VOLUME 5, ISSUE 4 | FEBRUARY 3, 2009

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VOLUME 5, ISSUE 4 | FEBRUARY 3, 2009

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Companies

This Week: Since torture is illegal, this market should be locked up. Bad news rains on investors every day. Yet, somehow, 8,000 is holding as the floor. Will it last? In terms of inherent values, it should. But Mr. Market is irrational these days.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	2	Medtronic	30.27%	9.66%	Having an April fiscal year helps MDT this time—no earnings reports. By default, is #1 this week.
2	3	Synthes	33.70	(3.72)	Swimming in cash, cash flow and dominant market shares in trauma and spine.
3	7	Osteotech	2.94	77.78	Rob Cohen and Mike McCarthy join Sam et al to give OSTE a kick-ass management team.
4	4	Stryker	21.60	7.21	8.9% orthopedic sales increase (constant currency) in Q4'08. Not bad. 2009 guidance is comparatively strong.
5	5	Johnson & Johnson	24.90	(2.50)	DePuy closes the year on a very high note, growing sales 10% for the quarter vs. 6% for the year.
6	6	Smith & Nephew	19.54	15.72	Claw back—means getting money back—on Plus is successful. Who said bad decisions can't be partially reversed?
7	1	Zimmer	29.86	(8.73)	Obviously still a major work in progress. Underperforms even reduced expectations.
8	8	Orthofix	7.66	3.97	Problems with Blackstone still challenging, but glimmer of improvement appear on the horizon.
9	NR	Kensey Nash	19.53	13.01	Back on the power rankings with 110% earnings increase for the December quarter.
10	9	Alphatec	(11.03)	(4.82)	ATEC's #1 issue is profitability. Great positioning should mean stronger sales growth.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Osteotech	OSTE	$3.04	$54	77.8%
2	ArthroCare	ARTC	$6.92	$184	43.9%
3	Smith & Nephew	SNN	$36.36	$6,460	15.7%
4	Kensey Nash	KNSY	$20.67	$240	13.0%
5	Medtronic	MDT	$33.49	$37,560	9.7%
6	NuVasive	NUVA	$37.34	$1,350	8.5%
7	Mako Surgical	MAKO	$6.98	$174	7.2%
8	Stryker	SYK	$42.24	$16,870	7.2%
9	Wright Medical	WMGI	$20.74	$788	4.5%
10	Orthofix	OFIX	$15.96	$273	4.0%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	CONMED	CNMD	$15.65	$454	-32.2%
2	Exactech	EXAC	$12.74	$162	-22.1%
3	Integra LifeSciences	IART	$27.74	$767	-19.5%
4	RTI Biologics Inc	RTIX	$2.45	$132	-17.5%
5	Orthovita	VITA	$2.89	$219	-15.0%
6	Regen Biologics	RGBO.OB	$3.75	$20	-13.2%
7	Symmetry Medical	SMA	$6.85	$245	-12.0%
8	CryoLife	CRY	$8.24	$232	-10.0%
9	Zimmer Holdings	ZMH	$36.40	$8,170	-8.7%
10	TranS1	TSON	$6.25	$128	-6.9%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	ArthroCare	ARTC	$6.92	$184	4.38
2	Orthofix	OFIX	$15.96	$273	6.67
3	Zimmer Holdings	ZMH	$36.40	$8,170	8.69
4	CONMED	CNMD	$15.65	$454	9.64
5	Medtronic	MDT	$33.49	$37,560	11.93

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	NuVasive	NUVA	$37.34	$1,350	74.52
2	Smith & Nephew	SNN	$36.36	$6,460	65.46
3	RTI Biologics Inc	RTIX	$2.45	$132	24.56
4	Synthes	SYST.VX	$121.77	$14,454	21.28
5	I Flow Corp	IFLO	$4.11	$101	20.92

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	ArthroCare	ARTC	$6.92	$184	0.19
2	Orthofix	OFIX	$15.96	$273	0.53
3	Integra LifeSciences	IART	$27.74	$767	0.72
4	CONMED	CNMD	$15.65	$454	0.80
5	Stryker	SYK	$42.24	$16,870	0.83

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$37.34	$1,350	15.92
2	RTI Biologics Inc	RTIX	$2.45	$132	2.38
3	Exactech	EXAC	$12.74	$162	1.60
4	Johnson & Johnson	JNJ	$57.69	$160,060	1.53
5	***Average***			***$9,588***	***1.43***

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$3.04	$54	0.51
2	ArthroCare	ARTC	$6.92	$184	0.54
3	Orthofix	OFIX	$15.96	$273	0.56
4	CONMED	CNMD	$15.65	$454	0.60
5	Symmetry Medical	SMA	$6.85	$245	0.62

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$3.31	$81	202.36
2	Mako Surgical	MAKO	$6.98	$174	70.56
3	Regen Biologics	RGBO.OB	$3.75	$20	15.62
4	TranS1	TSON	$6.25	$128	6.20
5	NuVasive	NUVA	$37.34	$1,350	6.11

5 Orthopedics This Week
VOLUME 5, ISSUE 4 | FEBRUARY 3, 2009

Are Orthopedic Surgeons Abandoning the Emergency Department?

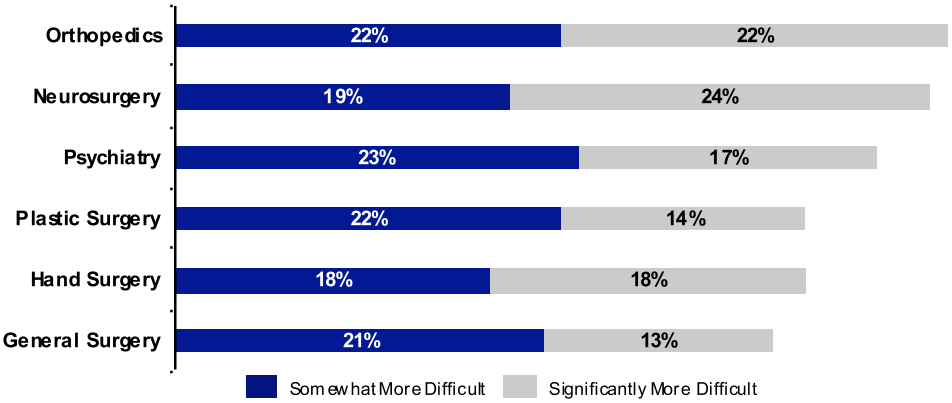
By Matthew Sturm and Kevin Kennedy

Special to *Orthopedics This Week*

The days of physicians competing to fill the Emergency Department (ED) call roster seem like a distant memory. Today, 55% of hospitals report that they have lost specialty coverage some time during the last 24 months. Orthopedics tops the list of challenging specialties, with 44% of hospitals reporting difficulty in maintaining coverage in 2007 (see Figure 1) and 26% of hospitals actually losing coverage for orthopedics at some point in 2007 (see Figure 2).

The current call coverage environment is a result of numerous macro-environmental trends, including growing ED volumes (especially of uninsured patients) and physician shortages in key specialties. Moreover, physicians in many specialties do not feel that ED call is important in building their practices, and they perceive that their burden vastly

Figure 1: Hospitals Reporting Increased Difficulty in Maintaining ED Coverage



Source: 2007 American Hospital Association (AHA) Survey of Hospital Leaders

exceeds the benefits of call. Many physicians say that they would prefer to stop taking call entirely and are demanding payment for call. Hospital administrators are scrambling to negotiate solutions and physicians are left to ponder the best way to balance their economic and lifestyle needs with community care requirements.

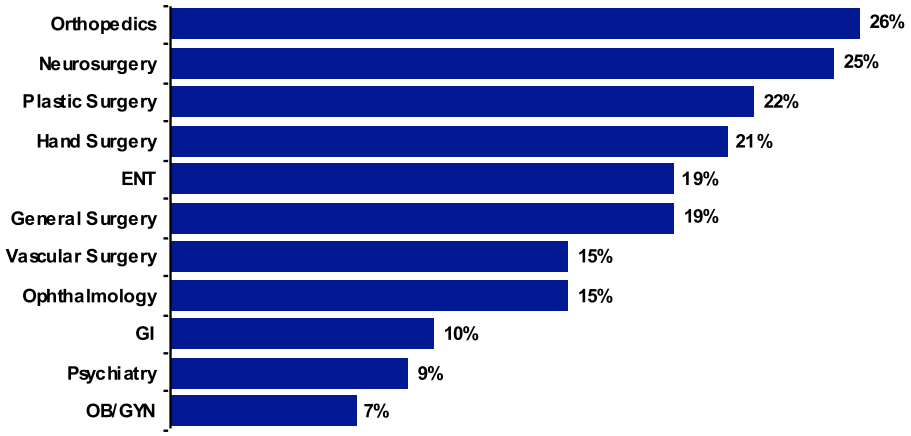
The Call Coverage Death-Spiral

Difficulties in providing call coverage have become particularly pronounced in orthopedic surgery for a variety of reasons, including:

Patient Volume	Orthopedic surgeons nearly always lead the pack in the number of calls from the ED and sheer number of cases requiring care.
Slow Pay, Low Pay, No Pay	When compared to the rest of a physician's practice, ED cases are often poorly reimbursed.
Day-After Syndrome	Many orthopedic cases can be postponed until the next day, typically flooding the physician's schedule the day after call with follow-up cases referred from the ED.
Operating Room (OR) Scheduling Difficulties	As many orthopedic cases are non-emergent, orthopedic surgeons on call are frequently "bumped" from OR time by more emergent cases in other specialties. For orthopedic surgeons, the burden of call sometimes stretches far beyond the actual call night as cases "stack up" waiting for an available OR.
Independence	Many orthopedic surgeons perform the majority of their elective casework in an outpatient setting, which decreases their reliance on the hospital. Some orthopedic surgeons can therefore easily drop their hospital privileges, thus increasing the call burden for the remaining on-call orthopedic surgeons.
Super-Subspecialization-	Increasingly, orthopedic surgeons are focusing their elective practices on specific body parts (spine, hand, hips, knees, shoulders, etc.), which leads many physicians to be uncomfortable taking general orthopedic call. Also, once a physician builds a practice in a highly specialized area, other physicians may see their skills atrophy as the specializing physician begins to perform the bulk of elective cases in that area.

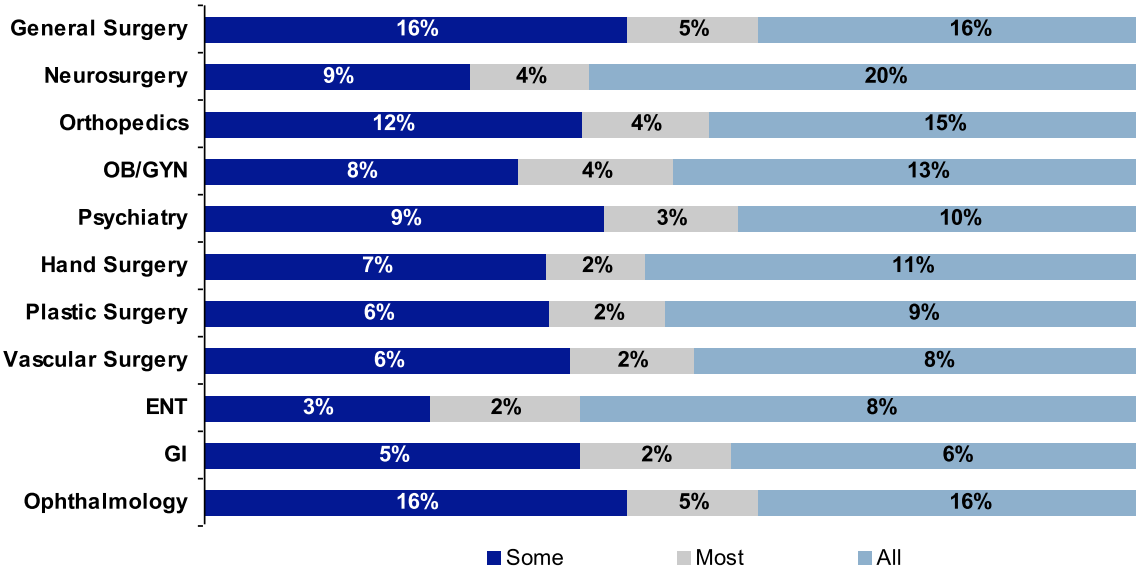
Though orthopedic surgeons tend to have a lower incidence of emergent surgical cases (e.g., middle-of-the-night surgeries) as compared to other surgeons, the factors described above create a unique set of challenges for maintaining a stable orthopedic call panel. The remainder of this article explores a variety of strategies that have been successfully implemented to address the burden of orthopedic call.

Figure 2: Percentage of Hospitals Reporting Payment for ED



Source: 2007 American Hospital Association (AHA) Survey of Hospital Leaders

Figure 3: On-Call Coverage by Specialty, 2007



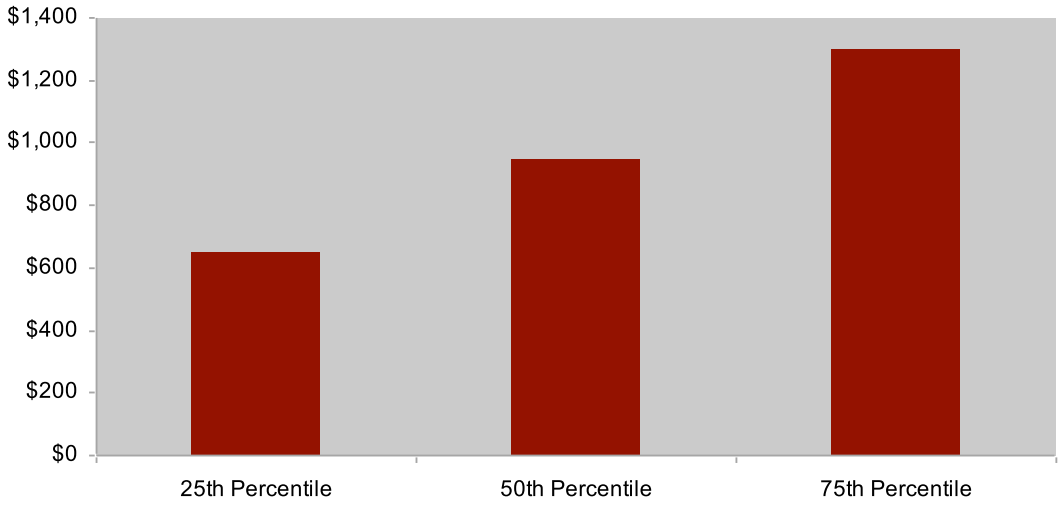
Source: 2007 American Hospital Association (AHA) Survey of Hospital Leaders

The On-Call Payment Solution

Fueled by messages from specialty societies and peers at other hospitals, many physicians view on-call payment as the solution to their call coverage concerns. While many hospitals have addressed these burdens by simply paying for orthopedic call (about 30% of hospitals now pay), these solutions do not address the root causes of call burden. Per diem payments for orthopedic call coverage range from $500 to $1,500, with 64% of hospitals reporting that their call coverage payments increased during the last year (see Figure 4). In reality, paying an orthopedic surgeon for call can create a short-term sense of fairness for the surgeon for finally getting paid for the worst part of his/her job, BUT it has little impact on reducing the overall burden of call.

