Ligament Repair	81.45
Synovectomy of the Knee	80.76
Removal of Implanted Device Tibia/Fibula	78.67
Hemiarthroplasty	81.52
Hip Resurfacing	00.85

Extremity Market Reports	Code
Ankle Fusion	81.11
Triple Arthrodesis	81.12
Subtalar Fusion	81.13
Total Shoulder Replacement	81.80
Partial Shoulder Replacement	81.81
Rotator Cuff Repair	83.63
Total Ankle Replacement	81.56
Open Reduction of Fracture Radius & Ulna w/ Internal Fixation	79.32
Open Reduction of Fracture Humerus w/ Internal Fixation	79.31
Open Reduction of Fracture Tarsals Metatarsals w/ Internal Fixation	79.37

- *U.S. procedure volumes and forecasts to 2013*
- *Regional and State charging data*
- *Reimbursement rates*
- *Associated diagnoses*
- *Associated procedures*
- *State reimbursement data*
- *Private payer and Medicare data*
- *Comorbidities*
- *Patient demographics*

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(2004-2008 U.S. Procedure, Sales, Charging and Demographic Data as derived from Medicare AND Private Payer datasets)

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Orthopedics This Week

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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Earnings season is in full swing and the news so far is fair. DePuy's sales growth and operating margin helped save JNJ's lackluster pharma and consumer products business while Biomet continues to show that it's a large joint company and still hasn't figured out EBI. SYK outperformed.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	11.00%	-1.20%	It's earnings season. Time for the sixth upside and cash flow surprise in a row.
2	3	Integra LifeSciences	15.37	1.45	Analysts are expecting nearly a 25% pop in earnings this quarter on a respectable 6% sales rise.
3	2	Stryker	24.71	3.59	Strong earnings growth is good but then what do you do with all that cash? How strategic can SYK be?
4	4	Symmetry	11.48	18.78	Analysts expecting a nickel in earnings down from 19 cents a year ago. So who's buying SMA?
5	6	Medtronic	31.37	-2.86	I have a feeling about MDT. Despite the lawsuits and the eroding spine market share, it feels like the calm before resurgence.
6	5	Johnson & Johnson	27.1	-0.49	Free DePuy, Free DePuy, Free DePuy. Seriously, shareholder value would rise.
7	7	Alphatec	-0.44	2.61	This quarter can't look good. Expecting write-offs from Scient'x purchase, but setting stage for strong second half.
8	8	Orthovita	-0.07	-2.08	Analysts are expecting a modest loss to break even this quarter. These are the key quarters for VITA.
9	10	Exactech	12.61	4.68	This quarter should be the last negative comparison of the year.
10	9	CONMED	7.73	-1.19	Can CNMD hit the lofty analysts expectations for this quarter? Consensus calls for nearly 30% EPS growth.

Orthopedics This Week

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Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Symmetry Medical	SMA	$10.88	$390	18.8%
2	Osteotech	OSTE	$4.67	$84	18.2%
3	Wright Medical	WMGI	$18.50	$717	7.8%
4	Exactech	EXAC	$19.89	$256	4.7%
5	Mako Surgical	MAKO	$14.19	$477	4.6%
6	Zimmer Holdings	ZMH	$60.97	$12,360	4.3%
7	Stryker	SYK	$58.89	$23,390	3.6%
8	Smith & Nephew	SNN	$51.87	$9,160	3.0%
9	Kensey Nash	KNSY	$24.10	$264	2.9%
10	Alphatec Holdings	ATEC	$6.69	$362	2.6%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGBO.PK	$0.20	$2	-70.6%
2	TiGenix	TIG.BR	$3.59	$111	-11.3%
3	NuVasive	NUVA	$42.43	$1,650	-8.6%
4	Capstone Therapeutics	CAPS	$0.95	$39	-7.8%
5	CryoLife	CRY	$6.17	$176	-5.7%
6	Medtronic	MDT	$44.21	$48,700	-2.9%
7	Orthovita	VITA	$4.24	$325	-2.1%
8	TranS1	TSON	$3.45	$71	-2.0%
9	Orthofix	OFIX	$35.29	$618	-1.2%
10	CONMED	CNMD	$24.93	$727	-1.2%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Kensey Nash	KNSY	$24.10	$264	13.08
2	Medtronic	MDT	$44.21	$48,700	13.64
3	Johnson & Johnson	JNJ	$65.04	$178,990	13.94
4	*Average*			*$11,828*	*14.40*
5	Zimmer Holdings	ZMH	$60.97	$12,360	14.69

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$51.87	$9,160	79.15
2	RTI Biologics Inc	RTIX	$4.35	$237	49.23
3	NuVasive	NUVA	$42.43	$1,650	38.37
4	ArthroCare	ARTC	$31.65	$852	29.26
5	CONMED	CNMD	$24.93	$727	25.06

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CryoLife	CRY	$6.17	$176	0.69
2	NuVasive	NUVA	$42.43	$1,650	0.95
3	Smith & Nephew	SNN	$51.87	$9,160	1.12
4	Integra LifeSciences	IART	$45.54	$1,310	1.15
5	Exactech	EXAC	$19.89	$256	1.32

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CONMED	CNMD	$24.93	$727	10.14
2	Orthovita	VITA	$4.24	$325	7.07
3	Symmetry Medical	SMA	$10.88	$390	1.92
4	Johnson & Johnson	JNJ	$65.04	178,990	1.86
5	*Average*			*$11,828*	*1.71*

Lowest Price to Sales Ratio (TTM)

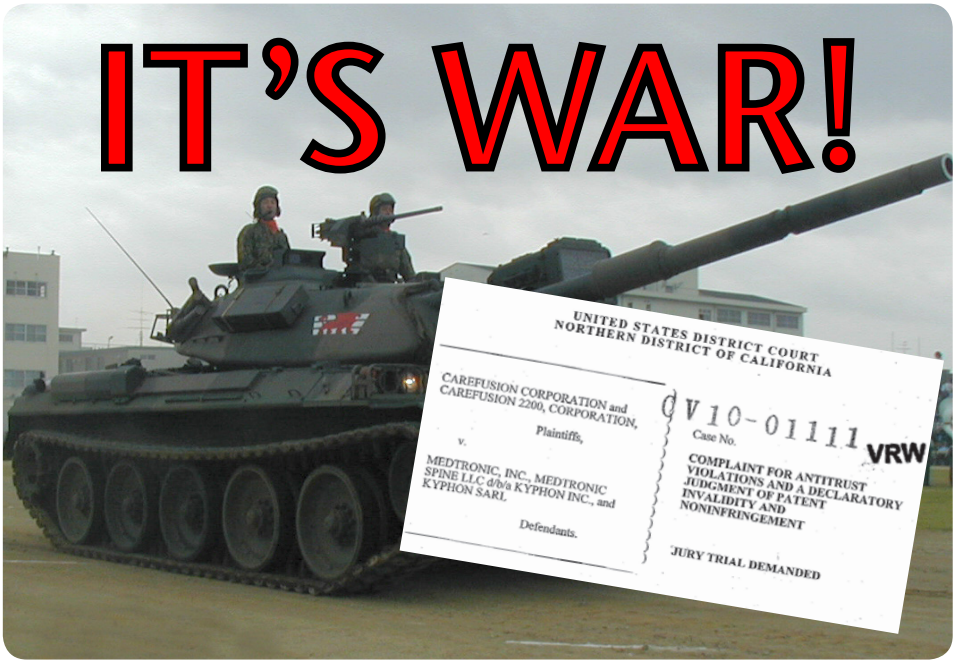
	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$4.67	$84	0.87
2	CONMED	CNMD	$24.93	$727	1.05
3	Symmetry Medical	SMA	$10.88	$390	1.06
4	Orthofix	OFIX	$35.29	$618	1.13
5	Regen Biologics	RGBO.PK	$0.20	$2	1.30

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$3.59	$111	107.34
2	Mako Surgical	MAKO	$14.19	$477	13.95
3	Synthes	SYST.VX	$121.60	$14,431	4.25
4	NuVasive	NUVA	$42.43	$1,650	4.13
5	Orthovita	VITA	$4.24	$325	3.50

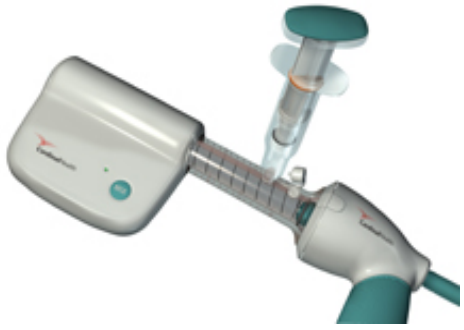
It's War! CareFusion v Medtronic Over Kyphoplasty

By Walter Eisner



CareFusion has a unique strategy for taking on Medtronic/Kyphon, the 800-pound gorilla of kyphoplasty.

First, wait for Kyphon's original kyphoplasty patents to expire, launch your own product and then go to court and accuse Medtronic of cheating to gain a near-monopoly in the marketplace.



AVAmax® Advanced Vertebral Augmentation System/CareFusion.com

On March 15, San Diego-based CareFusion, a recent spin-off from health care giant Cardinal Health, announced its entry into the kyphoplasty market.

CareFusion says the company made a "business decision" to wait until the '888 and '404 patents expired on February 9, 2009, before launching their own balloon kyphoplasty product and seeking FDA clearance for their device. The FDA granted CareFusion clearance on February 23, 2010.

CareFusion's Attack

The first attack came with the introduction of CareFusion's own kyphoplasty product, the AVAmax Vertebral Balloon. The company says it is now the first company to offer surgeons the option of choosing a vertebroplasty or kyphoplasty procedure in one package.

CareFusion's second attack, on the same day, came in the form of a preemptive legal strike to convince a federal judge that Medtronic/Kyphon used invalid patents to gain a near monopoly in their market.

Then out of the blue, Stryker joins the fray by announcing on April 13 that it too was launching its own kyphoplasty product.

Medtronic's Kyphon Challenges

Given Medtronic's well-known challenges since acquiring Kyphon for over $4.1 billion in 2007, we had to

ask CareFusion and Stryker what were they thinking?

First, Medtronic had to settle a $75 million whistleblower case with the feds that accused Kyphon of defrauding Medicare by artificially inflating the price of the product and enticing hospitals to bill Medicare for unnecessary overnight stays.

Then in the fall of 2008, various spine societies, led by NASS (North American Spine Society), wrote a letter to CMS (Centers for Medicare and Medicaid Services), saying that vertebroplasty and kyphoplasty are equally effective in treating VCFs (vertebral compression fractures). But with a significant difference in price, the societies didn't think the more expensive kyphoplasty procedure "added value" to the less expensive vertebroplasty procedure.

Tough stuff in a new era of "Comparative Effectiveness."

Then, to add fuel to the fire, an unsettling study out of the Mayo clinic last summer, questioned whether the actual injection of cement in a vertebral fracture was any more effective then simply fooling patients into believing that cement had actually been injected into the vertebrae.

CareFusion and Stryker Opportunities

Given such challenges, why did CareFusion and Stryker decide to take on Medtronic/Kyphon?

Jim Leitl, Vice President and General Manager of Interventional Specialties for CareFusion told *OTW* during an interview on April 7 that the company estimates the kyphoplasty market to be approximately $600 million globally, with about 65,000 vertebroplasty procedures and 103,000 kyphoplasty procedures performed in the U.S. alone last year.

"We view this as a growth market for CareFusion, and that's why we've launched the AVAmax Vertebral Balloon for kyphoplasty procedures," said Leitl.

He says his company's entry into the kyphoplasty market builds upon their existing leadership in vertebroplasty. Its new device gives doctors the choice and flexibility to perform a kyphoplasty or vertebroplasty at the time of patient care.

Features and Price

Leitl added, "The average selling price of our product will cost approximately 30% to 40% below what we understand the competitor's price to be."

This is no idle challenge by an upstart. CareFusion has over 15,000 employees worldwide, had revenues of $3.7 billion in 2009 and trades on the New York Stock Exchange.

What about Stryker?

David Veino, Director of Marketing and Sales, Stryker Interventional Spine, offered *OTW* following statement:

"It is Stryker's corporate policy not to comment on other companies' litigation or its business strategy behind the release of new products."

He did say that Stryker's new device, the iVas, is part of a single-source system that "is designed to provide surgeons with the option to select the equipment that they believe will be most effective, based on patient indication and individual surgeon comfort level."

Medtronic informed us on April 5 that the company is aware of the filing of CareFusion's lawsuit. "Medtronic expects to prevail in its defense of this complaint and will file its response to the complaint with the court at the appropriate time."

Photo courtesy Stryker

Preemptive Legal Strike

CareFusion may believe that it has a better and less expensive device and will win market share, but why the preemptive lawsuit?

Company officials told *OTW* that Medtronic had made it very clear in various public statements that it intended to use the courts to protect their market position in kyphoplasty. CareFusion executives knew they'd get sued, so they decided to beat Medtronic to the punch.

What exactly is CareFusion accusing Medtronic of doing? Didn't Medtronic win their hard earned 95%+ market dominance in kyphoplasty fair and square by finding and acquiring a better mouse trap?

"Illegal Monopoly and Invalid Patents"

Nope, says the CareFusion suit. The suit alleges that Medtronic made an "illegal attempt to monopolize" the market and acquired "invalid and unenforceable patents" to do so.

The company charges Medtronic with "anticompetitive, predatory, exclusionary, and/or inequitable conduct in violation of the antitrust laws and seeks declaration that Patents '043 ('Inflatable Device For Use In Surgical Protocol Relating To Fixation Of Bone'); '734 ('Systems And Methods For Placing Materials Into Bone'); '110 ('Systems And Methods For Treating Fractured Or Diseased Bone Using Expandable Bodies') and; '054 ('Systems And Methods For Placing Materials Into Bone') are invalid and/or not infringed by CareFusion."

CareFusion claims Medtronic/Kyphon acquired the invalid patents to keep competitive products out of the market. The alleged flawed and "frivolous" patents cited in their complaint include Dr. Peter Bonutti's 23 patents acquired by Kyphon in 2002 for $12.3 million; a $3.2 million buyout in 2003 of Sanatis GmbH that included four pending patent applications; Dr. J. Lee Berger's five patents for $1 million; and the acquisition of an exclusive license of Dr. Harvinder Sandhu's property rights for an undisclosed sum.

Ironically, CareFusion is using the very same arguments made by Medtronic when it was sued by Kyphon, before acquiring them in 2007. In that case, Medtronic claimed Kyphon's patents were invalid.

Two patents that are not in question are the original kyphoplasty '888 ("Surgical Protocol For Fixation Of Osteoporotic Bone Using Inflatable Device") Reiley-Scholten patent initially filed in 1989 and issued on November 13, 1990, and a "continuation-in-part" patent, the '404, issued on April 28, 1992.

Reiley and Scholten, among others, founded Kyphon in 1994 and assigned their patents to the company in 1996.

Lawsuits and Acquisitions

As an example of Kyphon's judicial efforts to keep competitors out of the market, CareFusion cites Kyphon's 2004 lawsuit against Disc-O-Tech Medical. That suit was ultimately settled when Kyphon acquired Disc-O-Tech.

In 2005, Kyphon and Dr. Sandhu sued Medtronic alleging Medtronic "stole Dr. Sandhu's trade secrets…filing patent applications…without naming Dr. Sandhu as an inventor."

During that suit, CareFusion says Medtronic admitted and alleged that the patents asserted by Kyphon were invalid. They say Medtronic asserted that Kyphon's patents "intentionally misrepresented to [Patent Office] that the only known treatment for vertebral compression fractures was bed rest and aspirin."

Before the court could issue a final ruling on Medtronic's claims, Medtronic acquired Kyphon.

CareFusion says that after acquiring Kyphon, Medtronic stopped marketing its own vertebroplasty and kyphoplasty products, "thus eliminating yet another competitive line of products…in furtherance of [Medtronic/Kyphon's] scheme to eliminate competition."

CareFusion's initial January 28, 2009, FDA application for clearance of its kyphoplasty device was "strategically timed" so the company would receive clearance after the '888 and '404 patents had expired. The company received clearance from the FDA on July 1, 2009.

CareFusion's Demands

CareFusion wants a jury trial to make Medtronic account for, as of yet, undiscovered damages sustained as a result of alleged violations of the antitrust laws; to stop threatening CareFusion; to stop enforcing its flawed patents and, declare that CareFusion is not liable for any infringement of those flawed patents.

If CareFusion is accusing Medtronic/Kyphon of suing competitors, before buying them out, is CareFusion looking to be bought out?

Absolutely not, said CareFusion's Jim Leitl during our interview.

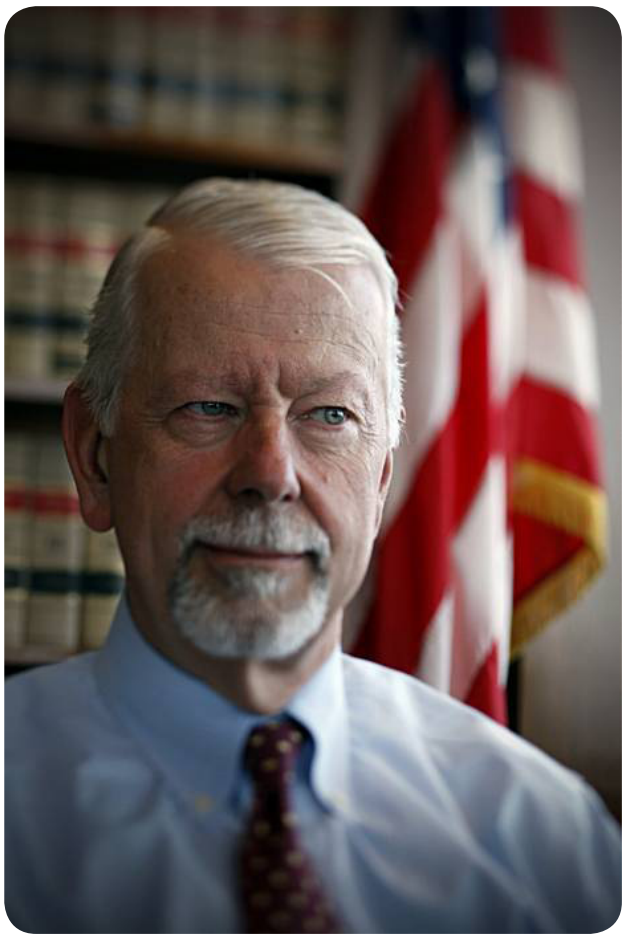
The Judge

"It is hard to predict at this point what will happen in this fight, since Medtronic has not yet been required to file any responsive pleadings so we have no idea what facts support their side of the story," said Melissa Maxman, a Washington, D.C., anti-trust attorney with Cozen O'Connor.

Maxman told us that the judge assigned to the case, Vaughn R. Walker, Chief Judge for the United States District Court for the Northern District of California, has presided over numerous antitrust cases during his more than 20 years on the bench.

She says his rulings have been far from predictable while some have called them unorthodox and controversial. Most recently, Walker has been presiding over the challenge to California Proposition 8, a state referendum that overturned same-sex marriage in California.

Whatever the outcome of this lawsuit, the fight for kyphoplasty market share has begun. Add it to the list of continuing challenges from Medtronic's Kyphon acquisition.



Vaughn R. Walker, Chief Judge

The Tiny Problem of Obese Patients

By Robin Young

Morguefile.com

If Centers for Disease Control data is to be believed, roughly one in four patients crossing the clinic threshold in Oklahoma, Mississippi, Tennessee, South Carolina—indeed 32 states, is technically obese. For reasons every physician understands, the obese patient presents a series of unique challenges and risks. But, the "problem" of the obese patient is both less than expected and, based on a review of the literature, not nearly as critical to clinical outcomes as aging or, interestingly, malnutrition.

Before Your Very Eyes, Obesity Transforms

One complication that does NOT appear to be associated with the obese orthopedic patient is cardiovascular disease. In a Mayo clinic study titled "Body Mass Index and Risk of Adverse Cardiac Events in Elderly Patients with Hip Fracture: A Population-Based Study" which was conducted by Batsis, Huddleston, et al., (Dartmouth-Hitchcock Medical Center, Orthopedic Surgery, College of Medicine, Mayo Clinic) between 1988 and 2002 the conclusion was that overweight and obese patients had NO excess risk of ANY cardiac complications. (We added the emphasis).

The Mayo study was designed to discover the relationship between patient obesity and the incidence of cardiac complications after hip fracture repair. Patient body size in the study was measured using the standard body mass index (BMI) and was categorized as:

- underweight (<18.5 kg/m2)—184 repaired hip fractures
- normal-weight (18.5–24.9 kg/m2)—640 repaired hip fractures
- overweight (25.0–29.9 kg/m2)—251 repaired hip fractures
- obese (≥30 kg/m2)—105 repaired hip fractures

Postoperative complications for the purposes of the study were defined as:

- myocardial infarction
- angina pectoris
- congestive heart failure
- new-onset arrhythmias

All within one year of surgery.