Often orthopedic surgeons assert that they would rather not take ED call than be paid for something they do not want to do in the first place. This means that the costs of call are likely to escalate while more and more orthopedic surgeons eschew call completely in favor of improving their lifestyles. As an alternative to paying for call, administrators could consider a range of operational solutions to improve the current delivery model, and physicians might well encourage the adoption of solutions that reduce the burden of call.

Figure 4: 2007 Call Coverage Per Diem Stipends for Orthopedic Surgery



Source: Sullivan, Cotter and Associates, Inc.'s 2008 Physician On-Call Pay Survey Report. Data is for unrestricted call for orthopedic surgeons. The per diem rate is calculated by multiplying the "equated hourly rate" by 24 hours. The sample includes 79 hospitals.

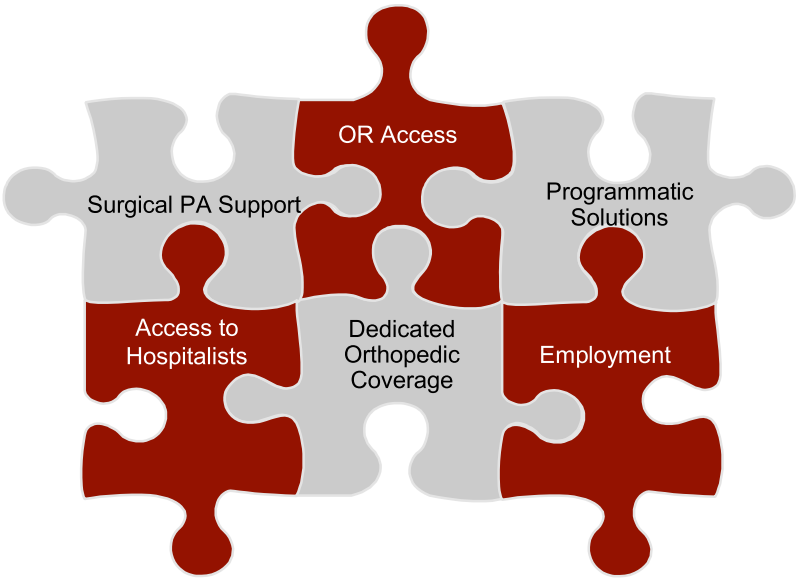
Reducing Call Burden – A Prescription to Action

OR Access	OR access for orthopedic cases may be improved by staffing additional rooms later in the day or by dedicating a room to post-call orthopedic cases.
Surgical PA Support	Surgical PAs may be utilized to provide first-call support, prepare patients for surgery, admit patients, and/or provide follow-up care. The scope of a surgical PA program will be dependent upon the hospital's bylaws, physician willingness to support the program, and state regulations regarding the scope of services PAs may provide.
Access to Hospitalists	The hospitalist program may be used to admit, after hours, orthopedic patients who are stable but will require surgery the following day.
Dedicated Orthopedic Coverage	Dedicated coverage for orthopedic injuries seen in the ED may be provided either by employed orthopedic hospitalists or via contractual arrangements with community physicians. While coverage requirements will be dictated by the local market, successful models range from those that provide coverage 24x7 to those that cover daytime hours or weekends only.
Programmatic Solutions	Often, programmatic solutions focus on orthopedic fractures, and they may include OR access, mid-level support, and dedicated ED coverage. One hospital tied the continuation of call coverage payments to the achievement of goals in other areas, such as cost reduction and quality improvement.
Employment	In situations where the volume of emergent orthopedic care exceeds that of elective orthopedic care, employment of orthopedic surgeons may be required to address the economic imbalances that threaten the ability to provide emergency services.

Each of the options presented above has the potential to decrease the burden of call coverage for orthopedic surgeons. It is important to keep in mind that the approach for evaluating call coverage strategies should be a dynamic one that involves physicians and hospital administrators. Successfully implementing a call coverage solution that reduces the burden of call will benefit both the hospital and physicians, and it will ultimately lead to a more sustainable call coverage model.

For more information, Matt Strum or Kevin Kennedy may be reached at **ECG Management Consultants,** Inc., Phone 206-689-2200, msturm@ecgmc.com, 1111 Third Avenue, Suite 2700, Seattle, Washington 98101-3201.

Figure 5:
Operational Improvements – Fitting the Pieces Together



The John Insall Travelling Fellowship

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

Insall Travelling Fellows with Drs. Adolph Lombardi and Keith Berend in New Albany, Ohio. (left to right: Bruno Violante, Adolph Lombardi, Keith Berend, Bryan Springer, Martin Logan, Raymond Kim)

"This was the highlight of my career," thought Dr. Raymond Kim, an orthopedic surgeon with the Porter Center for Joint Replacement in Denver, Colorado. Standing in the ORs of venerable surgeons such as Drs. Robert Booth, Giles Scuderi, and Richard Scott, Dr. Kim, one of four promising physicians to be selected for the 2008 John Insall Travelling Fellowship, knew that little could surpass the intense, rich learning experience of the fellowship's five weeks.

A program that honors the legacy of famed knee surgeon Dr. John Insall, the eponymous travelling fellowship was established in 2000 upon the death of this masterful surgeon. Dr. Kim: "Dr. Norman Scott, cofounder of the Insall Scott Kelly Institute for Orthopaedics and Sports Medicine (ISK), created the fellowship to ensure that Dr. Insall's dedication to excellence in research and patient care would be handed down to future generations of knee surgeons. Dr. Insall, the father of knee replacement surgery, was himself committed to educating surgeons both in the U.S. and around the world."

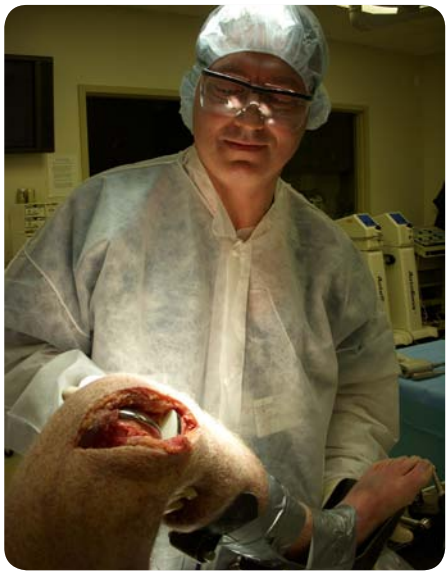
An agenda replete with a "Who's Who" of knee virtuosos, the Insall Travelling Fellowship consists of 13 different sites, with several days in each location. Dr. Norman Scott explains, "The applicants for the Insall Travelling Fellowship must have completed the American equivalent of a fellowship in Adult Reconstruction or Sports Medicine. The candidates have been from North America, Europe, Japan, Australia and China. Four recipients are chosen each year and are under the tutelage of the Knee Society. They travel to major centers throughout the

United States where they are hosted by Knee Society members. The program has been in existence since 2002."

A modest Dr. Kim says, "The fellowship organizers are looking for surgeons who have an interest in academics and who are involved with cutting-edge techniques and research involving knee surgery. I am thrilled and honored to have been selected to help promote the legacy of Dr. Insall. Along with the other fellows, Drs. Bryan Springer, Martin Logan, and Bruno Violante, I gave presentations on a variety of knee surgery topics and attended conferences promoting the latest research and technologies. We watched legendary surgeons perform multiple surgeries, including primary and revision knee replacements. The high point of this fellowship was that we had the opportunity to interact with prominent knee surgeons and observe their surgical techniques. It is quite different from just seeing these individuals on the podium… we are seeing them functioning in *their* operating rooms, something few surgeons have the opportunity to do."

Setting the stage for the program was an academic event of knee luminaries. Dr. Kim explains, "Early in the trip we were invited to attend a closed meeting of the Knee Society, hosted by Dr. Douglas Dennis, the Society's President. It was phenomenal to participate in this high-level academic conference, learn about the latest research, and gain an intimate knowledge of the workings of the organization."

Delving into site descriptions, Dr. Kim talks of a customized experience… straight down to the customized knees. "Adolf Lombardi's site, Joint Implant Surgeons, Inc. in New Albany, Ohio, was outstanding. Dr. Lombardi was a gracious host, inviting us to his home, and managing to rally an academic conference of 100 people on a Sunday morning. We observed new surgical procedures, performed total and partial knee replacements in the site's cadaver lab, and saw the latest techniques in custom-fit knee replacement. The process involves sending patients for preop MRIs and creating custom-fit jigs so that the knee replacements can be placed precisely to restore perfect alignment. Being able to have access to this innovative technology made New Albany a standout experience."



The i-talian Dr. Bruno Violante admiring his i-Uni during a cadaver workshop at Northwestern University hosted by Dr. David Stuhlberg.

Also making a lasting impression was the Mooresville, Indiana, site, hosted by Dr. Mike Berend. Dr. Kim: "Dr. Berend, a previous Insall Travelling Fellow, along with the senior partner, Dr. Merrill Ritter, provided us with a highly academic experience. Dr. Ritter, a legend in total knee arthroplasty, presented clinical results of total knee patients with direct compression molded polyethylene. The great success of these results was reflected in their excellent long-term survivorship. Dr. Ritter readily admits to putting a knee in without stringent attention to perfect mechanical axis alignment and with the use of crude instruments…and yet there is great long-term survivorship, something he attributes to direct compression molded polyethylene."

And when they landed in Philadelphia, the fellows didn't know they would be attending lessons in artistic performance. "Dr. Robert Booth, famed for his podium talks on the 'Gender Knee,' was a stellar host because of the breadth of his talents and interests. The most incredible thing, however, was the level of efficiency

in his OR. He and his team are just beautiful to watch; Dr. Booth himself flips between two ORs. Watching him operate is like witnessing a beautifully choreographed ballet. His teammates know exactly what roles they are to play, meaning that there is little need for talk—even asking for instruments is unnecessary as people know when to hand him what. He did at least 10 knee replacements and was finished by mid-afternoon. This is the kind of efficiency which leaves time for research that advances the field."

Just as synovial fluid makes things operate smoothly in the knee, Dr. Norman Scott of the Insall Scott Kelly Institute for Orthopaedics and Sports Medicine (ISK) worked his magic in New York and made things flow for the fellows. Dr. Kim: "Dr. Scott and his team were amazing hosts who thought through not only the clinical experiences we would need, but other things that would add to our time at the site. They actually flew our spouses in and held social functions so people could really get to know one another. Dr. Scott also arranged for us to have a combined academic conference which included Dr. Steve Haas and the Hospital for Special Surgery. This was particularly meaningful because of Dr. Insall's roots with both institutions; it was neat to see the two orthopedic families (ISK and HSS) come together in his honor."

In Boston, the fellows would be met by a talented trio at Brigham and Women's Hospital. "In Boston we were hosted by Drs. Richard Scott, Tom Thornhill, and Wolfgang Fitz, the latter of whom was an Insall fellow in 2002. It was truly edifying to see the meticulous Dr. Scott, known for his ligament balancing in the knee, actually perform his knee balancing techniques in the OR…and much more powerful that just hearing about these procedures. Dr. Thornhill was amazing in his ability to eloquently lecture while performing a complex revision total knee replacement at the same time. As for Dr. Fitz, we experienced his enthusiasm regarding a new custom knee system as well as his warm hospitality when he brought us to his home for a meal."

And at Mayo they would meet their mentors. Dr. Kim: "The Mecca of total joint arthroplasty, the Mayo Clinic, was special because the fellows were asked to speak at grand rounds and participate in the Clinic's total joint conference. This site was particularly meaningful for both Dr. Springer and me because it is where we completed our residency training. We saw a lot of our mentors there, including Drs. Arlen Hanssen, Mark Pagnano, Dan Berry, and Dave Lewallen—all attendings who have inspired us and have had a critical impact on our development as surgeons."

Perhaps the most valuable part of the Insall Fellowship is the mental shift it encourages. "This experience was much more than I had anticipated," states Dr. Kim. "There aren't many opportunities in life where a surgeon can spend time traveling, witnessing other's ORs, and getting to see what's on the forefront of technology in the field. All throughout the program I filed mental notes about tricks I was seeing in the OR, including ways to do things more efficiently. From Dr. Booth I learned that it is not just the surgeon that makes an operation successful. You must have a cohesive team and a hospital that is supportive of highly efficient, high-volume surgery. In terms of patient care we witnessed a variety of models of how things run on the floor postoperatively, such as pain protocols and physical therapy protocols. This 'there are many ways to skin a cat' lesson will stay with me as I advance in my career. Part of the value of these interactions is that they reinforce and validate one's own practice. At the same time, I am a better surgeon because this fellowship made me step outside my own world and learn new things. Surgeons are creatures of habit so sometimes we need something new to change our perspective and force us to look at things in different ways."

That includes the host surgeons. Dr. Kim: "Having these prominent surgeons involved in the fellowship

meant that we saw a different dimension to their personalities. We saw a human side of them, in part by meeting their families and discussing non-orthopedic topics. This experience went a long way toward teaching me that there is more to life than just performing technically good orthopedic surgery. Part of being a physician is balancing the other important things in life besides work—faith, family, and friends."

Dr. Kim gives kudos to Dr. Norman Scott and his ability to bring together such a sophisticated group of surgeons who delivered a rich learning experience. "The program was terrifically well organized, with complete fluidity in our travel and seamless flow from site to site," says Dr. Kim. "What really made it special was Dr. Scott's ability to rally these talented surgeons who have an interest in sharing in Dr. Insall's legacy. Most of the surgeons who hosted had a connection with Dr. Insall, so they were able to share stories of working with him."

And what did they say? "The refrain," states Dr. Kim, "was that Dr. Insall was a true gentleman who moved through his days with an air of grace. He was an innovator par excellence and was always trying to develop new ways of improving knee replacement surgery, whether through design or technique. This outstanding experience has inspired me to continue pursuing Dr. Insall's vision and commitment to the field."

The brotherhood of the Travelling Fellowship. Bryan Springer, Bruno Violante, Martin Logan, and Raymond Kim sit next to the Mayo Brothers statue in Rochester

NASS Disclosure in a Time of Sunshine

By Walter Eisner

If 2008 was the year of disrupted relationships between surgeons and device companies, 2009 will be a year of redefining relationships.

On January 22, the world's largest spine surgeon society, the North American Spine Society (NASS), made a dramatic move in that direction by announcing that its members were now going to have to disclose actual dollar amounts received from device companies. The Society also announced that it was adding an ethicist to its Board of Directors.

The same day, U.S. Senators Charles Grassley of Iowa and Herb Kohl of Wisconsin reintroduced their Physician Payments Sunshine Act.

Looks like sunshine is breaking out all over the place.

The legislation was expected, but the NASS announcement came as a surprise and is a welcomed stand (at least in our opinion), by physicians who have not been at the center in defining the new relationship with industry. Both actions could define how industry and physicians will work together for years to come.

The new NASS policy dramatically revises its existing disclosure policy for both members and nonmembers participating in NASS activities. The goal of the new policy, according to NASS, is to create "an environment of scientific validity, in which learners can trust the information they receive is objective and unbiased, and to be sure that our members are current and forthright in their dealings with one another and with their colleagues and patients."

Quality, Evidence and Ethics

The policy created by the NASS Ethics Committee, which was adopted by the Board of Directors at the Society's Toronto Annual Meeting in October 2008, requires that participants disclose actual dollar amounts received from all relationships held in the 12 months preceding disclosure.

Failure to disclose is considered a "sanctionable offense" where sanctions could include suspension, expulsion, or public letters of censure.

The Society has also rewritten its mission to include ethics as a pillar: "NASS is a multidisciplinary medical organization dedicated to fostering the highest quality, evidence-based, and ethical spine care by promoting education, research, and advocacy."

Dr. David J. Rothman

The Board has also restructured to add a nonmember, academic ethicist to its ranks. The first three-year term will be filled by David J. Rothman, PhD. Rothman's term started in January.

Dr. Rothman is President of the Institute on Medicine as a Profession (www.imapny.org) and Bernard Schoenberg Professor of Social Medicine at Columbia University's College of Physicians & Surgeons. Trained in social history at Harvard, David Rothman joined the Columbia medical school faculty in 1983, and his subsequent work has examined the history of health care practice and policy. He is the recipient of the Robert Wood Johnson Health Policy Investigator Award, and he is now addressing the place of professionalism in medicine.

The Society didn't stop there.

Divesting Conflicts

To address potential conflicts of interest by Society leaders, NASS also put in place a stringent divestment policy that will govern leaders of the Board and committees.

This "Policy on Conflict of Interest in Leadership Positions" governs relationships that "any Committee or Board member serving in each specific volunteer role may have with industry. The policy establishes three levels of divestment from industry relationships, with the most stringent divestment occurring within the presidential line and including the chairs of certain highly influential committees. Relationships at this level are severely restricted and are examined in detail by the vetting committee, with consideration of the exact nature of remuneration (including dollar amounts for financial arrangements) and services provided. If a potential candidate for a leadership position has an industry relationship deemed unacceptable for the desired leadership level, the individual will be given the opportunity to divest from that relationship before assuming a new position."

To monitor and enforce this new guideline, the Society will use a Conflict of Interests (COI) Review Board that was approved in May 2008.

According to the NASS announcement, the COI Board will "serve as a consulting entity for NASS members seeking advice on how to disclose, and even help determine appropriate relationships between NASS leaders and outside organizations. It may also act in a consulting capacity to the Professional Conduct & Ethics Committee for its hearings, which may encompass COI issues. In addition, the COI review committee plays a significant role in the vetting of nominees for the presidential line, Board of Directors, and certain committee chairs."

Binding Covenant

These new guidelines are not voluntary; they are a "binding covenant which applies to all relationships engaged in by all participants in all NASS activities." If a member is found to have failed to follow the disclosure policy, he or she is considered to be in violation of the Society's Code of Ethics.

The COI Review Board will determine if the member is guilty of violating the policy and can be sanctioned. "Sanctions may include but are not limited to: one- or two-year suspension of membership, membership expulsion, public letters of censure, and/or—in conjunction with NASS Education Council Chairs—barring the member from presenting at a specified number of future meetings."

Marjorie Eskay-Auerbach, MD, the current Chair of the NASS Ethics Committee, said "NASS strives to raise the bar for ethics and professionalism, not only within NASS but in the entire field of spine care." Dr. Eskay-Auerbach also owns a J.D. degree....

Senator Grassley praised the NASS policy. "This initiative is impressive because of the sanctions it contains for violating the Society's own code," according to the *Wall Street Journal*.

Physician Payments Sunshine Act of 2009

As NASS announced its new disclosure rules, Senators Grassley and Kohl reintroduced their Sunshine Act, which requires pharmaceutical and medical device companies to publicly report money in excess of $100 that they pay to physicians every year.


Senator Charles Grassley

The Physician Payments Sunshine Act of 2009 would establish a nationwide standard requiring drug, device and biologic makers to report payments to doctors to the Department of Health and Human

Services, and for those payments to be posted online in a user-friendly way for public consumption. While the NASS requirements cover that Society's members, who could potentially be kicked out of the Society for disclosure violations, this proposed law covers the companies and would establish penalties as high as $1 million for knowingly failing to report the information. The proposal incorporates many of the new recommendations of the Medicare Payment Advisory Commission, an independent congressional agency which advises Congress on issues affecting the Medicare program.

Senators Grassley and Kohl introduced similar legislation two years ago, but the bill was never considered.

The Sunshine Act will require companies to disclose the dates on which the payment or other transfer of value was provided to the covered recipient as well as the nature of the payment.

A description of the nature of the payment or other transfer of value includes:

- consulting fees;
- compensation for services other than consulting;
- honoraria;
- gifts;
- entertainment;
- food;
- travel;
- education;
- research;
- charitable contributions;
- royalties or licenses;
- current or prospective ownership or investment interests;
- compensation for serving as faculty or as a speaker for a continuing medical education program;
- grants; or
- any other nature of the payment or other transfer of value (as defined by the Secretary of HHS).

Physician-Owned Companies

The Act will also require manufacturers and purchasing groups receiving government payments to report if there was any ownership or investment interest held by a physician (or an immediate family member of such physician) in the company during the preceding year. They must report:

- The dollar amount invested by each physician holding such an ownership or investment interest.
- The value and terms of each such ownership or investment interest.
- Any payment or other transfer of value provided to a physician holding such an ownership or investment interest.

"Shedding light on industry payments to physicians would be good for the system," Grassley said in introducing the bill. "Transparency fosters accountability, and the public has a right to know about financial relationships. Patients rely on their doctors' advice. Taxpayers spend billions every year on prescription drugs and medical devices through Medicare and Medicaid. They also fund tens of billions of dollars of medical research each year, and the doctors conducting that research have a big influence on the practice of medicine."

Senator Kohl has convened several hearings as Chairman of the Senate Special Committee on Aging, including the famous "Surgeons for Sale" hearing in 2008, to look at conflicts of interest created by industry payments to physicians. Senator Grassley has been particularly active in publicizing payments to surgeons by Medtronic.

Physician Impact

Most recently he focused on payments made to University of Wisconsin physician Thomas Zdeblick, M.D. Because of the imprecise disclosure requirements in place at the University, Zdeblick became the focus of a recent *Wall Street Journal* article which revealed that he had been paid millions of dollars by Medtronic, but he reported only that he received "over $40,000" from the company. He complied with University disclosure policy and broke no rules, but the impression of unreported payments raised public attention.

Had the NASS requirements been in place, there probably would have been no story.

Some physicians have multiple streams of income and have been reluctant to share the level of that income with their employers. If physicians want to stay in good standing with NASS and the companies want to comply with new proposed law, some physicians' privacy of income will be a thing of the past.

Senator Grassley has also put pressure on the National Institutes of Health to help achieve disclosure. He has urged the NIH to fully exercise its authority to track financial relationships between the drug and device industry and doctors conducting federally sponsored medical research.

Grassley said the movement during the last year toward greater tracking of financial relationships by individual drug companies, professional associations and medical centers shows that the reform movement is gaining traction. "The goal of our legislation is to lay it all out, make the information available for everyone to see, and let people make their own judgments about what the relationships mean or don't mean," Grassley said. "If something's wrong, then exposure will help to correct it. Like Justice Brandeis said almost a century ago, 'sunshine is the best disinfectant.'"

Company Impact

What impact these actions will have on orthopedic device companies and their ability to compete for market share is still unknown. Mike Matson, Senior Analyst at Wachovia, believes that the large-cap orthopedics firms have largely cleaned up their acts given the Department of Justice settlements. "But some smaller (particularly private) firms may have to rein in physician payments or suffer under the glare of the Sunshine Act," wrote Matson in an investor note on January 23.

Matson wrote that investors have become increasingly concerned about spine firms receiving DOJ subpoenas since Medtronic announced a subpoena last fall. "The fear is that a subpoena might cause growth to slow as companies become increasingly cautious with compliance practices. Transparency legislation could have a similar effect and may serve to further increase investor concerns. Interestingly, one benefit of transparency to the public spine firms might be increased pressure on private spine firms, which are already struggling with a lack of financing."

Physician Responsibility

The next big meeting to bring physicians and device companies together will be in Las Vegas in February when the American Academy of Orthopaedic Surgeons holds its annual meeting. At last year's meeting, the first of the post DOJ settlement era, we noticed a "toning down" of the glitz and entertainment of attendees by companies.

This year we may see further restraint. Smith and Nephew has reportedly instructed its salespeople to limit their interactions with physicians to business hours at the meeting. Physicians may well be left to find their own entertainment in Vegas.

We applaud the efforts of NASS. The primary efforts to regulate the relationships between physicians and device companies have come by lawmakers and prosecutors and have focused on the business practices of the device companies. By stepping up and taking responsibility for the actions of the physicians, the North American Spine Society has made it clear that the physicians, not companies, are ultimately responsible for relationships that impact their patients.

Beyond Kyphoplasty

By Matt Menze, PearlDiver Spine Analyst

On October 20, 2008, Medtronic sent out a press release marking World Osteoporosis Day by announcing that over 500,000 vertebral compression fractures (VCF) have been treated worldwide with balloon kyphoplasty since 2000. VCF treatment, however, is evolving rapidly and ten years from now, in 2019, Medtronic's VCF press release could look very different. Based on PearlDiver research and a survey of new VCF products, we believe that a new era of VCF treatment is coming. This new era, we think, will be marked by preventative treatments, controlled fracture reduction, and improved control over viscosity in bone cements. Lastly, could Amgen impact the VCF market with two semi-annual injections?

Expandable Devices, Controlled Fracture Reduction, and Cement Viscosity in Treating VCFs

The future treatment of vertebral compression fractures will likely be different from today's standard of care. The goal of reducing or eliminating pain and stabilizing the vertebral body will remain the same. However, this will be accomplished by new technologies focused on correcting drawbacks and complications associated with current treatments. Beyond this, we believe that orthopedic and pharmaceutical companies may collaborate to provide fracture repair technology and prophylactic treatments aimed at preventing additional VCFs. Finally, there will be continued focus on reducing the incidence of adjacent level factures. Table 1 displays current VCF treatments by site of care, region of the spine, and level(s) treated.

Spine Wave: "Stacking" Up to Treat VCFs - StaXx FX Structural Kyphoplasty System

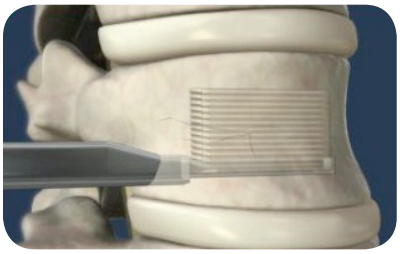
Everyone likes PEZ candy! Why? It's because of the cool dispensers with our favorite characters on them. Candy aside, this dispenser looks pretty sweet!

The Spine Wave, Inc. StaXx system was designed to treat VCFs in a minimally invasive fashion as an alternative to traditional vertebroplasty and kyphoplasty. The device is designed to allow for controlled fracture reduction in 1mm increments. The company cites the following benefits:

- No intra-operative reduction loss
- Controlled vertical expansion in 1mm increments
- Barrier to posterior extravasation
- Reduced bone cement volume

The device is composed of stackable, 1mm PEEK wafers, which are inserted into the vertebral body one at a time in order to provide for the appropriate height restoration. The system is

Figure 1: StaXx FX



Source: http://www.spinewave.com/products/fx_us.html
Database (2004-2007)

Table 1: VCF Treatment by Site of Care and Levels Treated

Site of Care	Vertebroplasty		Kyphoplasty	
	Thoracic	Lumbar	Thoracic	Lumbar
Office	10.0%	9.5%	1.2%	0.7%
Inpatient Hospital	26.4%	30.1%	46.7%	46.2%
Outpatient Hospital	59.5%	56.6%	50.4%	50.8%
Ambulatory Surgical Center	4.0%	3.8%	1.6%	2.3%
Levels Treated	**Vertebroplasty**		**Kyphoplasty**	
	Thoracic	Lumbar	Thoracic	Lumbar
Single Level	70.3%	78.7%	68.2%	79.8%
% Coded as Multiple Level	29.7%	21.3%	31.8%	20.2%

Source: PearlDiver Patient Records Database (2004-2007)

designed to be used with PMMA cement. Will this technology take market share from the established players? Investors think so. Spine Wave closed a series D round of financing to the tune of $45 million in April 2007.

Regulatory Status

Outside U.S. (OUS): The device is indicated for use in the treatment of vertebral compression fractures and bears the CE mark.

U.S.: The device is indicated for use in the treatment of vertebral compression fractures and was FDA approved in April 2007.

Alphatec Spine: Innovating for the Aging Spine Patient

Alphatec Spine has reinvented itself to serve what we believe will be, perhaps, the largest market in spine in the coming two decade. This market is the aging spine, which are patients 65 years of age and older. Innovative products that effectively treat patients with spine disorders who have osteoporosis will be a key component of Alphatec's aging spine portfolio. The strategy is working, as we believe revenues will grow to nearly $100 million in 2008, or 22% year-over-year.