Finally, overall cardiac complications were assessed using Cox proportional hazards models adjusted for age, sex,

year of surgery, use of beta-blockers, and the Revised Cardiac Risk Index.

Here is what the Mayo/Dartmouth researchers found:

1. Underweight patients had a *significantly higher risk* of developing myocardial infarction (odds ratio (OR) 1.44, 95% confidence interval (CI)=1.0–2.1; *P*=.05) and arrhythmias (OR=1.59, 95% CI=1.0–2.4; *P*=.04) than normal-weight patients. Multivariate analysis demonstrated that underweight patients had a higher risk of developing an adverse cardiac event of any type (OR=1.56, 95% CI=1.22–1.98; *P*<.001).
2. Overweight and obese patients with hip fracture had NO excess risk of any cardiac complication.

Then we happened upon this interesting and supporting paper titled *"Comparison of Tools for Nutrition Assessment and Screening for Predicting the Development of Complications in Orthopedic Surgery"* from Ozkalkanli, Ozkalkanli and Katircioglu, et al., (Izmir Ataturk Training and Research Hospital, Imir, Turkey).

In Imir, Turkey, the issue is patient malnutrition—which doesn't mean lack of nutrition. Malnutrition refers to poor nutrition—a condition that may be an independent variable to obesity. In other words, a patient may be obese AND malnourished or obese and NOT malnourished. The researchers used two assessment tools—the Nutritional Risk Screening 2002 (NRS 2002) and subjective global assessment (SGA)—to try to predict the incidence rate of complications in orthopedic surgery patients.

The researchers performed a nutrition screening on 256 consecutively admitted patients scheduled for orthopedic surgery as well as recording each patient's age, gender, body mass index, and American Society of Anesthesiologists (ASA) physical status.

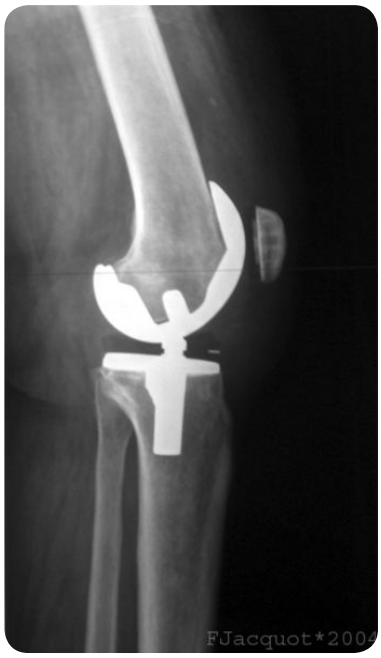
And here is what the researchers found:

1. Malnourished patients stayed in the hospital longer and had higher morbidity and mortality rates. Sensitivity was 50% with the SGA and 69% with the NRS 2002; specificity was 77% with the SGA and 80% with the NRS 2002. Agreement between two methods was 0.672. The odds ratio for the association between malnutrition or risk of malnutrition and the occurrence of complications was 3.5 (1.7-7.1) for the SGA and 4.1 (2.0-8.5) for NRS 2002.
2. Malnourished or nutritionally at-risk patients were **significantly older** than non-malnourished or not-at-risk patients according to the SGA and NRS 2002

For the elderly, both of these studies seem to be saying, malnourishment is a more worrisome co-morbidity than obesity.

Then there is this study by Naal, Neuerburg, et al., (Schulthess Clinic, Zurich, Switzerland and Technical University of Munich, Munich,

Germany) which was published online April 15, 2008, and which tackled the issue of unicompartmental knee arthroplasty (UKA) surgery and the obese patient.



Knee Replacement/Wikimedia Commons

The researchers in this study reviewed the clinical data for 83 consecutive UKAs, two years post- surgery and looked for any statistically significant connection between the patient's BMI and outcomes from a UKA. Naal, Neuerburg, et. al., measured the Knee Society Score (KSS), the University of California at Los Angeles (UCLA) activity level index, the anterior knee pain score (AKP), range of motion and, finally implant failure.

Here is what they found:

1. All of the changes in patient outcome measures occurred independently of the BMI index. So, for example, the fact that the KSS and UCLA indexes increased significantly (from 132 and 4.7 preoperatively to 187.5 and 7.1, respectively, postoperatively) or that knee flexion improved significantly (from 123.7 to 128.4o) or that knee extension deficiencies fell (from 28.9 to 15.7%)—there was no measurable connection to BMI. Three knees (3.6%) failed and were converted to total knee arthroplasty. But, again, none of these changes were associated with BMI.
2. Patient BMI had no significant association with KSS values, UCLA levels or implant failure. Indeed, there was a weak negative correlation between BMI and postoperative knee flexion (r= -0.285, *P*=0.0009) and a moderate positive correlation between BMI and the intensity of anterior pain score (r=0.525, *P*<0.001).
3. The BMI of patients undergoing UKA had no major impact on the clinical outcomes during the first two years post-surgery. There was, however, a definite correlation between BMI and AKP.

One element that may help the obese patient undergoing orthopedic surgery is a comparatively stronger bone stock and, indeed, several researchers noticed the association of obesity and a reduced risk of osteoporosis.

What about the obese spine patient? In a study titled *"Lumbar Spine Fusion in Obese and Morbidly Obese Patients"* by Vaidya, Carp, Bartol, et al., researchers found that obese patients:

- Had lower American Association of Anesthesiologists scores

advertisement

- Had the same surgical time as non-obese patients
- Lost marginally more blood during surgery
- All surgical outcome measures (Oswestry score, Visual Analog Scale) were independent of the BMI of the patient
- The incidence of postoperative complications was significant in 45% of morbidly obese and 44% of obese patients

How About the Formerly Obese?

In a study titled; *"The effects of obesity surgery on bone metabolism: what orthopedic surgeons need to know"* written by Wang A, Powell A. (Department of Orthopaedic Surgery, University of Utah) researchers took a look at the effects of the bariatric surgery on the bone stock of patients.

Bariatric surgery (for example, the Roux-en-Y procedure) reduces the size of the stomach or intestines in order to help obese patients (BMI 35+) lose weight. One of the effects of the surgery is that the primary sites for calcium absorption are bypassed. Bariatric surgery patients may become thinner, but they also become calcium and Vitamin D deficient.

The body's natural response to bariatric surgery is to up-regulate parathyroid hormones which, in turn, trigger production of Vitamin D—which

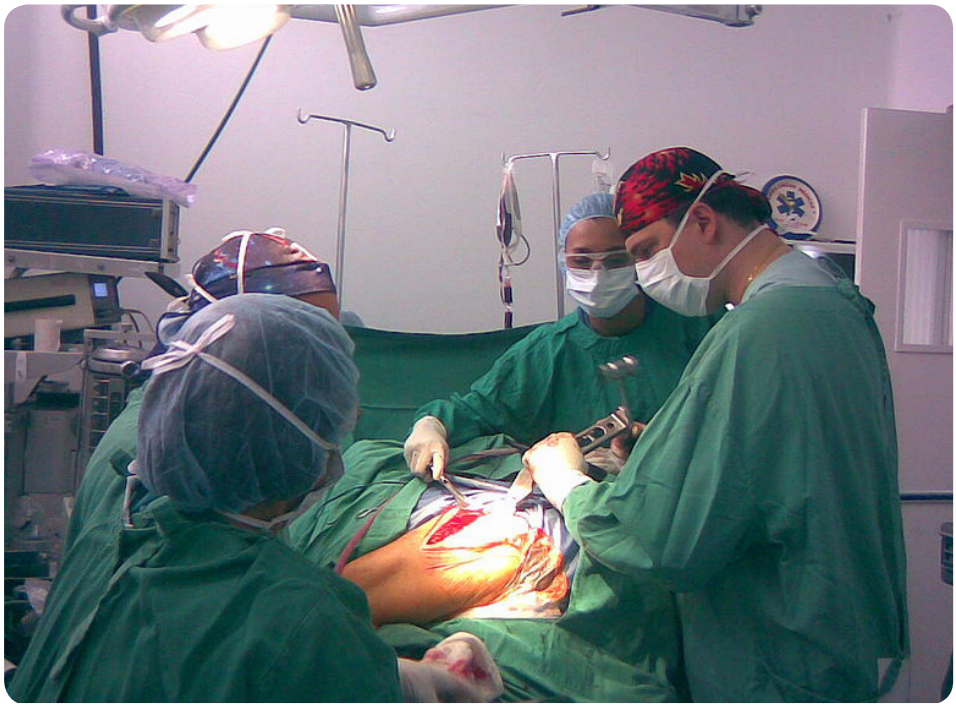
also creates higher rates of calcium resorption from the patient's bone.

Bottom line say Wang and Powell, surgeons treating gastric by-passed patients should be alert to bone density problems, fracture risk, and slow fracture healing.

Keys to a Successful Surgery in the Obese Patient

Generally, obese patients can successfully undergo virtually all orthopedic procedures. But the key to a successful surgery in the obese patient is about reducing risk. So, based on such studies as Drs. Daniel Guss and Timothy Bhattacharyya's (Harvard Combined Orthopedic Residency Program, Massachusetts General Hospital and Brigham and Women's Hospital) study and Winiarsky, Barth and Lotke's study *"Total Knee Arthroplasty in Morbidly Obese Patients (The Journal of Bone and Joint Surgery* 80:1770-4 (1998) here are the keys to successful surgery in the obese patient:

1. Prepare for increased risks of:
   a. Post-op deep vein thrombosis
   b. Avulsion of the medial collateral ligament (TKA patients)
   c. Post-op wound sepsis
   d. Higher rates of hardware failure long term
   e. Fracture mal-union
2. Make use of:
   a. Adaptive OR equipment
   b. Proper patient positioning and alignment
   c. New tools which improve component alignments
   d. Aggressive post-op infection control
   e. Careful and proper intravenous line placement
   f. Central monitoring lines
   g. Anesthesia specific to the physiologic changes in obese patients



Knee surgery/Wikimedia Commons

Finally, pay attention to the nutritional health of the patient. Patients who live at or below the poverty level or are elderly and do not live in areas where they have easy access to healthy foods and dietary supplements or have, for whatever reason, begun consuming foods that are high in fats, sugars, and calories are, in effect, starving themselves. These patients may be obese, but they are also starving—nutritionally.