Consider the OsseoFix Spinal Fracture Reduction System for use in the T1-L5 region, which is used to treat VCFs. Benefits of the technology include:

- Creation of bony channels during implant deployment and retention of bone within the implant promotes cement interdigitation
- Implant construct has potential to provide enhanced ability for vertebral height maintenance
- Controlled implant deployment delivers reproducible results
- Deployed implant is designed to maintain fracture reduction throughout cement delivery

The last point highlights an important feature of the product. In standard vertebroplasty, vertebral height restoration can decline as the cement cures. However, with Alphatec's technology, the implant allows for the vertebral height to be maintained during the procedure.

Additionally, Alphatec offers OsseoFix+ Radiopaque Bone Cement for use with the OsseoFix technology. According to the company, OsseoFix is a self-hardening, ready to use, medium-viscosity bone cement. OsseoFix+ contains a high percentage of radiopaque agent (45%) for maximum visibility and radiological control during a percutaneous vertebroplasty procedure.

Regulatory Status

OUS: On October 13, 2008, the company announced it had received a European CE mark for the device, allowing it to market the device in the European Union to treat vertebral compression fractures. On December 17, the company announced it was beginning its European commercial training program for OsseoFix.

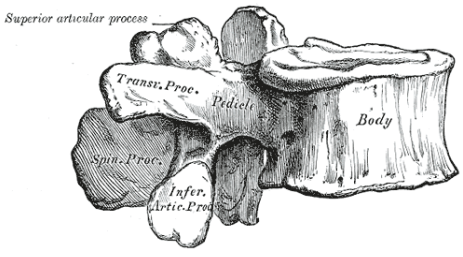
U.S.: OsseoFix is currently not available for sale in the U.S. The company is beginning a clinical study to support its 510k application.

Amgen: Attacking the "Silent Epidemic" by Stopping VCF's Before They Occur

Consider these facts from the International Osteoporosis Foundation:

- A woman 65 years of age with one vertebral fracture has a one in four chance of another fracture within five years, which can be

Figure 2: Lumbar Vertebra



Source: http://commons.wikimedia.org/wiki/File:Gray92.png

reduced to a one in eight chance by treatment
- After hospitalization for a vertebral fracture, there is a greatly increased risk of requiring hospitalization for an additional fracture in the years following initial hospitalization
- Vertebral fractures are associated with an increased risk of both further vertebral and non-vertebral fractures
- Women who develop a vertebral fracture are at substantial risk for additional fracture within the next one to two years

Most VCF treatments are reactive in nature and are aimed at restoring height in the collapsed vertebral body. Based on the facts above, an effective prophylactic treatment aimed at preventing subsequent VCFs would be a monumental achievement, and quite possibly a major threat to the VCF market.

Denosumab is potentially a blockbuster drug for Amgen. Amgen describes denosumab as a "fully monoclonal antibody that specifically targets the receptor activator of nuclear factor kappa B lingand (RANKL), a key mediator of the cells responsible for bone breakdown." Amgen believes that the drug has application across a number of conditions including osteoporosis, treatment-induced bone loss, bone metastases, rheumatoid arthritis, and multiple myeloma. denosumab inhibits RANKL, and because of this is considered a potential game changer in the way osteoporosis is treated. The drug is administered by subcutaneous injection (60 mg) twice yearly.

A key market for denosumab is postmenopausal women. There is a marked decline in bone mineral density (BMD) in women over 50 and senile osteoporosis accelerates after menopause. According to the United States Department of Health and Human Services, over 80% of VCFs are seen in patients 65 and older, with women being diagnosed 77% of the time. VCFs affect about 25% of all postmenopausal women. The condition is prevalent in 40% of women over 80 years of age. Furthermore, osteoporosis is associated with 85% of vertebral compression fractures.

In April, Amgen released Pivital Phase 3 data regarding the effects of denosumab on bone mineral density and biomechanical markers of bone turnover in postmenopausal woman with low bone mass. According to www.clinicaltrials.gov the primary outcome measures were "Reduction in the number of new vertebral fractures in post menopausal osteoporotic women treated with denosumab compared to placebo and to characterize safety and tolerability profile of denosumab." Part of the data released dealt with the effect denosumab had on BMD in the lumbar spine. The study stated that "denosumab treatment significantly increased lumbar spine BMD compared with a placebo at 24 months (6.5% vs. -0.6%)."

In Amgen's second quarter conference call the company further commented on the results of its Pivital Phase 3 study, noting "denosumab treatment resulted in a statistically significant reduction in the incidence of new vertebral fractures as compared with placebo treatment."

If it can be shown that denosumab reduces the incidence of vertebral fractures, this could significantly impact the VCF market.

Vexim: The SpineJack

Vexim SAS is based in France that is seeking to create a comprehensive portfolio focused on treating the symptoms, causes, and consequences of vertebral compression fractures. Vexim was set up in 2006 as a spin-off of Teknimed SA. The Vexim SpineJack allows for controlled fracture reduction. The device is left in the facture site while the cement is injected to maintain height restoration. According the company's website the technology allows for "the possibility of placing one or two implants and adjusting the plane and height of expansion."

The expansion of the device in the fractured vertebral body enables more

controlled cement flow and lower pressure injection. This reduces the risk of extravasation.

Regulatory Status

OUS: In May 2008 the company received the CE mark for the SpineJack system.

U.S.: Vexim is pursuing the 510k path to FDA clearance. In June 2008, the company announced the completion of enrollment in the 1a clinical trial. In July 2008, the company began enrolling in a multicentric post-market clinical study. Patients from France, Spain, Portugal, Italy, and Turkey are being enrolled in the study.

European investors have warmed up to the idea. In June 2006, Vexim received an investment of €3 million from Truffle Venture (Paris) in Series A financing.

DFine: Controlling Cement Viscosity

Currently, most VCF treatments consist of injecting relatively low viscosity, rapidly curing bone cement into the vertebral body. One potential complication with traditional vertebroplasty or kyphoplasty procedures is cement leakage or extravasation. DFine is focusing on solving this potential complication.

According to the company, "The StabiliT Vertebral Augmentation System enables the cement viscosity to be controlled by warming it with the application of energy in the delivery system, thereby accelerating the polymerization process." DFine's technology is centered at enabling cement viscosity to be controlled by warming it with the application of energy in the delivery system, thereby accelerating the polymerization process. The device utilizes the companies proprietary StabiliT ER Bone Cement, which is a PMMA-based bone cement that can increase viscosity on demand by applying energy.

Regulatory Status

OUS: The StabiliT is available exclusively for Clinical Investigation in the European Union.

U.S.: The system is commercially available.

This new technology continues to attract capital. On October 28, 2008, the company secured $30 million in Series D financing.

BioMimeticTherapeutics, Inc.

BioMimetics is focused on developing two primary orthopedic products, which are GEM OS 1 (now Augment Bone Graft) and GEM OS 2, (now Augment Injectable Bone Graft). According to the company's 2007 annual report, "*GEM OS1* (bone graft) and *GEM OS2* (injectable bone graft), use recombinant human Platelet-Derived Growth Factor (rhPDGF-BB), which is one of the principal naturally occurring wound healing stimulators in the body to kick start the tissue regeneration process."

GEM OS2 has the potential to impact the VCF repair market by reducing the risk of adjacent level fracture. Again, the basic thesis is that products which are proven clinically successful at reducing the incidence of vertebral fractures will negatively impact revenue growth of technologies centered at fracture repair.

According the company's 2007 annual report, indications for GEM-OS2 will be bone augmentation for osteoporosis and injected as a prophylactic treatment. After kyphoplasty or vertebroplasty, GEM-OS2 is a candidate for percutaneous injection into the adjacent level vertebrae.

Regulatory Status

Augment Injectable Bone Graft as indicated for the spine is currently in pre-clinical studies.

Sintea Biotech's SPIDER

Leave the cannoli, bring the spine implant. We are traveling to Milano, Italy, where Sintea Biotech is located. Sintea operates in both the spine and trauma areas of orthopedics. The company's spine portfolio includes anterior cervical plates, cages, lumbar fusion instrumentation, and occipital-cervical fixation devices.

However, for our purposes, we are concerned with Sintea's Spider as it is related to treating vertebral compression fractures. This device allows for controlled expansion/distraction inside the vertebra. The device is intended for use in the thoracic and lumbar spine for vertebral compression fractures caused by osteoporosis and metastatic tumors.

Regulatory Status

OUS: The device has received the European Union's CE mark.

U.S.: In June 2008, the device was FDA cleared via the 510k pathway.

VCF Treatment Moving Forward

We hear about potentially disruptive technologies and how they are going to be game changers. Often, they either take a decade longer than anticipated to make an impact, or make no impact at all. What makes the technologies above so interesting is that they are going to hit the market soon or are already approved. So the question is not if, but when. In our assessment, we were careful to look at the regulatory status of the technologies mentioned.

Here are potential trends in these devices.

- A movement toward devices that allow for controlled/adjustable height restoration
- A focus on devices that decrease the potential for cement leakage
- A trend toward adopting technologies that can be offered at a discount to kyphoplasty
- Devices that allow for increased control over cement viscosity and lower-pressure injection
- Devices that maintain vertebral height while cement cures preventing further damage to the vertebral body

Here are potential trends we see involving prophylactic treatments focused on preventing subsequent or initial osteoporotic fractures.

- Orthopedic companies may collaborate with pharmaceutical companies that have prophylactic treatments, decreasing the risk of subsequent or adjacent level fractures
- Products such as Amgen's denosumab could literally decrease the incidence of osteoporosis related fractures
- A focus on preventative medicine and prophylactic treatments could shift former fracture repair related revenues to pharma/biotech companies

Our thesis remains: companies developing innovative treatments to treat compression fractures should know that VCF still stands for **V**ery **C**ompelling **F**uture!

company news

BioMimetic Closes Enrollment for Augment Study

That's a wrap. BioMimetic Therapeutics, Inc. is announcing that as of December 31, 2008, 436 patients were enrolled in its North American pivotal clinical study for Augment Bone Graft, a project that will assess the safety and efficacy of this product for the treatment of foot and ankle fusions as compared to autograft. While 396 was the initial target, enrollment continued through December 31to accommodate those additional patients who had already been consented into the study and scheduled for surgery.

"A strong acceleration of enrollment in the fourth quarter enabled the completion of enrollment in December," said Dr. Samuel Lynch in the news release. Dr. Lynch, President and CEO of BioMimetic Therapeutics, added, "We are gratified by the surgeons' commitment and confidence, and as a result, we expect to be able to file the clinical data with the FDA in the fourth quarter of this year as the last element of our modular PMA filing. The other two sections of the PMA, the pre-clinical and the quality/manufacturing sections, are on schedule to be filed this spring allowing time for the Agency to review these data in advance of the clinical data. I want to once again acknowledge the ongoing efforts of our clinical investigators for their considerable work on the study."

Commenting to *OTW* was Kearstin Patterson, Director of Corporate Communications for BioMimetic, who stated, "This modular PMA, a three prong approach to the filing process—Pre-clinical, Manufacturing, Clinical Data, has become common in the last several years. According to the FDA, they intended the modular review approach to provide a mechanism by which applicants may submit preclinical data and manufacturing information for review while still collecting, compiling, and analyzing the clinical data. Additionally, the modular approach allows the applicant to potentially resolve any deficiencies noted by FDA earlier in the review process than would occur with a traditional PMA application."

The North American pivotal study is designed as a randomized controlled non-inferiority trial where participants are randomized 2:1, respectively (Augment and autograft). The primary endpoint of the study is the percent of patients fused, as measured by CT scans, at six months. Secondary endpoints include clinical assessment, plain film radiographic evaluation and several functional and pain assessments. The evaluation of all CT scans and X-rays will be done by a blinded, independent radiologist, who will assess the key parameters of radiographic fusion.

The company is also announcing that the United States Patent Office issued patent number 7,473,678 entitled "Platelet-Derived Growth Factor Compositions and Methods of Use

company news

Thereof." Although this patent was set to expire in 2024, as part of the issuance process, a term extension was granted by the Patent Office that will provide the company protection for its Augment product line, as well as certain other PDGF product formulations, until at least June 2025.

—*EH (January 22, 2009)*

All Calm at Biomet for 2Q09

Biomet CEO, Jeff Binder, by accident of the calendar, has been the first of the major orthopedic company CEOs to hold his quarterly conference call with Wall Street analysts.

He was the first in October, during the height of the credit crisis hysteria, to calm analysts by reporting a healthy previous quarter and noting he hadn't seen any signs that the orthopedic sector, or Biomet are about to enter a period of contraction.

On January 13, he was the first to report numbers from a quarter that ended November 30 and included the start of the financial crisis. Those numbers showed continued growth in revenues due to gaining market share in hips and signs of awakening at their spine business. Binder also continued to tell analysts that the company was not seeing signs of a feared slow-down in surgical procedures.

The second quarter revenue numbers for 2009 showed total sales up 6% to $643 million.

Hips – up 10%
Knees – up 7%
Spine – up 8%
Fixation – up 2%
Dental – down 2%

Binder attributed the growth in hips to recently introduced E-Poly Acetabular Liners and the Regenerex Ringloc Modular Acetabular System. He acknowledged that the company was taking market share from competitors. He didn't attribute that market poaching to any particular competitor or product, but said when a competitor is experiencing some stress; it's a good time to take advantage of market opportunities.

Spine had new product introductions and improved sales force effectiveness, according to Binder. During the question period with analysts, Binder said beyond the objective factors of new products, the spine division had undergone a transformation of perception. He said the spine business had been successful in attracting sales reps and distributors because people perceive it is exciting again to rep Biomet spine products. He said sales people want to sell products that will make them successful and there is new spirit in the spine franchise that is attracting sales people.

The economy and health care are facing considerable challenges, allowed Binder. But he continued to inform analysts that Biomet had not seen any changes in procedure volumes and might only see some "modest" deceleration in growth. "We're just not seeing it" [a slowdown], Binder told the analysts.

We'll see if Biomet is the canary in the coal mine after the rest of the orthopedic companies report their quarterly numbers. For now, it's all calm over at Biomet.

—*WE (January 22, 2009)*

DePuy
a Johnson & Johnson company

DePuy Revenues Climb in 4th Quarter

Its parent, Johnson & Johnson, didn't fare as well as the entire company's operational growth declined by 1%. It was the first revenue decline in many years at J&J. Revenue growth for DePuy in the U.S. was up 10%; while worldwide it was up 6.2%.

On an operational basis, DePuy's reported the following fourth quarter results:

Hips – up 11%
Knees – up 6%
Spine – up 8%

company news

Bill Weldon, J&J's Chairman and CEO, said the rate of growth in spine business accelerated throughout the year due to the successful launch of a number of new products. He said Mitek, their sports medicine business, grew 12%.

Weldon also took the opportunity during a quarterly conference call with analysts to address the impact of the recession on health care companies.

"Many of us are going to remember 2008 as a year of extraordinary economic events that shook our financial markets and global economy," Weldon told analysts.

Weldon cited major factors that will influence J&J's business performance in 2009. They included:

- General health care environment and trends.
  - Every three and a half seconds someone in the world turns 65.
  - Significant changes in health care systems and reimbursement models are being considered in the United States and elsewhere.
- J&J's own near-term business pressures.
  - Aggressive new competitors in some of their surgical and comprehensive care businesses.

Weldon noted that many analysts have reported that surgeries, especially elective procedures, are being postponed. Hospitals and health care providers are tightening their inventory levels and budgets while consumers are watching their spending more closely. "At Johnson & Johnson we are seeing early affects in a few parts of our business," added Weldon.

As an example, while growth is still strong in an area like sports medicine, the company has recently seen slight declines in growth rates in the market. Also in markets that require more out of pocket spending like diabetes test strips and contact lenses, J&J is seeing some signs that consumers and patients are becoming more frugal.

With $1 billion of net cash and a growing orthopedics business, J&J seems well positioned to survive a recession and even snap up any competitors who may have trouble surviving.

—*WE (January 22, 2009)*

Stryker DNA Aiming High

"It's clear that 2008 presented us with unprecedented internal and external challenges, including a global economy that contracted sharply in Q4, the considerable and rapid strengthening of the U.S. dollar, the Trident Hip recall early in the year, $50 million to $55 million of incremental investment in compliance, and the Department of Justice monitoring costs." So summarized Stryker President and CEO Stephen MacMillan, 2008 during the company's fourth quarter conference call with analysts on January 27.

There was something soothing about MacMillan acknowledging that he doesn't have a "high degree of conviction" about Stryker's 2009 projections and that "it's a hard time to plan." Or, that the coming year will present unprecedented challenges and anyone giving definitive answers about the coming year "don't know what they're talking about."


Stephen MacMillan

That's candor one can believe in.

Stryker's fourth quarter numbers looked like this for selected business segments.

Fourth Quarter 2008:

Total Revenues – up 3.6%
Orthopedic Implants up 4.2%
Hips – down 6%
Knees – up 9%
Spine – up 15%

These fourth quarter numbers weren't the usual stellar numbers put out by the Kalamazoo orthopedic giant whose market value now dwarfs the former automotive engines of the Michigan economy and dragged down year-end numbers that showed the depth of the slowdown.

For the full year revenues showed:

Total Revenue – up 2%
Orthopedic Implants – up 10.6%
Hips – up 3%
Knees – up 14%
Spine – up 19%

company news

Looking ahead to 2009, MacMillan said the company expects to increase revenues by 6%–9%. MacMillan said that while some analysts believe these numbers to be too optimistic, he noted, "Our DNA is to aim high" and expects growth in 2009 to be meaningful.

No Stryker quarterly call would be complete without an update on the long awaited OP-1 biologic product. The company said the product was to be reviewed by the FDA Orthopedic and Rehabilitation Devices Panel on February 3rd. But owing to scheduling conflicts, the FDA has informed them that the panel will be rescheduled to March 31, 2009, in order to ensure that the appropriate personnel can be in attendance.

Another long standing agenda item is Stryker's ongoing efforts to get back into the good graces of the FDA after a series of warning letters.

Katherine Owen, Stryker's VP, Strategy and Investor Relations got that one: "We invested an incremental $50 [million] to $55 million in 2008 in compliance versus 2007 and expect the 2009 incremental investment versus 2007 to be in the $60 [million] to $90 million range. Encouragingly, during 2008, we had twice as many FDA inspections of our facilities compared to the prior year and we think we are demonstrating meaningful progress."

She said the compliance efforts include implementing a common set of quality standards throughout the company, allowing them to not only address the issues raised in the warning letters, but also "galvanizing the organization around moving towards excellence and compliance."

MacMillan said he believed that the federal monitoring program of physician contracts with device companies has caused a "fundamental shift in the industry" and doesn't think it would behoove the industry to return to the days of the "Wild West" when the monitoring comes to an end in the spring.

Given all that sobering candidness, MacMillan predicted that after a slow first half of 2009, the company will see a ramping up of revenues later in 2009.

In an investor note the day after the call, Wachovia's senior analyst Mike Matson wrote that product cycles and comps do provide some justification for that optimism. "We expect new products to lead to improving growth in both the endoscopy and hip businesses. Endoscopy is launching a new camera (the 1288), wireless high definition monitor, and light source (the L9000). With these product categories making up a substantial part of endoscopy's revenue, we expect accelerating growth through 2009 despite the economic headwinds. In hips, SYK has launched the Tritanium primary hip cup which uses porous titanium for fixation and is being sold at a discount to competitive products intended for revisions. We expect hip growth to improve as well during 2009."

Investors seemed to appreciate and believe the candor. The company's stock was up over 5% by noon the day after the release of the fourth quarter numbers.

—*WE (January 28, 2009)*

ApaTech's Growing Pedigree

Britain's fastest growing private medical technology company, ApaTech Inc., has added the pedigree of Johnson and Johnson, Medtronic and Kyphon to their front office as the company announced major new appointments in January.

The producer of Actifuse, a silicate-substituted calcium phosphate bone graft material, has operations in London, Boston, and Berlin and sells products in 21 countries.

Simon Cartmell, ApaTech's CEO made the announcements on January 9. He said the company's growth has been driven by the quality of the people the company has been able to hire and who are committed to the mission of redefining the orthobiologics market place.

The new hires include:

Jill Schiaparelli, Vice President - Commercial Strategy and Business Development, will be responsible for

company news

global commercial strategy and all U.S. and OUS marketing activities including commercial input to new product development and portfolio expansion through acquisition and licensing. Prior to joining ApaTech she held a series of global strategy and marketing positions at Johnson and Johnson, including Ethicon/ Ethicon Endo.

Melanie Marshall, Vice President - Clinical Operations, will be responsible for the conduct of pre and post approval clinical studies and the acquisition of clinical data in support of marketing and regulatory objectives. Immediately before joining ApaTech, Marshall was responsible for clinical strategy and execution across several divisions of Boston Scientific, prior to which she gained extensive experience in the spine division of Medtronic.

Todd Clearwater, U.S. Vice President - National Sales, will be responsible for all U.S. sales and sales-related activities and previously set up and managed Kyphon's national market expansion activities. Following his time at Kyphon, Todd served as Senior Vice President Sales at Interventional Spine Inc.

Both Schiaparelli and Marshall will report to Cartmell and become members of the company's senior management team. Clearwater will report to ApaTech's President, Steve Czick.

ApaTech was recognized as Britain's fastest growing medical technology company in both the 2008 and 2007 *Sunday Times* Fast Track 100 fastest growing private companies review.

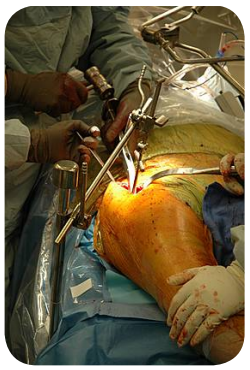
—WE (January 27, 2009)

Integra Buys Omni-Tract Surgical

Based in St. Paul, Minnesota, Omni-Tract Surgical (aka: Minnesota Scientific) is now a part of Integra LifeSciences of Plainsboro, New Jersey.

Omni-Tract is part of the, no pun intended, burgeoning market for plus sized table mounted retractors. For the bariatric market (read obesity market), Omni-Tract is key player. But for all surgeries, Omni-Tract has the table mounted retractors for orthopedic, spine, general, vascular, and laparoscopic indications.

In orthopedic applications, Omni-Tract offers the femur elevator for direct anterior hip replacement procedures. No need, when you're using the Omni-Tract elevator to rely on a special table ith complex pre-operative patient positioning. Instead, surgeons can use the Omni-Tract, keep the same table they've always used, assess leg length and stability like always but still get the additional mechanical assist and manual elevation required.


Omni –Tract Femoral Elevator in Action

Integra plans to add the Omni-Tract line to its existing JARIT, Padgett, R&B Redmond, and Luxtec lines of surgical instruments and illumination systems.

No terms of the purchase were released but, given Integra's famous eye for the smart buy, we suspect that it is below Integra's current 1.20x sales or 2.4x book value.

—RRY (January 27, 2009)

"SickKids" Acquires Biospace med's EOS

Prescription for the little ones? Low dose radiation. Biospace med is announcing that the Hospital for Sick Kids ('SickKids'), Toronto, has purchased the company's EOS 2D/3D ultra-low-dose X imaging system.

company news

EOS is designed to quickly capture high quality head-to-toe images of patients in a standing, weight-bearing position while reducing up to 90% of the radiation dose compared to a conventional x-ray and up to 500 times less radiation than a conventional CT scan.

In the news release, Paul S. Babyn, M.D., Radiologist-in-Chief in the Department of Diagnostic Imaging at SickKids, stated, "We performed a preliminary study to compare EOS imaging with prior exams of the same patient and found the image quality to be excellent. Also, we have compared the 3D measurement system against CT in an initial 'phantom' study, and it performed very accurately. We see these capabilities as helping to improve the accuracy of surgical and therapeutic decision-making in musculoskeletal pathologies. But more than anything else, decreasing the dose of radiation that children receive from medical x-rays is extremely important to us, and is the primary reason that we are committed to working to advance the applications of this new technology."

Also commenting was Ellen Charkot, Director of Diagnostic Imaging at SickKids, who stated, "EOS not only represents a significant advancement in *safer* medical-imaging technology, but it also offers an extremely pragmatic benefit to a busy children's hospital-the speed with which EOS can safely and effectively image patients is likely to reduce our clinic wait-times, as it has in other children's medical institutions in Canada."

"Daily use of EOS by one of the largest children's hospitals in North America signifies momentous progress in radiation dose reduction, as supported by the *Image Gently* initiative of the Alliance for Radiation Safety in Pediatric Imaging," said Biospace med CEO, Marie Meynadier, Ph.D., in the news release. "We are in discussions with many more hospitals throughout North America that will be giving serious consideration in this new year to lowering radiation dosage in their imaging of children."

Recently cleared by the FDA, *EOS* acquires two simultaneous low-dose planar AP/PA and LAT images, which can cover the full body. The sterEOS workstation allows a review of the images, the production of clinical parameters, and the reconstruction of a 3D image of the adult spine. The company has also developed additional software to address pediatric spine and a lower extremity package for hip and knee assessment. The workstation software is designed to enable measurements within 3D space, which eliminates errors made from projected planar x-ray images.

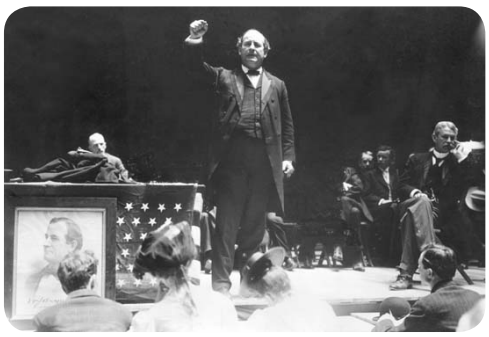
The Image Gently program is supported by the Alliance for Radiation Safety in Pediatric Imaging, a consortium involving 13 societies representing the fields of radiology, pediatrics, medical physics and radiation safety.

—EH (January 20, 2009)

Orthofix Fate in the Hands of Voters

The battle for the Board of Orthofix is now being taken to the shareholder voters.

On January 12, dissident shareholder, Ramius LLC sent out a letter to Orthofix shareholders asking them



to vote in favor of calling a special meeting of the shareholders. At the meeting, Ramius wants to elect its own slate of board members who want the company to dump Blackstone Medical, Orthofix's spine business.

company news

Orthofix responded by sending out their own letter saying that the call for a meeting was unnecessary and a distraction.

The battle for votes intensified on January 20 when Orthofix accused Ramius of misleading shareholders in a press release implying that a proxy adviser was supporting the ouster of board members. Ramius had announced earlier in the day that RiskMetrics Group was advising that shareholders, "vote for Ramius' proposal to call a special general meeting for the purpose of making substantial changes to the composition of Orthofix's Board of Directors."

Orthofix Chairman James Gero said this was misleading and that RiskMetrics Group was simply supporting a call for a meeting. "It is important that we exercise responsibility, professionalism and respect for all of our shareholders during this process, and we are concerned that Ramius' statements today do not meet those standards."

Ramius and Orthofix have both hired New York PR firms specializing in campaigns and crisis management. If 10% of shareholders support the call for the special meeting, the company will call the meeting and the battle for the board will take on the aura of a political convention. Arguments will be made and a vote will be taken.

Seems like we just did this.

—*WE (January 21, 2009)*

legal & regulatory

GAO Report Blasts FDA Approval Process

One can almost feel sorry for the FDA. Almost.

First, its own science board says it's broken and can't protect the public's health. Then nine dissident physicians and scientists within its ranks went off the reservation and complained to Congress that non-scientific leaders at the agency were ignoring their advice and recommendations.

The only good news recently was when American device manufacturers complimented Japanese regulators for starting to emulating the FDA's approval process.

Now the investigators from the General Accounting Office (GAO) have piled on.

On January 15, in a long anticipated report, the GAO stated that "it is imperative that FDA take immediate steps" to fix its system for approving devices.

The current process for approving devices was created in 1976. Class I devices such as reading glass are largely exempt from agency reviews. Class II devices such as mercury thermometers get quick reviews. Class III devices such as artificial orthopedic replacements or biologic products were allowed by Congress to receive perfunctory reviews if they were identical to devices already on the market in 1976.

Congress told the agency to write rules that would set a firm deadline for when all Class III devices would have to go undergo the rigorous testing process. The GAO report said the agency came up with a plan in 1995, but never implemented it.

The GAO findings were based on devices reviewed between fiscal years 2003 and 2007. During that time, 228 high-risk devices were approved after the less-stringent review, the GAO said.

On Tuesday, January 20, outgoing FDA Commissioner and cancer doc Andrew C. von Eschenbach, M.D., said during a press conference that the agency was like a cancer patient. "It's a shock when someone says you have cancer."