Studies clearly say that malnutrition may be more important than obesity in determining the likelihood of successful orthopedic surgery. For the wellbeing of patients, the final key is address deficiencies of vitamins and minerals and put steps in place to improve the nutritional content of patient's diet with fish, meat, fresh fruits and vegetables, and whole grains.

The Next Generation Orthopedists: Two Years On

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

Two years ago we traveled through the residency match process with Matt Popa, then a fourth-year student at Case Western Reserve University School of Medicine in Cleveland, and Scott Tucker, then a fourth year student at Tulane University School of Medicine in New Orleans. Recommendation letters, interviews, lists of preferred programs, and what they would like to see done differently were all addressed. Now we're checking in to see how their orthopedic education is progressing.

Scott Tucker, who got his first choice in the match—Tulane University—says that the first year was a bit like wandering through the woods without an Ortho GPS. "Frankly, the first week was rather frightening…and I felt pretty dumb. Suddenly being in a position to write orders, direct students, tell nurses what to do, and interact with patients…well, it was definitely unfamiliar territory. We were fortunate that the upper level residents were willing to let us lean on them."

Dr. Scott Tucker

Indeed, says Dr. Tucker, the issue of independence is one that takes some getting used to. "Learning how to be autonomous in making decisions and taking the initiative to act really takes the entire internship year. It is not until May that you are comfortable and feel that you can defend your decisions if need be. Now that I am finishing up my second year I say to those in the intern year, 'How do you want to proceed?' when it comes to cases. I hope that helps them focus their thoughts and gain some independence."

Dr. Tucker raises an issue that some in the field are pushing for…more orthopedics in medical school. "I would have felt much more prepared for residency if I had encountered more musculoskeletal information in medical school. Orthopedic injuries are so prevalent that it would seem that institutions would want to add time to the musculoskeletal curriculum. This would be especially useful in the beginning of residency, particularly with general fracture management. For example, the curriculum should cover how to handle a sprain versus a displaced fracture. It would also help new residents to understand what are true orthopedic emergencies and what can wait. More orthopedic instruction in medical school would benefit budding general surgeons as well. If general surgeons were required to do a month of orthopedics as interns they would have a better idea of what we orthopedists are looking for. Many times, in a trauma case, for instance, the general surgeons are on the front lines and are calling us for assistance. It would help if they had some preliminary information."

Describing the breakdown of year one, Dr. Tucker states, "During the intern year, we had three months of orthopedics, along with nine months of things like radiology, plastic surgery, ER, general surgery, trauma surgery etc. I think an anesthesia rotation would be interesting, and would give us a basic understanding of why certain types of anesthesia are given to which patients. We would be able to learn about local and regional blocks, the former of which is useful when we have to do fracture reductions in the ER. Plastic surgery is an area where we could have probably used a bit more information regarding wound care. The plastic surgeon at our institution did take pains to show us how to handle anything involving the lower extremities where there was a soft tissue defect. It was helpful to learn about the best ways to prepare a wound, and to find out what kind of flap should be applied."

"I wish I had spent more time in a true trauma ICU." While most patients wouldn't utter these words, some novice surgeons might. Dr. Tucker: "I could have used more exposure to a true ICU setting. We were in a general surgery stepdown ICU where the patients were recuperating after elective surgery. Being in a real ICU would have made it clear when someone really needs to be operated

on immediately, or when the surgery can wait. The only exposure to true trauma ICU patients was during the on-call nights during my trauma surgery rotation (and they had ICU residents covering most of those patients). More exposure to resuscitative measures would have been helpful."

The reality of his newly minted doctor status settling in, Scott Tucker entered the second year to find, well, more of everything. He notes, "Year two is harder, busier, and involves longer hours. The counterweight was that it was more interesting and I found myself caring more and feeling more wedded to the field. Starting Post Graduate Year 2 (PGY2) did involve more of a fear of the unknown, however, since I had become the first orthopedic responder and was responsible for things that I wasn't in my intern year. Like most of my fellow residents, I became overly vigilant as I went about my day. I spent a lot of time trying to get comfortable with fracture reductions, made especially challenging because various fracture patterns behave differently. It was also a time that we learned how to physically manipulate people, something you don't do in your first year."

So much of orthopedic treatment is dependent on imaging these days so knowing how to interpret films is especially important. Dr. Tucker states, "I have worked hard to learn how to read the films correctly; I read them all myself and then look to the radiologists for input if I'm having a difficult time. On the history and physical front, we have not delved into that much. Most of my second year has been taking call and learning to take care of trauma patients."

He concludes, "Despite my early hesitancy, I feel much more comfortable with nearly any orthopedic trauma situation when I'm on call, so I think I've achieved the goals intended for a second year orthopedic resident. That being said, I'm more than ready to hand off the primary call duties to the incoming residents! We orthopedic residents essentially get two intern years, so I'm looking forward to a little more sleep and more time to study. I've been lucky to have the opportunity to do a lot of surgeries this year, particularly in the trauma setting, which has laid the ideal groundwork for moving forward."

Dr. Matt Popa, now completing his second year of residency at Grand Rapids Medical Education and Research Center, reflects: "PGY1 involved three months dedicated to orthopedics, but an entire six months of orthopedic call. With all of this experience, I felt comfortable heading into my second year where I would have much less direct supervision in the ER. Having more responsibility meant that I was doing more procedures, which always looked easier than it actually was. Any skill took a few attempts before I got a feel for it (perhaps I wasn't quite going in the right direction, etc.). Although the first year was very satisfying, it was full of trying times as well. It's through mistakes that we often learn best and each day brought its own humbling educational moments."

He adds, "I'm thankful that I no longer have to rotate on the surgical critical care unit. It was an excellent educational experience because I learned a great deal about the medical management of very ill patients as well as the signs that a patient is in serious trouble. At the same time, it was also rather depressing for the very same reasons…in addition to the occasional poor outcome."


Dr. Matt Popa

As they move forward, orthopedic residents gradually learn how to balance anticipation and trepidation. For Matt Popa, there was more of the former. "Although the second year brought more responsibility, I found it very exciting—especially when I was the only orthopedist on call in the ER. I began my PGY2 call schedule in the summer at our trauma center. I had taken a lot of calls in my first year, so I felt fairly well prepared. On the July 4th weekend we had the basic assortment of wrist, forearm, and tibia fractures. But we did have a dramatic case involving a 15-year-old kid who had stolen a car and sustained a traumatic below knee amputation with a complete fibulectomy when he crashed during the police chase."

With so much knowledge to incorporate, says Dr. Popa, time is very valuable. His advice? "There has been a lot of talk about a reduction in resident duty hours. I would really like to encourage the American Academy of Orthopaedic Surgeons to maintain the 80 hour per week limit. Going to fewer hours per week would handicap us because there would be less time to experience the kind of education you can only obtain by being in the hospital."

The conversation in the hallways is indeed intense regarding changes in the health care environment. Dr. Popa: "We talk a lot these days about the upcoming changes to resident education by the Accreditation Council for Graduate Medical Education/Institute of Medicine and the current health care reform legislation. I would prefer that the government have a much more limited role in health care and health care decision-making, as would most of the residents in my program."

On the patient communication front, Dr. Popa has learned one thing that is not quite what his previous instructors said it would be. "In medical school there was a strong emphasis on patient autonomy, certainly a fine ideal with regard to patient interaction. I am finding that, practically speaking, there are a number of patients that are comfortable deferring to the doctor's opinion. Most importantly, honesty, humility, and a sense of humor form the foundation for a solid patient-doctor relationship."

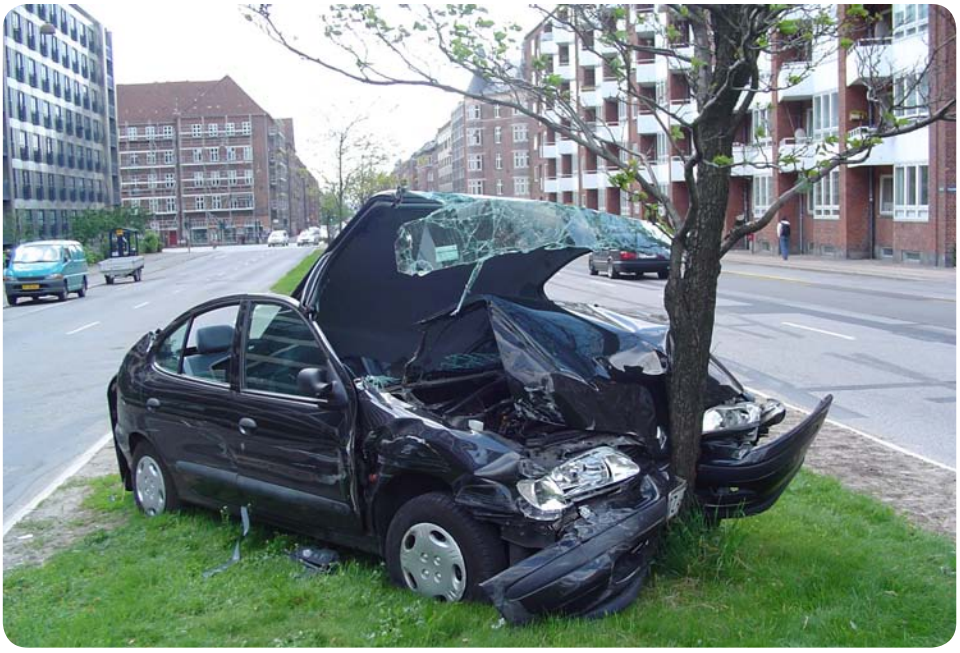
Then there are those patients, says Dr. Popa, who require extra care and attention. "Many of the patients referred to our resident clinic tend to be more difficult individuals. These patients end up in our clinic because of insurance or compliance issues or both. They can be trying and are often not the most rewarding. The bottom line is that it is hard to help people who won't help themselves."

"My knowledge and patient care have really developed these past two years, but I also understand more and more each day just how much there is to learn and to experience. As I've been told more than a few times, there's a reason it's a five-year program."

And we will check in with Matt and Scott as they progress through their programs.

Car Crashes Aid Grappling With the FDA

By Biloine Young



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Lisa Ferrara credits her experience working as a forensic scientist investigating car crashes and child abuse victims with teaching her how to negotiate with the FDA.

As she explained between sessions at the recent "Preservation of Motion in the Spine" conference at Hawks Cay, Florida,

> *"The hardest part of forensic science was dealing with the attorneys and learning how to play the game. It was not about what you knew but about strategy, how you present it. That is why working with the FDA now works out so well for me. I had all that prep. If I can do it with attorneys I can do it with anyone."*

Ferrara, who holds an undergraduate degree in electrical engineering, a masters in neuroscience and bioengineering and a Ph.D. in biomedical engineering, was looking to earn extra money while doing research at the Cleveland Clinic and took a job moon-lighting as a forensic engineer. She admits that, at the beginning, she hardly knew what she was doing but quickly found that her laboratory research testing bone and tissues and understanding how they failed or how they responded to various forms of stress was fundamental information that could be applied to anything.

Ferrara was soon the head of the musculoskeletal and brain injury division of the Robson Forensic Engineering Company. She participated in the development of a ski helmet, called the "Team Wendy Helmet," using a novel smart polymer. But plastic helmets have limitations—including wear from sun exposure and, often, incorrect strap adjustment by the skier. Her analysis of the effects of head trauma, which she used to help design "Team Wendy Helmet" led Lisa to be asked to serve as an expert bone trauma witness testifying at trials. Her forensic analysis would begin with such evidence as accident reconstruction reports that showed the movement of the vehicles, the damage, the forces involved, skid marks and other patterns, before moving on to medical records, photographs and physical evidence such as blood or blood patterns.

Her vehicular experience ranged from head injuries to deaths. One plaintiff complained, "I broke my finger on the air bag," while another, who must have had his arm raised at the time of impact, lost an arm from the air bag deployment.

Ferrara's most memorable case, the one she is most proud of, was one in which a family had had its three

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children taken from it for two years because the mother was suspected of child abuse. One child was believed to be suffering from "shaken baby syndrome," a rotational type of brain injury because he had mild retinal hemorrhage.

Ferrara spent a great deal of time studying records and the literature on shaken brain injuries and discovered that impacts to the brain can also cause retinal hemorrhaging. Her investigation convinced her that the child had not been shaken but had fallen on carpeted steps, had rehabilitated successfully and exhibited no signs of child abuse. She was able to convince the jury of that fact with the result that the mother did not go to prison, as would have been the case if the defense had not prevailed, and the children were returned to their parents.

Currently, Ferrara will only participate on the defense side for medical device companies. One attorney called her about a client, a 27-year-old man suing over a fractured pedicle screw.

When Ferrara questioned further she learned that the plaintiff weighed 450 pounds, was a smoker who had emphysema, and was also a diabetic—a high risk for a non-fusion. "They were trying to say that the screw broke due to a faulty design causing him extreme pain. However, his prior medical history put him at a much greater risk of a non-fusion that could result in screw or implant failure over time. The screw, if you read the label, is for temporary fixation until the bone heals. Of course it did not fuse based on his poor health at the time. The attorney later dropped the case against the medical device company"

Ferrara and her husband now own a consulting company and a testing company for medical devices based in Southport, North Carolina, called Orthokinetics Technologies LLC. She

takes her client companies through all of their pre-clinical work and makes all of their submissions to the FDA for them. She maintains that...

> ***"what you have to prove to the FDA is different from what you have to prove clinically and they do not always overlap."***

She explains. "Take cervical discs. I always ask my clients about whiplash in vehicular crashes and the possibility of implant migration. If the manufacturer is developing a cervical implant and the implant extrudes during a vehicular crash, they will have a law suit on their hands *even if the device is not to blame!* If someone with a cervical disc is in a low-speed rear-end collision and their implant migrates, they will blame the medical device company."

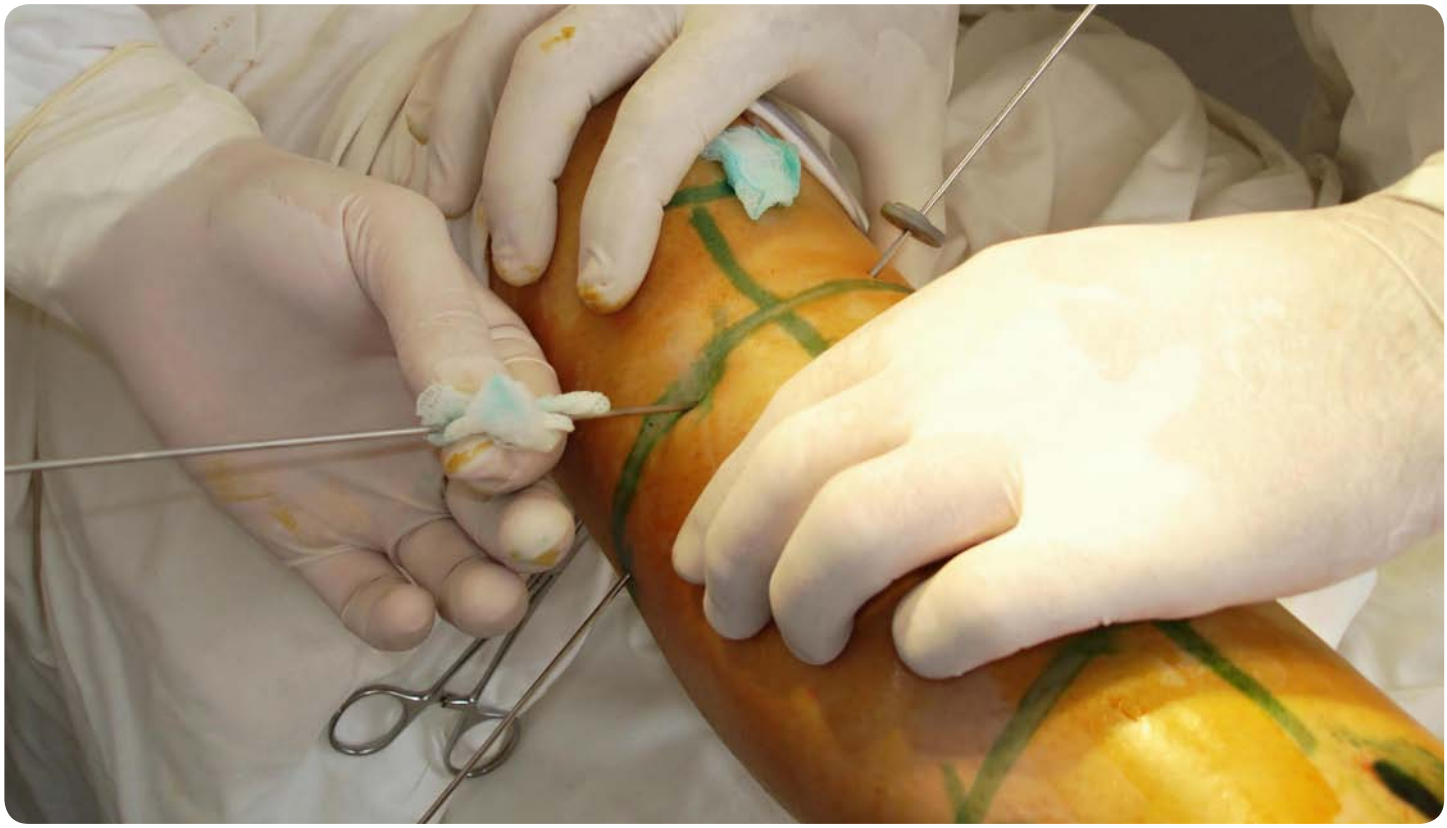
Ferrara urges medical device companies to run whiplash studies with their implants in place and document as carefully as possible the migration patterns as a possible way to minimize potential liability. She wants her client companies to be prepared, to have tested their devices in advance for all kinds of eventualities. "What you do for the FDA may not answer all of the questions in the future," she says.

> ***"If someone gets injured, how are you going to protect yourself from lawsuits? Can you say, we did enough testing before hand to protect the company from liability—here is our test report?"***

Ferrara finds dealing with the FDA "currently a struggle." She believes some of the problem is political "which has nothing to do with science," and young FDA reviewers with little actual clinical experience. She also points out that much of the Department of Justice crackdown on orthopedic surgeon consulting contracts and recent articles in the national media may have led to mistrust between the agency and device manufacturers. Her opinion is that the FDA has become isolated in recent months.

"We need to open up that communication chain with the FDA," she said. "We need to work together, not as separate entities or as adversaries. These surgeons and engineers are brilliant people. The FDA needs to have more trust and work with them as a team. We need the FDA to say, 'Look, we will talk with you guys. Let's form a group and raise the questions together. What are your concerns? What evidence do you have to allay those concerns? Let's address these questions, look at them from all angles.' We need to act as a team with many different disciplines that can contribute to the evaluation of medical devices in a clinically relevant manner."

Ferrera sees communication as a joint obligation. Surgeons and device companies have to make sure they are putting safe products into people. "It is our reputation too," she adds.



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The result of the uncertainty with the FDA, in Ferrara's opinion, is a stifling of innovation. "The FDA is requiring clinical studies with many 510(k) submissions—which are based on predicate devices. Those kinds of demands have slowed innovation. I do not want to see innovation disrupted. The result of all this is that innovation is going abroad," she said. "I have had five companies call me in the last month to say, 'We are not going to develop in the United States.' The American medical care system has been famous for innovation, for developing devices that are safe, and helping people live longer lives. "That is what we have been known for," Ferrara says. "To stifle that activity is frightening."

For more information about Lisa Ferrara and her consulting firm, go to www.orthokintech.com.

company

Stryker Launches Kyphoplasty

Stryker is taking on Medtronic in the kyphoplasty business.

On April 13, Stryker's Interventional Spine unit announced the release of the iVAS inflatable vertebral augmentation system. The device is cleared for use in treating vertebral compression fractures (VCFs).

A company announcement stated that with the introduction of iVAS, "physicians now have a single source for VCF solutions. The device is part of a portfolio of mixer and delivery systems, bone cements and needles for both vertebral augmentation (also known as balloon kyphoplasty) and vertebroplasty, widely used to treat the intense pain caused by VCFs."

This follows on the heels of San Diego-based CareFusion's release on March 15 of their own kyphoplasty device, the "AVAmax."

Why?

Why would Stryker release a kyphoplasty device when spine societies have told Centers for Medicare and Medicaid Services that the more expensive procedure does not offer additional benefits over the cheaper vertebroplasty?

David Veino, Director of Sales and Marketing for Stryker Interventional Spine, offered a glimpse to that answer.

> "Every spine is unique and every fracture is different, that's why we've invested in developing the largest, most complete portfolio of products for treating VCFs. Stryker offers solutions for both vertebral augmentation and vertebroplasty procedures, giving physicians the flexibility to customize their treatment approach based on the type of compression fracture and patient anatomy."