A few days earlier, *The New York Times* reported on January 15 that in response to the question of why it took eight years for the agency to recognize the problem, von Eschenbach replied that "sometimes it takes a crisis before" such recognition occurs.

legal & regulatory

Medtronic's chief regulatory officer, Dr. Susan Alpert was also mentioned in the article and said that the impression that the FDA is approving new technologies with little review is "erroneous." She said that many of the Class III devices that currently receive less scrutiny before approval would, once the agency completes its overhaul, be reclassified as less risky Class II devices. Artificial knee manufacturers have been trying to down-classify certain knee replacements for the past few years.

Steve Ubl, AdvaMed's chief responded that, "The [GAO's] report on the FDA's review process limited its comments primarily to a small subset of 20 devices that the FDA has yet to classify, not the review process as a whole. In fact, the GAO report demonstrates that the FDA's process is working as intended."

New Jersey Representative Frank Pallone, who chairs the health subcommittee of the House of Representatives Energy and Commerce Committee, said he would hold hearings if the process wasn't fixed.

—*WE (January 23, 2009)*

FDA Journeys to India

New Delhi and Mumbai, India are sporting new FDA offices under the U.S. government's Beyond Our Borders Initiative.

India is the fourth largest exporter by volume of drugs and biologics, especially generic pharmaceuticals, to the United States. It is also a significant exporter of food products. The Indian pharmaceutical industry exported drugs worth about $7.4 billion in 2008 according to *The Telegraph* of Calcutta.

The FDA initiative will eventually put 25 FDA staffers in 14 U.S. Embassy, Consulate and Mission locations around the world. So far the FDA has a presence in China, Central America, India, and Europe, with plans to expand this year in Mexico, South America, Europe, and the Middle East.

Ten FDA officials will be in India and work with industries that export food and medical products to the United States. Along with the Office Director, the FDA will have four inspectors and five senior technical experts to work


FDA Beyond Our
BORDERS

with Indian companies to improve the safety and quality of the products. The staffers will provide technical advice, conduct inspections of facilities exporting to the U.S. and work with Indian government agencies and the private sector to develop certificate programs.

In the past five years, the number of FDA agreements with regulatory counterparts throughout the world more than doubled and continues to grow. The FDA has over 100 formal agreements with its counterparts in 29 countries, 18 with the European Commission or its European Union members, and two with the World Health Organization.

The FDA says its in-country offices will allow the agency to:

- build or further strengthen a trusted regulator-to-regulator relationship
- learn more about the industries and challenges of how products are regulated in these countries
- more easily inspect manufacturing and processing facilities in these countries or determine how FDA can further leverage inspections already performed by its counterparts in certain regions, such as Europe
- have increased interactions with foreign manufacturers to help ensure that products shipped to the United States meet FDA standards for safety and manufacturing quality
- verify that imported products and the way they are manufactured meet U.S. health and safety requirements

While the FDA struggles to regain the confidence of Congress, its own Science Board and scientific staff, it remains to be seen whether its overseas efforts will help assure the public that the safety of drugs and

biologics

devices coming into the U.S. are improving.

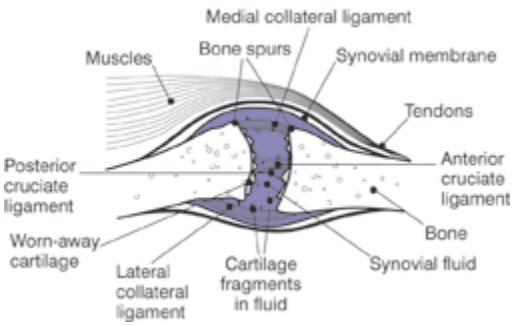
— *WE (January 27, 2009)*

Knee OA Stem Cell Trial

Last week Mesoblast Limited announced that the Australian department in charge of institutional ethics (?) had granted the firm approval to conduct a test of stem cells for knee osteoarthritis. The study, which will be conducted at Melbourne's Orthopedic Research Foundation, will be treating knee osteoarthritis ***prophylactically*** following acute traumatic knee injuries.

The study will be randomized and placebo-controlled. The Phase 2 clinical trial will attempt to answer the question of whether Mesoblast's allogeneic, or "off-the-shelf", adult stem cell product, RepliCart, can slow or prevent the development of knee osteoarthritis after reconstruction of a ruptured anterior cruciate ligament (ACL).

Mesoblast hopes to enroll 24 patients between the ages of 18 and 40 who have undergone recent ACL surgical reconstruction within six months of a traumatic knee injury. The patients will receive either one of two doses of RepliCart (injected into the knee joint) together with hyaluronan, or hyaluronan alone.



The trial's primary endpoint will be safety of the stem cell therapy at 12 months, and its secondary endpoint prevention of cartilage loss and knee osteoarthritis during this period.

In earlier preclinical trials, a single injection of Mesoblast's allogeneic stem cells into the knee joint shortly after knee surgery resulted in sustained and significant protection of joint cartilage and reduced the severity of knee osteoarthritis.

Roughly 15 million people are diagnosed with osteoarthritis of the knee annually in the United States. Up to 70% of the patients who rupture their anterior cruciate ligament go on to develop osteoarthritis 15 to 20 years earlier than the general population. In the U.S. osteoarthritis after a single acute traumatic incident comprises about 12% of all osteoarthritis cases with approximately 300,000 new cases reported annually.

— *RRY (January 27, 2009)*

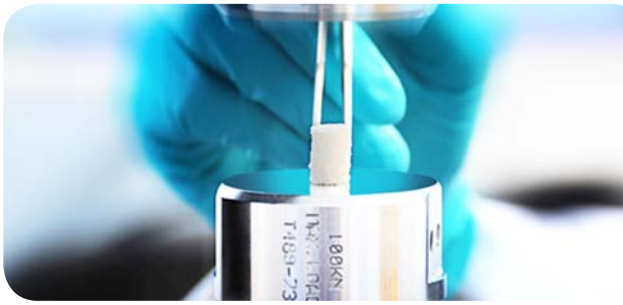
Orthomimetics Gets CE Mark for Chondromimetic

A stamp of approval from across the pond…U.K.-based Orthomimetics Limited, a regenerative medicine company, is announcing receipt of CE Mark approval for Chondromimetic, its flagship product for the repair of articular cartilage and bone.

This approval means the marketing can begin on the company's line of bioresorbable implants for bone and/or soft tissue repair in the EU. Orthomimetics' family of products was developed during a groundbreaking collaboration between the University of Cambridge and the Massachusetts Institute of Technology.

Chondromimetic is an off-the-shelf implant that helps to support the repair of defects involving both articular cartilage and bone—defects that can result from sports injuries, surgical intervention and other trauma.

The company indicates that CE-mark approval has been granted earlier than originally forecast at the time of the company's December 2006 Series A financing. Orthomimetics will immediately launch a comprehensive post-market clinical-trial program for Chondromimetic, and is currently negotiating distribution agreements for key European territories. The company will pursue additional approvals in other global territories throughout 2009.
In the news release, Andrew Lynn,



biologics

CEO of Orthomimetics, said: "Orthomimetics is extremely pleased to be able to make Chondromimetic available for surgeons and patients in Europe. This approval is the result of a tremendous amount of hard work on the part of our surgeon advisors, scientific collaborators, and—most of all—our professional, dedicated team. We look forward to making Chondromimetic a clinical and commercial success."

Commenting to *OTW*, Lynn stated, "Today's surgeons demand treatments proven effective by sound, clinical evidence. To meet this demand, Orthomimetics will gather a bank of strong clinical data based on a controlled launch of Chondromimetic that actively encourages thorough patient follow-up. Orthomimetics is committed to providing sound evidence to support the long-term success of our innovative flagship product."

— EH (January 16, 2009)

large joints

Study: Patients, Providers Disagree on TKR

Yes, you do. No, I don't. What is he saying? A recent article on *MedPage Today* (Charles Bankhead, "Knee Replacement Recommendations May Be Misunderstood," January 9, 2009) discussed a study that looked at whether communication factors affect provider and patient agreement on the need for, risks of, and benefits of joint replacement. The study also investigated whether degree of agreement predicts patient satisfaction and intent to follow treatment recommendations.

The research, published online December 30, 2008, in *Arthritis and Rheumatism,* involved 27 health care providers, along with 74 patients who had severe osteoarthritis (OA). The patients, who were recruited from clinics in Houston, Texas, completed a baseline survey prior to their consultation. After the visit, both patients and providers completed measures of the severity of the patient's OA, the expected benefits of total knee replacement (TKR), and concern about surgical complications. Patients also completed a survey regarding their level of satisfaction, as well as an "intent to adhere" measure.

Patient self reports were assessed, as were audio recordings of the provider-patient consultations. Analysis found that patients and providers agreed that total knee replacement had not been recommended in 46 cases; in 13 cases, the patient-provider pairs agreed that the physician had recommended the surgery. In the remaining cases, the patients and providers disagreed as to whether joint replacement had been recommended.

The researchers included Dr. Richard L. Street, Jr., and colleagues of Texas A & M University. They pointed out that providers and patients were more in agreement on the patient's OA severity when providers used more partnership building but spent less time simply giving information. Differences between providers' and patients' concerns about surgery were greater when patients were less participatory, African American, or expressed lower trust in their doctors. Patient satisfaction and intent to adhere were predicted by provider-patient agreement on the benefits of TKR.

Patients and providers often differ in their beliefs about the need for, risks of, and benefits of TKR, and these differences can affect patient satisfaction and commitment to treatment. Facilitating active patient participation might contribute to

large joints

greater physician-patient agreement on the patient's concerns about OA and surgical interventions.

Commenting to *OTW* on how patients and providers can come together on these issues, Dr. Street noted, "It is important for patient's to check their level of understanding, i.e., 'OK, doc, now let me see if I understand. What you're saying is that I might need joint replacement because....' Or, the doctor to the patient, 'So tell me what you see as the potential benefits of joint replacement?' This lets the doctor see what the patient understands, what the patient's beliefs and concerns might be, and provides opportunity to either clarify or provide more information on topics the patient may not know."

Dr. Street added, "Active patient participation is also necessary. For example, 'Dr. Smith, I think I could benefit from joint replacement, but I am really worried about the surgery. I mean I've heard stories where...' Here we see the patient speaking up, discussing concerns and stating preferences. The doctor can encourage patient participation through partnership-building comments like, 'Tell me about what you would like joint replacement to do for you?' and 'What concerns do you have about the procedure and recovery?'"

As for how to provide clear and easy to understand information, Dr. Street told *OTW*, "That really depends on the patient. One without much understanding of orthopedics might need analogies, metaphors, and pictures to understand the surgery and how the new joint works. On the other hand, someone who has gone online and done research may be fairly well informed or they may be suffering from information overload. In that case, it may be less about how to use lay language and more about how to straighten out the patient's confusion."

— EH (January 20, 2009)

PT DVD: OrthoCareRN Joins Bonesmart Website

Insurance ran out? Turn on the DVD player. OrthoCareRN is announcing that it has recently joined F.A.R.M. Orthopedics as a Sponsor Partner on their Bonesmart website, http://www.bonesmart.org/, to promote Orthopedic Home Care and "Transitional Physical Therapy" on DVD.

The company indicates that its experience in total joint aftercare has laid the foundation for the development of a unique experience for patients who exhaust their physical therapy benefits through Medicare, as well as private insurances. Dr. Terry L. Whipple and OrthoCareRN, Inc. are now reaching out to the many patients who have the misfortune of being told that continued therapy will be an out of pocket expense, many of whom do not return to full function or remain in need of assistance to motivate their independent recovery.

The Transitional Physical Therapy series consists of instructional DVD's designed to motivate, instruct and encourage a return to independent function. They can also be used for pre and post-surgical muscle strengthening and conditioning. OrthoCareRN says they are also a valuable reference for chronic sufferers in need of refresher exercises.

Commenting to *OTW* was Rob Crotser, Executive V.P. and COO of OrthoCareRN, who said, "The exercises on the DVD are comprehensive in nature. For example, our Spine DVD is appropriate for everything from chronic lumbago to discectomy and fusion. The Knee DVD is designed for patients with any knee injury, surgical procedure or replacement. Hip covers joint replacement and fractures. All cover arthritis. Each DVD focuses on the essential components of comprehensive therapy—SSSRB: stretching, strength, stamina, reflexes and balance."

— EH (January 20, 2009)

large joints

Study: Placenta Growth Factor's Role in RA

A new window into rheumatoid arthritis…A recent article in *Medical News Today* ("Discovery Of Process Found To Play Role In Rheumatoid Arthritis Could Lead To New Treatment," January 30, 2009) discusses the results of a recent study indicating that placenta growth factor (PIGF) may play an important role in inflammation in rheumatoid arthritis (RA) joints. Several cytokines (bioactive proteins), especially TNFåand IL-6, are involved in inflammation and contribute to joint and tissue destruction. PIGF, another cytokine, has been thought to be critical for a new blood vessel formation in the placenta to sufficiently deliver oxygen and nutrients to fetus. This study, led by Wan-Uk Kim of Catholic University of Korea in Seoul, Korea, examined the effects of PIGF on the inflammatory process of RA.

After analyzing blood and synovial fluid cells from RA patients and healthy controls, the researchers found that synovial cells were the major source of PIGF production in RA patients and that PIGF stimulates TNFå and IL-6 production. They also found that the PIGF-induced increases in TNFå and IL-6 production may be caused by high levels of flt-1, a PIGF receptor, which are linked to the inflammatory response of RA patients. In addition, the researchers identified a novel peptide to inhibit PIGF action. When injected into arthritic mice, this peptide reduced the severity of arthritis and prevented its progression. They also found that elimination of PIGF gene in mice prevented the development of antibody-induced arthritis. The peptide identified by researchers inhibits binding of PIGF to its receptor flt-1and could be valuable from a clinical standpoint, since it is easily synthesized and does not elicit unwanted immune response.

As quoted in the article, the authors stated, "These findings provide new insight into the pathogenic mechanism of RA and emphasize the importance of PIGF and flt-1 as potential candidates for therapy, in addition to their being a common cue of angiogenesis and the inflammatory process." The investigators are now conducting research to improve the activity of the anti-flt-1 peptide by modifying its structure and length.

— *EH (January 30, 2009)*

people

Lew Bennett Takes the Helm at Custom Spine

You can't keep a good luminary down…Lew Bennett, that is. After retiring and re-entering the market six times, Bennett has now taken the lead at Custom Spine, a spinal implant and instrument company founded by engineers and industry professionals in partnership with orthopedic and neurological spine surgeons. Bennett will serve as President and on the Board of Directors.