Veino went on to explain that Stryker's ability to be a single source of VCF solutions "allows physicians to form a cost-efficient partnership with a single vendor, potentially saving them time and money."

Stryker Kypho Features

The company cites five key features, which, "help promote enhanced procedure efficiency and outcomes":

- The stiff distal balloon catheter provides rigidity for smooth insertion
- A flexible proximal catheter allows for easy maneuverability
- The radiopaque markers on the balloon catheter help facilitate accurate visualization and placement of the balloon
- The hand drill cuts cleanly through cancellous bone to create a channel for balloon placement
- Graduation markings on the access cannula assist in measuring needle depth

Room for Competition

There's plenty of room for competition as Medtronic has a reported 95% market share for kyphoplasty procedures. In fact, CareFusion is suing Medtronic for trying to monopolize the marketplace. We will have a feature story on that lawsuit.

—WE (April 19, 2010)

Stryker iVAS/Stryker Corporation

company

DePuy and Devices Save J&J's Quarter

DePuy's parent, Johnson & Johnson reported on April 20 that first quarter reported revenues for 2010 were up 4%.

The conglomerate's medical device division's reported revenues rose 12.5% to $6.22 billion and DePuy's revenues rose 12.5% to $1.45 billion.

On a reported basis, hips rose 15%, knees were up 14% and spine rose 3% on a constant currency basis.

This has become a recurring theme over the past few quarters as medical devices have pulled revenue growth along.

J&J Profits Tempered

Medical devices will have to continue to shore up anemic pharmaceutical and consumer products sales. The company posted its first annual revenue decline since the Great Depression last year and expects the combined impact of the health care overhaul, currency fluctuations and generic competition together to hold down profits the rest of the year by a nickel per share.

However, company CFO Dominic Caruso spoke favorably of the new health care bill.

Reform Offers Growth, Access and Stability

Caruso told analysts that the company now has a clear view of the coming financial picture with the 2.3% excise tax on medical devices that takes effect in 2013. He said the new legislation offers the company potential for growth, increased patient access and a more stable and sustainable health care system. In response to an analyst

Created by RRY Publications / Image sources: DePuy

company

question, Caruso said it was too early to tell whether or not the company will pass on the tax to consumers or how they might find internal savings to make up the extra cost.

Market Comments

In prepared comments, Caruso said pressure on DePuy's pricing continued as a result of the economic trend, however, positive mix due to continuing product innovation has mitigated much of the impact.

Continued Caruso, "Our estimated [hip] market share leadership position in the U.S. widened sequentially throughout most of 2009 with the year-end position estimated to be four points higher than the next competitor. The growth outside the U.S. was driven by the success of the Acetabular and Cementless systems."

He noted growth in knees was due to the strength of the underlying business complemented by the new product launches.

Pricing pressure in spine impacted the growth in the U.S. where sales were flat for the quarter.

PearlDiver Senior Analyst Scott Ellison told *OTW*, "Based upon the quarterly call, operational growth was 11% and 9% for hips and knees respectively—overall a very good quarter. Both hip and knee revenue growth was in line with PearlDiver estimates of 13% and 8%. The best news for large joints was the improvements to OUS (outside U.S.) numbers with 16% in hips and 8% in knees."

Cash Hoard

A final note. During the quarter, the company increased its cash hoard by $1 billion, to $6 billion. Caruso didn't tip his hand about what the company might do with that pile of cash. With consolidation in the spine industry on everyone's mind, J&J is well positioned to act when its opportunities seem ripe.

—*WE (April 21, 2010)*

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Stryker Scores With Small Ball

You can always tell when Stryker's Steve MacMillan is happy. He starts talking like the baseball manager of the Kalamazoo Kings, who play at Homer Stryker Field.

Wikimedia Commons

Describing the past year of challenges for Stryker and the orthopedics industry in general, MacMillan told analysts on a quarterly conference all on April 20, that while the company had to play lots of defense during the past year, they also went on the offensive.

"We have been a company in triage, but kept our heads above water with lots of singles and doubles."

On a reported basis, Stryker's revenues for the first quarter of 2010 rose 12.4% to $1.799 billion.

company

Stryker 1Q10	Sales ($ in millions)	% Change
Net Sales (Reported)	$1799	Up 12.4%
Orthopedic Implants	$1077	Up 10.7%
Hips		Up 9.0%
Knees		Up 12.0%
Trauma		Up 15.0%
Spine		Up 10.0%

Source: Stryker

"There's a lot we feel good about," said MacMillan, not the least of which was finally making progress in resolving the FDA warning letter at its Mahwah, New Jersey, plant. He described a "cultural transformation" of the company's quality and compliance programs and said the company had reaffirmed its $200 million commitment to the FDA for quality assurance upgrades.

MacMillan said, "There is still work to do as our instruments, spine and some of our international businesses are not performing were we like to see them."

The only foul ball from analysts came when BMO analyst Joanne Wuensch asked the manager if he was ready to pull the plug on the disappointing draft pick, OP-1. MacMillan said the company was continuing to evaluate its options and would address that issue in the near future.

Wuensch wrote in an investor note that new products continue to be a catalyst for the company's recovery, including :

- The ADM hip, a large-head, mobile-bearing hip system—a competitive response to metal-on metal large-head systems without the risk, launched at AAOS
- Rejuvenate modular primary hip system launched at AAOS
- Customized or personalized knee systems through OtisMed—the benefit of this type of system is less instrument sets, better fit and less OR time; management expects 510k approval in 2010
- New cervical plate systems—expected to fill product gaps and meet price pressure, impacting the top line towards the 2H2010

Looking ahead, Wells Fargo senior analyst Mike Matson says with an improving economy and easy comps in the next two quarters, he thinks Stryker's revenue growth is likely to show further improvement. However, he doubts that the company can return to its historical double-digit revenue growth this year. He also believes, with $4 billion in cash, further acquisitions are likely.

—WE (April 23, 2010)

biologics

Millstone Medical: Human Tissue Bank

A license to provide white glove service…Millstone Medical Outsourcing, partner to numerous orthopedic companies, has announced that its Memphis, Tennessee, facility has registered with the FDA as a human tissue bank in order to expand services to manufacturers of products containing human cells or tissues used in surgical procedures. The company has also completed specific registration and licensing requirements necessary to store and distribute human tissue and bone products in six states and is pursuing registration or licensing in four more.

Millstone is a provider of advanced inspection, clean room packaging, loaner kit processing, and distribution services. The registration process that they have just come through involves fulfillment of a wide variety of technical requirements related to environmental controls, equipment, supplies, labeling, tracking, as well as processing, storage, and distribution. According to the company, the human tissue bank protocols will be provided in conjunction with the Memphis facility's services, including warehousing and distribution, returns processing, and loaner kit processing. The Memphis location was selected to enable customers to take advantage of later ship times, which will reduce transit times, enhance quality, and decrease costs.

"At Millstone we are continually looking for innovative ways to serve our customers," said Christopher Ramsden, Chief Executive Officer, in the news release. "Registration as a human tissue bank allows us to offer customers a broader range of services that enhance quality control and cost savings."

Regarding the process, Jonathan Tillman, Millstone Vice President of Sales told *OTW,* "We registered with the FDA first and then began the process of registering with individual states. Registration with the FDA was incredibly smooth because their guidelines are very clear and they provided outstanding support in meeting the necessary standards. State-by-state licensing and registering is sometimes challenging because each state has different requirements. We've completed the process in six states (Connecticut, Delaware, Illinois, Louisiana, Oregon, and Tennessee), and are on track to finalize four more (California, Florida, Maryland, and New York)."

—EH (April 21, 2010)

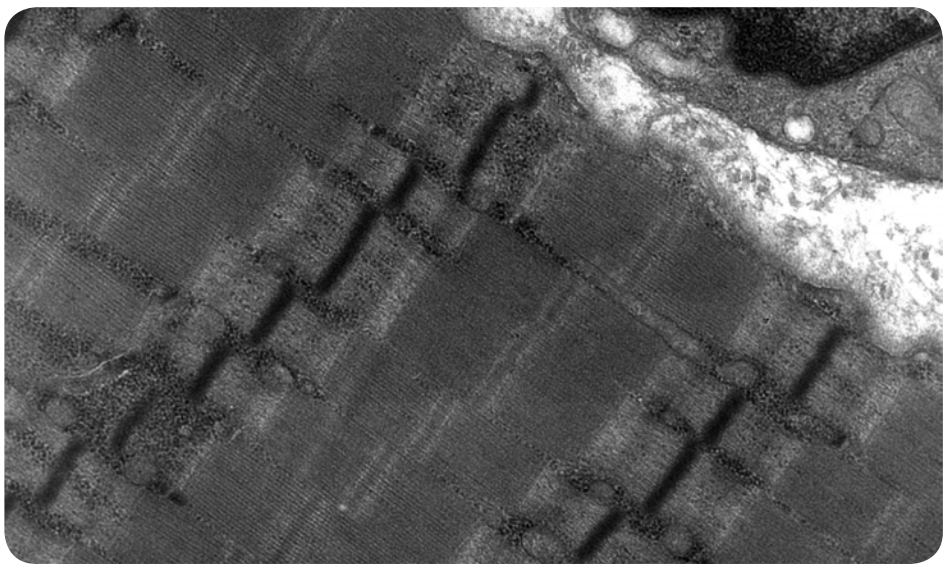

Image of a thin longitudinal section cut through an area of human skeletal muscle tissue
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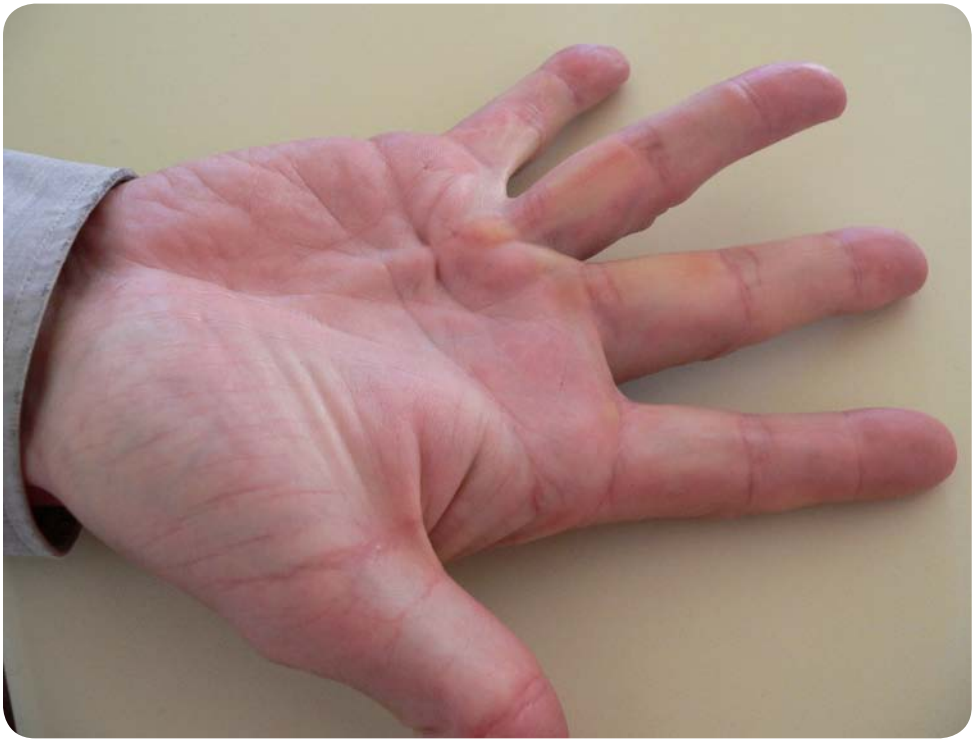
extremities