Bennett brings with him over 48 years experience in the medical device industry. Custom Spine founder and CEO, Mahmoud Abdelgany commented in the news release, "We are really excited to have Lew Bennett taking the helm of Custom Spine. He brings to the company a deep knowledge of the market and a passion for success."

Mr. Bennett has held senior executive positions with several companies in the orthopedic and spine industry including: Executive Vice President, Officer, and Board Member of NuVasive, Inc.; early investor, Executive Vice President, Officer and Director of Sofamor Danek (now a division of Medtronic, Inc.); President, General Medical Division, Smith & Nephew, Inc. and President of Dillion Manufacturing. In addition, he was one of the founders of Howmedica Corporation (now Stryker Howmedica Osteonics). Prior to founding Howmedica, he was Regional Manager for Ethicon Corporation, a division of Johnson & Johnson. Mr. Bennett currently serves on the Boards of Directors for Custom Spine and HydroCision.

people

Bennett has been guest speaker at numerous medical conferences and a lecturer at over 300 orthopedic and neurological resident programs. He has consulted for over 550 orthopedic and neurological practices and universities.

In the news release, Bennett stated, "Custom Spine's engineers have developed innovative products and instrumentation that will provide great benefit to the surgeon and patient. I am excited to lead the team as we continue to pioneer new products for the spine industry."

Commenting to *OTW*, Bennett said, "I believe the key to success is finding out what people want and helping them get it. This philosophy can be translated into many areas of life. At Custom Spine, my first focus is to build a strong sales team and distribution network whose focus is to help surgeons get what they want in the spine business. Based on the same principal that I have lectured on countless times, I believe the key to building a successful team includes continued recruiting, training, and developing of people to help them be successful at helping surgeons."

He added, "I enjoy the challenge of working and love to meet new people. I have met some wonderful people in my career and feel so good that I often use the phrase, 'I feel like a million.'"

— EH (January 27, 2009)

Brent D. Mittelstadt Named President, CEO of CUREXO

(C)hampion of (E)fficient (O)perations here…CUREXO Technology Corporation has announced that Brent D. Mittelstadt, a pioneer in surgical robotics, will take the reins as President and Chief Executive Officer. Mittelstadt holds eight patents and has published extensively in the field of computer-assisted orthopedic surgery.

Twenty-three years ago Mittelstadt began spending his laboratory time in surgical robotics as a visiting research scientist at the IBM T.J. Watson Research Center. He is responsible for much of the early development of CT-guided robotic systems for joint replacement surgery. In 1990, with an initial investment from IBM, Mittelstadt cofounded Integrated Surgical Systems (ISS) to develop a surgical robot system to assist with hip and knee replacement surgery. In 2007, ISS transferred all of its assets to CUREXO Technology Corporation.

While at ISS, Mittelstadt served as Director of Surgical Applications, where he led the development and refinement of both the early pin based hip application, as well as the DigiMatch ROBODOC Surgical System for Total Hip Arthroplasty (THA), which received FDA clearance in August 2008. Following this position, Mittelstadt signed on at Consensus Orthopedics (formerly Hayes Medical Inc.), where he was Director of Marketing. Mittelstadt was part of a turnaround management team that was integral in transforming the company. When he first jointed Consensus, it was suffering from declining sales and a poor reputation in the market. Today, Consensus Orthopedics is achieving over 60% annual growth in revenue. While there, Mittelstadt was involved in the development of new implants and line extensions as well as re- designing the total knee instrumentation system to address changes in the joint replacement market.

"We are very excited to have Mr. Mittelstadt as a member of our senior management team. The unique combination of his ROBODOC knowledge and our recent FDA clearance provides Mr. Mittelstadt an immense opportunity to lead the company into the next phase of commercializing our products into the U.S. market. Mr. Mittelstadt brings his vast robotic experience along with integrity and vision to the company," stated Mr. Taehoon Kim, Chairman of CUREXO Technology Corporation, in the news release.

Commenting to *OTW* on his new role, Mittelstadt stated, "It is difficult to identify only one life experience which has best prepared me for my new role. However, I would have to say that the combination of being one of the pioneers in the development of surgical robotics, along with knowledge gained while at ISS and Consensus Orthopedics, has provided me the in-depth experience needed to move CUREXO Technology Corporation forward."

— EH (January 23, 2009)

spine

Dr. Iatridis and His Excellent Award

Mechanical engineer James Iatridis is the author of 50 peer review journal articles on the mechanics of the spine and last month he received the Presidential Early Career Award for Scientists and Engineers which brought with it a $1.5 million, five-year grant for the National Institutes of Health.

In his spare time, Dr. Iatridis is also an associate professor in the University of Vermont College of Engineering and Mathematical Sciences. As a mechanical engineer, he has unique and interesting task of mapping the motion and kinematics of the spine.

Among the areas of research that Dr. Iatridis finds "fascinating" and "remarkable" are the entire arena of disc repair and regeneration. Specifically, he and his team at the UVM lab are marshalling their considerable talents to unlocking the mysteries of soft-tissue bioengineering and the relationship between mechanical events and the biological response of living tissues in the spine. Without question, Iatridis and his team have been among the most prolific researchers regarding spine and intervertebral disc bioengineering.

And why the Presidential medal?

Because understanding the relationship between the mechanical, electrical, and chemical fields in the dynamic environment of the nucleus (including the biosynthetic and biomechanic response of cells) will almost certainly open up early detection of degenerative disc disease and successful repair of the intervertebral disc. For the tens of millions of back pain suffers in the world, that would be spectacular news indeed.

— *RRY (January 27, 2009)*

DiFUSION's Antimicrobial Spine Implant Passes Test

Go to the head of the class… DiFUSION Technologies, Inc. is trumpeting the fact that its silver ion-based antimicrobial technology—designed to mitigate surgical site infections (SSIs) in spinal surgery—has successfully completed a series of laboratory tests. The technology will be incorporated into DiFUSION's first spinal implant, CleanFUZE. Laboratory tests achieved a 5 log reduction in microbial counts, which is 99.999% effective—a level not achievable by any antibiotic on the market.

CleanFUZE is a PEEK interbody cage capable of stopping biofilm formation in the bone graft site and eliminating 650 types of bacteria (including antibiotic-resistant bacteria) for up to four weeks post-op. DiFUSION indicates that CleanFUZE will also save the patient from additional surgery, weeks of IV antibiotics, and in some cases life-long exposure to oral suppressive antibiotics, amputation, and even death.

"DiFUSION is targeting a problem that costs hospitals and insurance carriers over $100,000 per SSI incidence, and CleanFUZE has the potential to not only obviate spinal surgical site infections, but also save hospitals millions of dollars a year in associated costs to treat these infections," said Dr. Peter Whang in the news release. Dr. Whang, a member of DiFUSION's scientific advisory board and an Assistant Professor in the Department of Orthopaedics and Rehabilitation at the Yale University School of Medicine in New Haven, Connecticut, added, "Moreover, as of October 2008, the Centers for Medicare and Medicaid (CMS) are no longer paying for hospital-acquired infections; therefore, healthcare facilities are going to have to absorb these staggering costs."

Commenting to *OTW* was Dr. Nitin Bhatia, a member of DiFUSION's scientific advisory board and a board-certified orthopedic surgeon and Assistant Professor of Clinical Orthopaedic Surgery at the University of California, Irvine. Dr. Bhatia: "DiFUSION's antimicrobial technology can have a monumental impact on patients, hospitals, and the healthcare system. It is not commonplace for a single technology to have an impact on all three of these areas."

spine

"DiFUSION's solution addresses the U.S. Department of Health and Human Services' (HHS) action plan released January 2009 to reduce and eliminate healthcare-associated infections (HAIs), one of the key areas being surgical site infections," said Dr. Matthew Geck, founder and board member of DiFUSION, in the news release.

Unlike other devices on the market, DiFUSION's CleanFUZE will be capable of releasing its dosage amount

over time and the rate of diffusion can be controlled by parts-per-billion. Additionally, rather than antimicrobial coatings currently used in devices, CleanFUZE contains antimicrobial properties embedded in the device, which, says the company, significantly enhancing the effectiveness.

Also quoted in the news release was Dr. Hyun Bae, a member of DiFUSION's scientific advisory board and a board-certified orthopedic surgeon in Santa Monica, California, specializing in minimally invasive microsurgery and the treatment of cervical and lumbar spinal disease. He stated, "Larger companies have spent years and millions of dollars trying to address the SSI problem with antimicrobial coatings which do not fight infection past the first 48 hours. Our technology provides antimicrobial protection for four weeks due to 'controlled cationic release.' No other orthopaedic company has developed a technology with this kind of duration and efficacy; clearly DiFUSION is setting itself apart from the market with CleanFUZE."

The company estimates that hospital material managers will mandate the product's use because: orthopedic surgeons will not need to alter currently accepted surgical techniques, will not need new implantation instruments, and hospital and insurance carriers will not be required to implement new procedure codes.

DiFUSION intends to conduct the appropriate filings to facilitate full FDA clearance by the end of 2009. Agreements are also in place with 15 distributors and discussions have been initiated with an additional 20. This will position a U.S. sales force of 200 to 300 sales representatives to support the launch of CleanFUZE

Derrick Johns, President and CEO of DiFUSION, told *OTW*, "We currently have 17 U.S. distributors for a September launch of CleanFUZE. This will put 200 sales representatives in the field covering every major market in the country. DiFUSION's posterior spinal cage set will contain PLIF, POLAR and TLIF cages."

— *EH (January 26, 2009)*

4-Level En Block Cervical Resection!

In twelve hours no less. Yes, get the track shoes on, two UCSF neurosurgeons have reported the first ever 4-level, en block, cervical resection (C2-C7). Yes, sports fans, it's also one for the record book.

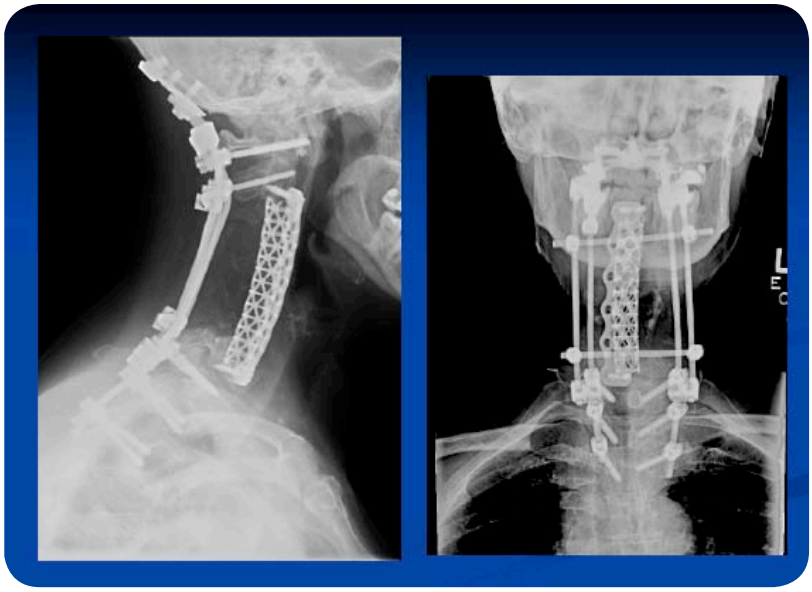
Dr. Christopher Ames, Associate Professor of Clinical Neurological Surgery, UCSF

Roughly three years ago Dr. Chris Bailey (Department of Surgery, Division of Orthopaedics, University of Western Ontario Victoria Hospital) demonstrated that a 3-level En Bloc resection can be successfully accomplished in cases where the patient presents with a seemingly unresectable C-2 chordoma.

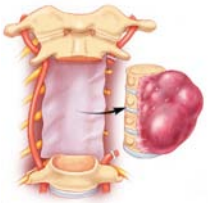
Chordomas are rare, slow growing malignant cancers. In most cases, aggressive surgical resection of the tumor followed by radiation therapy offers the best chance of long-term control. Chordomas are relatively radioresistant meaning that they require high doses of radiation to be controlled. Furthermore, since they are located next to structures such as the brain stem and cervical nerves, the

Dr. Vedat Deviren, Assistant Clinical Professor Orthopedic Surgery

spine



amount of radiation that can be safely delivered is highly limited. There are no drugs currently approved to treat chordoma.



So, the preferred but no less difficult approach is a wide or true en bloc resections of the tumor and cervical bone. The risks, of course, are abundantly obvious. The tumor abuts nerves, surrounds arteries, vertebrae, and dura mater and the type of neural injury that can result from such a massive resection at the cervical level is, potentially, extreme.

In 2006, Dr. Bailey successfully accomplished a 3-level en block resection and published his case report in the *Journal of Neurosurgery Spine* (2006 May;4(5):409-14). That surgery took 40 hours—which raised other, significant risk factors including the issue of post-op septic shock (which did occur—in the patient, not the surgeon).

But now, in a spectacular feat of surgical Ledger-Demain, two UCSF surgeons not only successfully accomplished a 4-level en block resection, but they did it in 12 hours. The patient, in her own words, is delighted with the results: "Oh, I feel really good. I can do just about everything that I could always do. My joy for life has come back."

How did they do it? Lots of planning, careful surgical mapping and then, like a ballet in scrubs, the two surgeons worked in tandem, side-by-side cutting and implanting ***simultaneously.*** Two stages: posterior approach took six hours and then the anterior approach took another five hours.

The 60-year-old, female patient, Mary Shorba (who'd allowed her name to be used in news reports about the surgery), was diagnosed with a spine tumor earlier in 2008. She was referred to Drs Deviren and Ames for possible "heroic" intervention. Among the issues confronting Drs. Deviren and Ames was the vasculature. One vertebral artery was completely involved in the tumor and the other was only partially involved. Ames and Deviren decided to skeletize the fully involved artery and try to save the other. That worked.

According to news reports in San Francisco, Ms. Shorba was quoted as saying " "The doctor told me I that I probably wouldn't die, that I'd be a quadriplegic at least 10 years before I died. That kind of motivated me to say yes to the surgery even though I was very scared."

In mapping out the surgery, Ames and Deviren focused as well on the implants required to cover such a vast space. There was NO bone between C2 and C7. One concern had to do with the strength of traditional titanium rods. In the literature, Ames and Deviren had noted that the force of a 4.5 Kg human head was enough to sometimes bend rods.

So Ames and Deviren used four 3.5mm titanium rods (DePuy Mountaineer System) in a "domino configuration" such that they sat side by side and slide over each other (see X-ray) in combination with cages (Medtronic).

Ames and Deviren promise that a case report is coming soon. It should be fascinating.

—*RRY (January 27, 2009)*

trauma

Study: Antibiotic in Bone Cement Could Prevent Amputations

A microorganism marked for destruction…The University of Rochester Medical Center is announcing the results of a study recently published in the *Journal of Orthopedic Research* indicating that there is hope for soldiers dealing with Acinetobacter baumannii osteomyelitis (OM) infections.

A bacteria that rarely causes OM in the U.S., Acinetobacter baumannii (A. baumannii) is readily found in the Middle East and, according to the news release, is now present in more than 30% of soldiers recovering from open fractures in field hospitals in Iraq and Afghanistan. Outbreaks began to occur among American soldiers returning from Iraq in 2003; at the same time, data began to emerge from hospitals treating soldiers suggesting that easily contracted A. baumannii may be arriving first at the fracture site and "priming" it so that it becomes more vulnerable to methicillin-resistant Staphylococcus aureus (MRSA).

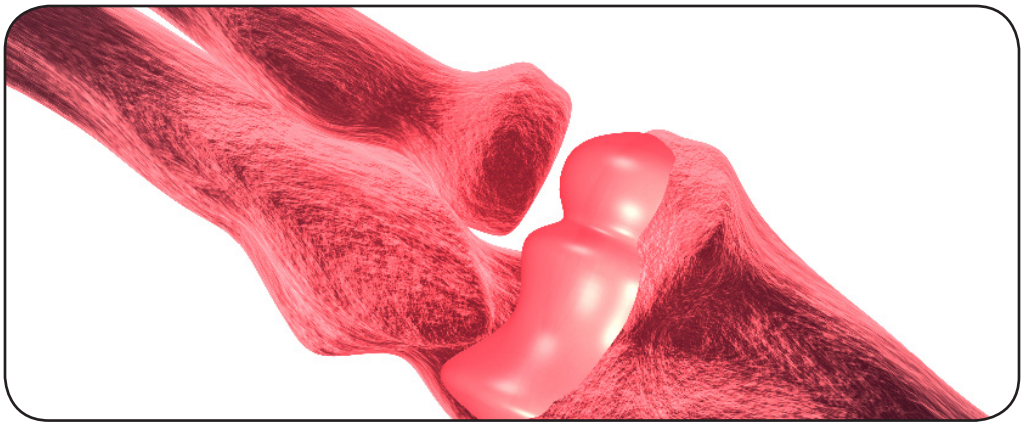
"If you apply the findings from two small studies to the entire U.S. military, which is a leap, perhaps 2,000 soldiers come into field hospitals with compound fractures each year that become infected with A. baumannii," said Edward Schwarz, Ph.D., in the news release. Dr. Schwarz, Professor of Orthopaedics within the Center for Musculoskeletal Research at the University of Rochester Medical Center, added, "About a third of them go on to get a staph infection after they reach the hospital, with about a third of those, perhaps 200 soldiers, suffering infectious complications that could cost them a limb. Studies already underway in our lab seek to clarify how the initial infections could gradually be replaced by catastrophic MRSA, and to prove that we can save limbs by putting an established antibiotic into bone cement for the first time."

As indicated in the news release, multi-drug resistant (MDR) Acinetobacter baumannii is oftentimes treated with an older class of drugs known as polymyxins, including colistin, one of the last-resort antibiotics for multi-drug resistant A. baumannii. One method of dealing with MDR infections after orthopedic injuries is to apply a large dose of antibiotic locally to the site of infection via bone cement. While bone cements laced antibiotics against staph and strep infections are common (e.g,. vancomycin), no group had ever developed a bone cement treatment using colistin against A. baumannii.

To investigate the possibilities of such treatment, a group of orthopedic, military and pharmaceutical researchers came together to conduct the current study. Dr. Schwarz and his colleagues developed a group of mice infected with drug resistant A. baumannii strains isolated directly from soldiers wounded in Iran and Afghanistan. The mice were then treated with either colistin by injection, local colistin via PMMA bead bone cement, or a bone cement control with no drug. Researchers measured the amount of bacteria in the mice as they responded to treatment with a new test of parC gene activity, a gene known to be present only in A. baumannii. Experiments confirmed that all study mice were infected with the bacteria, and that 75% of the strains were resistant to multiple antibiotics. The bone cement containing colistin was found to significantly reduce the infection rate such that only 29.2% of mice had detectable levels of parC after 19 days. Colistin via injection failed to control the infection and was no better than placebo.

The team also took the first close look at the effect of A. baumannii and S. aureus osteomyletis on bone biochemistry. The researchers found that staph infection did indeed encourage

trauma



bone breakdown, but were surprised to find that A. baumannii infection did the opposite, encouraging bone formation. "These findings have implications for clinical care, as imaging technologies that capture unusual bone cell growth may be used to diagnose A. baumannii earlier," Schwarz said in the news release.

Commenting to *OTW*, he added, "That A. baumannii caused bone formation is speculation based on the clinical finding that many A. baumannii initial infection are initially negative for staph and then become serious MRSA infections later, and on our experimental finding that pure A. baumannii infection of bone does not cause osteolysis (massive bone loss), like staph does. So the only explanation of osteolysis seen on patient x-rays of A. baumannii osteomyelitis is that there must be another bacteria present."

The researchers indicated that the results of their work make a good case for a human clinical trial with colistin-laced bone cement. Dr. Schwartz said to *OTW,* "Unfortunately there is no profit motive for this product, so there will not be a traditional placebo controlled trial. Instead, I believe that military physicians who treat these infections will make colistin-impregnated bone cement preparations in the operating room during surgery and report their clinical findings."

—*EH (January 27, 2009)*

Pfizer Gets Letter on Osteoporosis Drug

FDA to Pfizer: *do tell.* Pfizer Inc. has announced the receipt of a complete response letter from the FDA asking to hear more about lasofoxifene, an investigational compound under review for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

Lasofoxifene, a selective estrogen receptor modulator in the same chemical class as raloxifene, acts as an agonist in bone and as an antagonist in the breast. Thus, it modulates the estrogen receptor in a different manner than estrogen, which accounts for the effects of lasofoxifene observed in multiple target tissues.

On September 8, 2008, an FDA scientific advisory panel voted 9-3 (with one abstention) that there is a population of postmenopausal women with osteoporosis in which the benefits of lasofoxifene likely outweigh the risks. (The FDA is not required to follow the advice of the panel.)
Pfizer the submitted the current application for lasofoxifene on December 18, 2007.

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency issued a positive opinion on December 18, 2008, recommending marketing authorization for lasofoxifene. The CHMP's opinion will be reviewed by the European Commission, which has authority to approve medicines for the European Union.

Pfizer and the FDA are working together to determine the appropriate next steps regarding the company's application.

—EH (January 20, 2009)

The Picture of Success: Dr. Robert Hart

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

Dr. Robert Hart, Associate Professor in the Department of Orthopaedics and Rehabilitation at Oregon Health & Science University (OHSU), can be grateful to "the Dead" for his career. But no, he didn't rush onstage to play medic to Jerry Garcia. Something just struck a chord.

Dr. Hart: "I am from small-town Iowa, where I was raised by my dad, a mechanical engineer, and my mom, a teacher. In my sophomore year of college I attended a Grateful Dead show, a period during which I was trying to figure out what to do with my life. Although I can't quite explain it, somehow, while watching 'the Dead' in Des Moines that night the idea of being a doctor popped into my head. The next day I went to the premed guidance office. Over time I have come to believe that I was called to medicine. I did resist it at first, however, wondering if I wanted to commit the time for training and then for the job itself. I tried several other things first, including engineering, mathematics, and teaching. But ultimately, medicine was the right fit for me."

But his time had not been wasted. With a grounding in engineering, Dr. Hart would build his career into a mixture of analytic thinking and healing. "Prior to medical school I worked in a lab at UC Berkeley split between Dan Mote, a mechanical engineer, and Harry Skinner, an orthopedic surgeon; that was the first up-close interaction I had had with an orthopedist. I got a feeling that working with patients in the way surgeons do would appeal to me. I also came to think of orthopedics as solving mechanical problems in a very informal way. It requires an understanding of mechanics but at a more intuitive level than mechanical engineering. The variety was also appealing as I could see that an orthopedic surgeon has a new set of problems to deal with and learn from every day."

Entering the University of California, San Diego School of Medicine in 1988, Dr. Hart took a strategic approach in order to ensure he landed in the right specialty. "I decided that I would go through all of the rotations and not make my final decision until the end. Although I really enjoyed general surgery and trauma surgery, because I was married and had an infant daughter I hesitated on those specialties. Frankly, when I looked at the rough way general surgery residents were treated I couldn't picture doing that for six years with a family. Besides, I was leaning towards orthopedics anyway."

A natural questioner, Dr. Hart would select a residency where a touch of skepticism was employed to the benefit of patients. "I attended the University of Iowa for residency from 1992-97, in part because I had visited the program during medical school, my parents still lived in Iowa, and I felt comfortable because I knew the area. The most important reason for selecting Iowa, however, was that they ran a very academic educational program with a lot of emphasis on learning why and when to operate as well as when not to operate. There was an ethos of skepticism about whether operating was the right solution for any given patient."

You could say Dr. Hart took sort of an orthopedic "Walk of Fame" at Iowa. "I was so lucky to work with people like Dr. Ignacio Ponseti, who taught me patience and persistence. Here is a man who waited 20 years for orthopedists to catch up to his

methods for treating club foot. There was also Dr. Jim Weinstein, who left me with a sense of compassion for patients and their families who were in difficult situations. His willingness to take on challenging cases was also an inspiration. I recall one poignant case where we worked on a tumor patient undergoing a radical spinal procedure. Her personal situation was difficult in that she was a young married woman with young children. While her condition was not ultimately curable, our intervention preserved her mobility and gave her the best chance of survival."

Dr. Hart continues, "Dr. Stuart Weinstein similarly left me with the will to take on difficult cases. He is a very skilled surgeon and researcher and possesses an incredible work ethic and dedication to patients and the profession. Dr. Jody Buckwalter and Dr. Larry Marsh were also mentors in terms of their surgical skills and their dedication to education and research."

The lure of big cases and the requirement of quick thinking would lead Dr. Hart to decide on spine. "Dr. Ernie Found and I went in one Labor Day weekend for an anterior exposure on a trauma patient; it was complex and exciting. I also recall an anterior lumbar corpectomy for infection that I treated on call with Stu Weinstein. These experiences made me realize that I was being captured by the exposures and the anatomy. Although I liked arthroscopy and hand surgery well enough, crouching over a tiny incision or video didn't draw me in. I did like revision joint replacement, which also requires big incisions and off-the-cuff thinking. But the mechanical aspects of how to treat spine problems were for me the most fascinating and complicated things out there."

Following residency I spent a year doing a spine fellowship at Case Western Reserve University with Dr. Henry Bohlman. "This was truly an amazing experience. I was able to learn an incredible amount from Dr. Bohlman and his partners, including Sandy Emery, Jung Yoo, Greg Carlson, and Chip Davis. This fellowship really emphasized the fundamentals of spine surgery, such as principles of bony fusion, neurologic decompression, and stabilization. I feel especially fortunate to have Dr. Yoo as my current Chairman at OHSU."

As he became increasingly comfortable with his role as a surgeon, Dr. Hart decided it was time to refine his skills in the realm of research. "I spent the first three or four years out of training honing my surgical skills and building a practice, and then I began developing research projects. At first it was like doing surgery in that my initial goal was simply to successfully complete the procedure, or in this case, the research project. I set out to write papers and secure funding, but frankly did not think enough about the questions I was posing."

"More recently," says Dr. Hart, "I have been focusing on questions that appeal to me personally; these usually arise from my clinical practice. The topics are things that I'm not clear on *and* ones which I realize are lacking in existing information from which to make well-informed decisions. I also try to focus on questions that are important to the spine community. My realization was that it is important to select questions that draw you in. If you find a subject compelling, it is much easier to make it interesting to others. And in the end, even if there is not a great deal of interest from others, at least you've done something that you like. If it is done well, I believe eventually it will get noticed."

In this era of "show me the results," Dr. Hart is one of the coterie of researchers calling for more emphasis on outcomes research. "One of the things that interests me now is the objective measurement of adverse outcomes; another I refer to as 'collateral outcomes.' Any time we do surgery it's basically a controlled injury, and there are always plusses and minuses to the procedure. What has become known as the outcomes movement in orthopedics has

primarily been an effort to generate objective evidence demonstrating how our interventions are benefiting patients. I have been working recently on developing tools to measure the negative impacts of surgery. This can be either when an adverse event or complication occurs, or when there is a collateral negative impact; i.e., things that are an expected result of the procedure, but not necessarily beneficial for the patient. For example, when you do a spinal fusion that takes away motion in the spine, which is the trade-off for less pain."

Surgeons are known for liking concrete results and answers. When it comes to one area, however, Dr. Hart finds that there is not much he or anyone else can do. "I am of the opinion that spine surgeons in this country are probably doing too many surgeries. In my own practice I see a number of patients who have not done well following surgery. In some of those instances I am left scratching my head as to why the initial surgery was done. I feel strongly that the public needs to be protected from this situation. The surgeons involved should know better, but there is very little ability to police it. There is no licensing or hospital credentialing body that can affect this behavior; ultimately the only groups that are going to impact it are the payers and the government. In some ways it is a sad reflection on our profession that we've been unable to consistently hold ourselves accountable to an appropriate level of care. Every doctor sometimes makes bad decisions and has complications and I am not holding myself above those things. But I think there are some doctors out there—I think a small number, but in many cases very busy clinicians—who routinely do things they must know are not in the best interest of their patients. Somehow, we have to do a better job of controlling the relatively small number of overly aggressive surgeons."

When not immersed in work, Dr. Hart spends time with his family and gives his own spine a workout. "I am married to Susan Orloff, a liver transplant surgeon at OHSU whose schedule is actually worse than mine. We're so proud of our daughter, Annie, a cellist who has just started college at The Juilliard School. We also have 6-year-old, Jackson, who is a baseball nut. As for me, I stay active with kayaking, skiing, biking, golf, and fishing."

Dr. Robert Hart…elevating engineering to the human realm and looking out for patients along the way.

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