Stony Brook Holds Dupuytren's Symposium

Nothing like the power of numbers to conquer a villain. At Stony Brook University Medical Center, Stony Brook, New York, they're trying. The school's Department of Orthopaedics, along with the Office of Continuing Medical Education, has recently held a CME program on Dupuytren's disease, a debilitating hand disorder caused by progressive accumulation of collagen that deforms fingers and limits motion and affects millions worldwide.

large joints



Frank C. Müller/Wikimedia Commons

Among those in attendance were hand surgeons, hand therapists, rheumatologists, and researchers, who had access to a variety of programs, including more than 25 presentations by international leaders in the fields of hand surgery, therapy and orthopedic research. Presentations included: Pathoanatomy of Dupuytren's Disease, Open/Segmental/Dermato-Fasciectomy, Needle Fasciotomy, Managing Recurrent Dupuytren's Disease, Collagenase Clinical Development, Collagenase Storage/ Reconstruction, and Injection and Manipulation Techniques.

Also on the program was a discussion of the drug recently approved by the FDA for Dupuytren's disease that was discovered and developed by Marie A. Badalamente, Ph.D., and Lawrence C. Hurst, M.D., in the Department of Orthopaedics at Stony Brook University Medical Center. The new treatment, an injectable form of the enzyme, collagenase, that significantly improves outcomes in many patients with the disease, is the first FDA-approved non-surgical treatment for Dupuytren's disease.

The Department of Orthopaedics at Stony Brook University Medical Center is opening a "Dupuytren's Institute" to further support patient care, research, and educational aspects of this debilitating disease that so often interferes with the quality of life, particularly in later years.

Lawrence Hurst, M.D., Chair of Orthopaedics, told *OTW,* "The Dupuytren's Institute at Stony Brook is a patient education and management unit staffed by all six hand surgeons at Stony Brook University Medical Center. The bricks and mortar for the Institute is our current outpatient units which are used for plastic surgery, orthopaedic surgery, hand surgery, and now for the organized care of our Dupuytren's patients. The institute structure will standardize patient information, collect documents, patient education materials, make billing arrangements with various managed care companies, and provide therapeutic recommendations and post-treatment protocols."

Regarding the event itself, Dr. Hurst commented to *OTW,* "The meeting was very successful, with international and national faculty and approximately 100 participants in the CME portion (which was open to the public). We have recorded all the presentations from the CME and the workshop and hope to collaborate with the ASSH to produce a printed and electronic book on Dupuytren's disease."

—EH (April 21, 2010)

large joints

Martial Arts and Osteoporosis

If you're going to fall, you might as well learn how (and you might earn a Black Belt in the process). In an effort to explore whether martial arts (MA) fall training is safe for people with osteoporosis, researchers from the Sint Maartenskliniek hospital in The

large joints

Nakasone Genwa
Wikimedia Commons

Netherlands undertook a feasibility study—and found positive results.

With an eye toward whether MA fall training could help prevent hip fractures in persons with osteoporosis, the researchers extrapolated from the data of young adults and used stringent safety criteria. Young adults performed sideways and forward MA falls from a kneeling position on both a judo mat and a mattress as well as from a standing position on a mattress. Hip impact forces and kinematic data were collected. For each condition, the highest hip impact force was compared with two safety criteria based on the femoral fracture load and the use of a hip protector.

Based on the data of young adults and safety criteria, the MA fall training was found to be safe for persons with osteoporosis if appropriate safety measures are taken. The researchers indicate that during the training persons with osteoporosis should wear hip protectors that could attenuate the maximum hip impact force by at least 65%, perform the fall exercises on a thick mattress, and avoid forward fall exercises from a standing position.

Brenda Groen, an author on the study and scientist at Sint Maartenskliniek, told *OTW,* "This study was performed to determine whether martial arts training is safe for persons with osteoporosis. Based on this study we concluded that our MA fall training was safe for persons with osteoporosis if appropriate safety measures are taken. The martial arts training consists of five weekly training sessions of 45 minutes each and is one element of the Nijmegen Falls Prevention Program for Healthy Elderly and the modified martial arts training is an element of the Nijmegen Falls Prevention Program for Persons with Osteoporosis. In a previous study, published in Osteoporosis International, we found that healthy older individuals were able to learn these techniques and that better performance resulted in a reduced hip impact force."

—EH (April 23, 2010)

people

David Brumfield Joins Custom Spine

He was there when spine was young…and those at Custom Spine will now benefit from what David Brumfield has seen over his 31 years in the field. The company has recently announced that David Brumfield has joined the Custom Spine team as Senior Vice President of Research and Development.

David Brumfield

Brumfield told *OTW,* "I'm very happy to be partnering with the experienced professionals at Custom Spine, who have built a solid foundation of innovative products and superior service for spine surgeons and the patients they serve."

Brumfield, who holds 33 U.S. patents and is well-published in the orthopedic field, began his biomedical engineering career at Richards Manufacturing Company in Memphis in 1979. For 12 years, he moved "up the ladder" and was there as the company became Smith & Nephew, Inc. During his time at that company he made significant contributions to novel orthopedic trauma products, including cephalomedullary nails.

In 1991, Brumfield joined Danek Medical and was ultimately named Vice President of Product Development as the company became Medtronic Sofamor Danek. During his 15 year tenure, he helped pioneer the use of titanium in spinal implants as

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well as minimally invasive surgical instrumentation.

Returning to Smith & Nephew in 2006, Brumfield headed the company's R&D for its trauma division and for four years led that team in several novel developments, including a unique electromagnetic method for distal targeting of intramedullary nails and new biomaterial technologies for the treatment of difficult fractures.

"David is a great addition to the Custom Spine team. We are thrilled to have his depth of knowledge and experience in developing novel orthopedic and spine products. As head of our Research and Development team, David will further propel the company's initiative of providing a full line of advanced spinal products," commented Custom Spine President Lew Bennett, in the news release.

Brumfield told *OTW,* "I look forward to understanding the current challenges faced by spine surgeons in the treatment of spinal disorders and meeting those challenges with the balanced employment of creative design, proven biomechanical principles, and new technologies."

Concerning his experience, Brumfield commented to *OTW,* "My participation in the relatively earlier years of research and development in spinal instrumentation and my continued role in evaluating new designs and technologies for both spine and trauma devices in more recent years will help me to match surgeon and patient needs with technical solutions in the future."

—EH (April 19, 2010)

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Spine & the City

Alphatec Spine hits Times Square with its Technology Day on April 23, 2010, showing off a host of products and offering up information straight from top spine surgeons.

Start spreading the news, Alphatec Holdings, Inc., the parent company of Alphatec Spine, Inc. is hosting a Technology Day for investors and analysts on Friday, April 23, 2010, from 8:30am to 11:30am (EST) in Times Square. The Big Apple event includes a product portfolio with an interactive panel discussion that boasts leading spine surgeons and hands-on product demonstrations from members of Alphatec Spine's management team and business units.

Lynn Pieper, investor relations consultant, says this is the first investor technology day Alphatec Spine is holding in Times Square and in New York for that matter. "The company will be showcasing differentiated products, including certain products that are anticipated to be launched in the upcoming months," adds Pieper. Those in NYC might want to drop by the event's locale at the NASDAQ MarketSite in New York

Times Square, New York City, USA/Wikimedia Commons

spine

City, as there is also the opportunity to speak with spine surgeons about their personal experiences with various spine products, benefits of the products, and their applications.

"Featured in the presentation will be products to treat the Aging Spine (OsseoScrew and OsseoFix), The Arc Portal Access System (GLIF), Alphatec Spine's Advanced Biologics portfolio (including the ELA Osteoprogenitor Cell and AmnioShield), Dynamic Fusion, and other new and differentiated technologies (including the Solus ALIF cage and a Spinous Process Clamp)."

Pieper adds that clinicians may be interested in the webcast, which will feature Alphatec Spine President and CEO Dirk Kuyper, along with the surgeon panel. Besides presentations from each surgeon, an interactive question and answer session from the investment community will be included in the webcast.

In other Alphatec news, having closed the acquisition of Scient'x on March 26, 2010, the company is now moving forward with the integration of this new addition. "Alphatec Spine expects to operate as one entity, with several key benefits coming from Scient'x, including a complementary international distribution platform," explains Pieper. "In addition, Scient'x adds a non-fusion technology platform to Alphatec Spine's core product platform and innovative Aging Spine platform. The combined entity has distribution in over 50 countries and roughly 450 sales reps worldwide, a broad and innovative R&D pipeline, vertically integrated manufacturing and management expertise across all disciplines."

Alphatec is taking steps to combine divergent systems and locations. "Consolidation efforts are underway and through comprehensive planning, logistical issues have been minimized. Mr. Kuyper, and Oliver Burckhardt, the former President and Chief Executive Officer of Scient'x, worked together for several years at Aesculap, Inc., and have similar perspectives on corporate culture and management. Mr. Burckhardt's new role at Alphatec Spine is President of International Operations and Chief Marketing Officer, and he will work closely with Mr. Kuyper through the integration process to ensure its success." Pieper adds that immediate integration plans include the consolidation of U.S. headquarters and administrative costs as well as maximizing the efficiency of purchasing contracts and supply chain management. "With the addition of a significant global distribution platform, Alphatec Spine has also begun to cross-sell products into global markets and expects to accelerate the adoption of Aging Spine product outside of the U.S."

—JR (April 18, 2010)

Mobi-C Prepares for PMA

LDR has completed a two-year follow-up on their two-level cervical artificial disc IDE study. The device, the Mobi-C, will now be prepared for a PMA submission to the FDA. The company hopes to gain FDA approval in 2011.

This news makes LDR the first company to complete such a follow-up, according to company President and CEO Christophe Lavigne. Lavigne says the company is, "now poised to be the first in the U.S. market with a two-level approval for a cervical artificial disc. LDR is positioned to provide the best technology on the market for cervical disc arthroplasty."

The company previously finalized a two-year follow-up phase of the one-level study earlier this year. LDR is now the first company to fully enroll and reach two-year follow-up on a

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LDR's Mobi-C/Photo courtesy of LDR

concurrent one-level and two-level cervical artificial disc replacement study. LDR completed one-level enrollment in October 2007 and two-level enrollment in March 2008.

Introduced Outside U.S.

As we've seen with other innovative devices, the Mobi-C was first introduced outside the U.S. and has been implanted in over 8,000 patients worldwide.

> According to the company's April 20 announcement, the device's design philosophy of controlled mobility, "respects the instantaneous axes of rotation for a return to physiological mobility of the treated level. This innovative mobile bearing is designed to reduce the transmission of stresses to the bone-implant interface, minimizing the need for invasive anchoring features such as screws or keels. Free of this invasive fixation, the Mobi-C could become an excellent option for treating two consecutive levels."

Lavigne added, "We strongly believe that surgeons will select a single product that addresses their need to treat both one-level and two-level patient indications."

Surgeon: "Impressive Clinical Results"

Hyun W. Bae, M.D., an orthopedic surgeon at The Spine Institute in Santa Monica, California, said he found the device, "easy to use and [I] have seen impressive clinical results. Since about half of my patients present with two-level cervical disease, it would be ideal to have a treatment option with both the flexibility and FDA approval to treat two-level indications."

The company's ambitious hope for FDA approval will be closely watched as we've noted the FDA's caution in approving spine devices.

—WE (April 21, 2010)

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The Picture of Success: Dr. Leesa M. Galatz

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

Many orthopedists can thank a human being or two for sparking their interest in medicine. Dr. Leesa Galatz, Associate Professor of Orthopaedic Surgery at Washington University in St. Louis, can thank a few horses. "I grew up in Las Vegas and spent much of my youth as a competitive equestrian. Spending summers traveling to horse shows, and caring for the horses taught me a great sense of responsibility. It also taught me that anything is possible if you work hard. I can thank riding for helping me develop a strong sense of confidence…because of these experiences I never shied away from challenges. A lot of people are afraid of failure, but when you are competing you are going to have downturns and must learn to 'take your licks.' The lesson I learned early on is that these downturns are opportunities, and educational experiences that can lead to self improvement."

After briefly considering veterinary medicine, Leesa Galatz turned her attention toward medical school. The first doctor in her family, she spent family dinners discussing her future with her father, an attorney, and her mother, an administrator in his office. "I was always interested in the sciences, and in particular enjoyed laboratory experiences. I was especially fascinated by the scientific process and how one discovery led investigators to the next…it was the logical thinking and application of new technology that captivated me."

Also intrigued by E=mc2, Leesa Galatz began seriously considering medical school in her senior year of high school. "During an advanced physics course I found an insert on the practical application of physics. My interest was really piqued by an explanation of how the patella functioned as a pulley. I realized one could figure out how to move joints by solving physics problems. I began to see a way forward."

Leesa Galatz's forward movement would take her through a premed curriculum at the University of California at Berkeley. Then in 1989 it was on to medical school at George Washington University (GWU) in Washington, D.C. "I had some preliminary thoughts about orthopedic surgery…then I met Dr. Ken Yamaguchi, who encouraged my interest and mentored me through my last few years of medical school. I wanted to do research, and Ken, along with Dr. Dan Riew, needed someone to work on their rotator cuff project. I recruited a large portion of my medical school class to volunteer to have EMG's of their suprascapular and musculocutaneous nerves. It was a great chance to work with Ken, who gave me suggestions as to where to apply for residency, and Dan, who helped me think critically about my career plan. Dr. Robert Neviaser, the Chair and senior author on the project, sparked my interest in the field of shoulder surgery. He was an inspiration because of his extraordinary drive for perfection."

She would begin two institutions at once—residency and marriage. "David was on a military scholarship; we decided to stay in Washington, D.C., where he went to Walter Reed Army Hospital and I began an orthopedics residency at George

Washington University Hospital. It was an incredible experience, with the downtown campus being more of an academic environment, and Washington Hospital Center being a high volume, inner city facility with a tremendous trauma experience. After a few years, I felt like there was not much I couldn't handle. These experiences gave me a lot of confidence as I progressed through the program. I owe a lot to my faculty who invested time and effort into my education."

Under the tutelage of Dr. Robert Neviaser she would blossom into a clavicle/scapula/humerus aficionado.

> *"The shoulder is particularly interesting because it functions as a combination of bone and soft tissue. For example, in a fracture, you can fix the bone and make it perfect, but if the rotator cuff isn't working, the shoulder will not function. These multiple consideration, namely, bone, soft tissue, and joint stability make it challenging, interesting and a compelling subject for research."*

"Along the way, Dr. Tom Neviaser—the brother of Dr. Robert Neviaser—also influenced me. We residents were fortunate to work with him in his private practice setting, a busy shoulder and elbow practice. He helped me develop a common sense approach to evaluating and treating patients. It was at Dr. Tom Neviaser's hospital and under his mentorship that I did my first research project involving the shoulder—an anatomical study of the subscapularis and underlying capsule. During this time I was doing a lot of reading and learned that shoulder was quite a new subspecialty with a lot of potential—but, unfortunately, without many fellowships."

Facing a limited number of fellowships and a high level of competition, Dr. Galatz could have backed down. But being a natural competitor, she knew a test when she saw one. "Dr. Neviaser, although intimidating at times, was and continues to be incredibly supportive of my career. I chose to pursue fellowship training at the University of Pennsylvania in Philadelphia, in part because of Drs. Joseph Iannotti and Gerald Williams, two well known and respected surgeons. When I interviewed, I had a strong feeling that this fellowship would be a great fit for me. They worked hard—very hard—but loved their work and had a passion for research. They had a vision for the future of their program in the world of shoulder surgery. Drs. Iannotti and Williams, along with Dr. Matthew Ramsey, were terrific mentors, and had a strong influence on my ultimate career path."

It was "Fridays with Lou" that would deepen her understanding of the tendons and muscles of the shoulder One of the strongest reasons I chose 'Penn,' was because of the large basic science lab that was under the direction of Dr. Louis Soslowsky. Each Friday I worked in his lab where I learned a significant amount about not only the basic science of the rotator cuff, but also about the scientific process and the value of strong collaboration with others. Along with Steve Thomopoulos, then a Ph.D. candidate, I developed a rotator cuff repair rat model of injury and repair. While this model is now widely used, in retrospect few people were studying tendon healing in that context."

Recruited by Drs. Ken Yamaguchi and Richard Gelberman after fellowship, Dr. Galatz gladly accepted this academic position. "By then I decided that I really wanted to practice in an academic setting. This job gave me the opportunity to have a shoulder practice and to pursue basic science research, which I did with the chief of the orthopedic lab, Linda Sandell, Ph.D. Using the rat model, we looked at the biomechanics involved in healing of the rotator cuff. Specifically, we were interested in what happens to the structure and mechanical

properties of soft tissue as it heals. We found that the rotator cuff tendon will heal, but it heals with a scar and doesn't have normal biomechanical properties. Even in rats you never get back the qualities that are as good as normal tendon…it's a reparative rather than a regenerative process."

"Steve Thomopoulos later joined our department at Washington University, and has been one of my strongest collaborators. We created a delayed healing model in which we cut the tendon, repaired it three weeks later, and found that there were changes not only on the tendon side, but also on bone side. Even with a single tendon injury, bone density decreased after injury. We studied the effects of nicotine on cuff healing, and found decreases in cell proliferation and collagen production. It was greatly rewarding to be involved in such clinically relevant work."

"At present," says Dr. Galatz,

> ***"I'm studying the effects of growth factor delivery, specifically looking at TGF-beta 3, which is associated with scarless soft tissue healing. We are working on delivering growth factors using certain scaffolds and have begun delivering stem cells to the healing site. My research truly enriches my clinical practice because in the lab I get to study problems that I see in the office and the OR every day."***

Dr. Galatz recently completed a term as Member at Large on the Board of Directors of the American Academy of Orthopaedic Surgeons (AAOS). She learned the complexities of the organization and was impressed by the depth of the services it offers members. "Through board meetings, as well as the voluminous amount of reading material they give us before each meeting, I am learning a tremendous amount about how AAOS works and grows to meet the needs of its members. My particular strengths are probably maximized by working on the educational efforts of the AAOS. I have already been heavily involved in education programs for practicing surgeons and hope to be involved in these efforts on a larger scale at some point."

Her society participation is focused on the American Shoulder and Elbow Surgeons (ASES), where she brings her insight to several committees. One insight she offers researchers? Don't take grant writing skills for granted. "The most interesting activity I have been involved in with the ASES is the research committee, where we reviewed grant applications and manuscripts for research awards. Grant and manuscript writing skills are learned, so anyone planning on submitting should take a course or identify an appropriate mentor or both. Why? Because you will be competing with people who are very good at it."

Dr. Galatz has benefitted from the guidance and inspiration of her colleagues at Washington University. "I am fortunate to work with such a talented group of individuals. In particular, Richard Gelberman, our chair, and my partners on the shoulder service, Ken Yamaguchi and Jay Keener, who motivate me by setting examples of excellence and leadership. Working here has allowed me to build a career that has opened the doors to incredible opportunities such as the American British Canadian (ABC) Travelling Fellowship of the American Orthopedic Association. I often think back to my early life experiences, where with hard work and persistence I achieved things I didn't always think were possible. The hard part now is to identify and focus on what is really professionally meaningful to me."

And despite her having some power on the home committee, she can't get her son in a saddle. "My husband is a vascular surgeon who practices in nearby Belleville Illinois. We have one son who is six and who, despite my encouragements, has no interest in riding. Although he loves to go to the barn and travels with me to horseshows, he's happy to leave it at that. 'It has no motor,' he protests. We spend time as a family biking, hiking and otherwise enjoying the outdoors."

Dr. Leesa Galatz…learning—and creating—the how's and why's of the field.

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