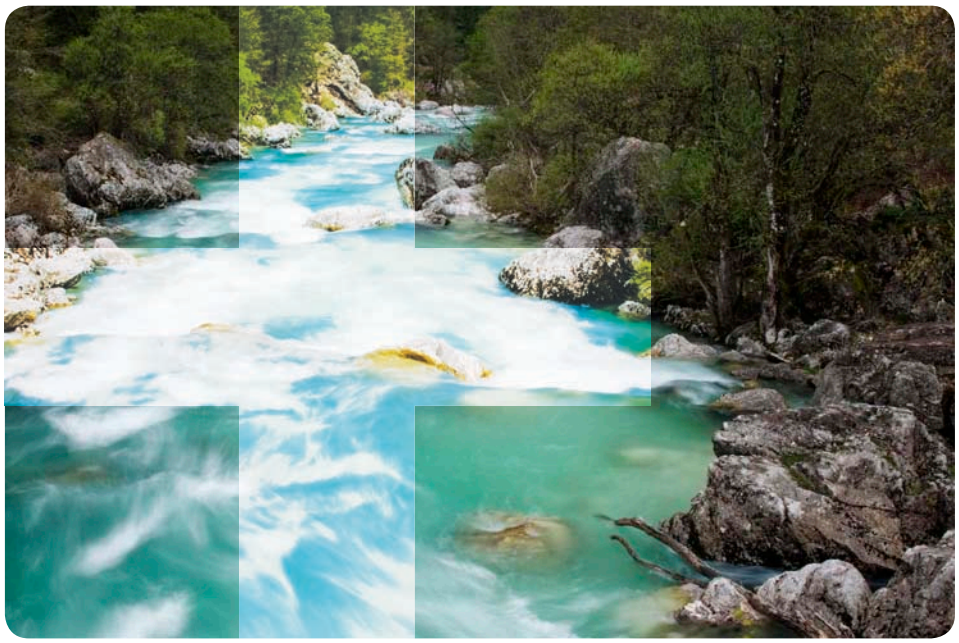
VOLUME 5, ISSUE 34 | NOVEMBER 3, 2009

Orthopedics This Week

week in review



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2009 Orthopedics This Week Spine technology Awards

Reserve your seats now for the gala banquet!

November 9, 2009 • The Palace Hotel • San Francisco

All of the spine technology submissions have been received, and seats for the Spine Technology Awards and Gala Banquet are going fast.

These awards are the first of their kind and are designed to honor the best spine products, engineering teams and inventors of 2009. Don't miss this unique and important night when 100 attending spine surgeons will vote on entries in eight categories:

- Device Technologies for Cervical Care
- Lumbar Care
- Motion Preservation of the Spine
- Minimally Invasive Care
- Biomaterials
- Diagnostics and Imaging
- Pain Management
- Regenerative Technologies

Each company or individual that submits products for evaluation will be recognized by *Orthopedics This Week* at the podium during the awards ceremony.

The 24 finalists and the first place, second place and third place **awards in each category will be determined by real-time surgeon votes at the November 9 event.** The engineers/inventors for the top three products in each of the eight categories will be invited to the podium to describe their invention. The top three products in each category will receive crystal awards at the ceremony.

Reserve your seats today—the number of spots remaining is extremely limited!

Click here to print a reservation form and obtain more information, or contact Tom Bishow at tom@ryortho.com or Lisa Carpenter at lisa@ryortho.com.

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Orthopedics This Week

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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Watch where you step in this market, there may be crevasses below. Buyers are very nervous in these final weeks of 2009. Poor institutional buying conviction. Low prices don't cut it (i.e., SMA, MDT, and IART). Only CNMD appears to be finding strong buyer support. Someone wants to own the owner of Linvatec—the surgical power tool leader.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	3	Stryker	23.28%	1.25%	Mac is kicked upstairs, raises dividend 52% and promises to pay it more often. If SYK was ever this cheap, I can't recall. #1 this week.
2	2	Orthofix	7.65	8.88	Awesome 3rd quarter report—3Q cash flow $11million vs. $167 thousand last year. OFIX pays more debt ahead of schedule.
3	1	Zimmer	29.18	(1.65)	Decent 3Q—beats Wall Street's low forecast. Ups R&D 11%. Conditions are clearly stabilizing.
4	5	Smith & Nephew	20.95	(1.14)	SNN's biggest problem is lack of visibility. Less coverage than companies literally 1/20th the size in orthopedics.
5	7	CONMED	8.28	10.54	Are CNMD's buyers strategic or professional? Average daily volume has doubled since September.
6	8	Alphatec	(8.51)	3.91	3Q results to kick off NASS week—the biggest spine meeting of the year.
7	6	Medtronic	31.37	(2.43)	Wall of worry over healthcare reform—both explicit and implicit—is keeping buyers at bay.
8	4	Exactech	12.87	(4.70)	12% jump in sales for 3Q. 29% jump in EPS. Not bad at all. Market yawned.
9	9	Integra LifeSciences	12.32	(10.57)	3Q results due this week. Consensus says IART grew sales 2% and earnings 13% in 3Q.
10	10	ArthroCare	16.87	(6.82)	75-year-old David Fitzgerald is now ARTC's official CEO—steady, knowledgeable hand on the tiller. Pfizer, Howmedica, LifeCell all benefited from Fitzgerald's skills.

Orthopedics This Week

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Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	I Flow Corp	IFLO	$12.62	$309	10.8%
2	CONMED	CNMD	$21.19	$616	10.5%
3	Orthofix	OFIX	$32.00	$549	8.9%
4	Alphatec Holdings	ATEC	$4.78	$250	3.9%
5	Mako Surgical	MAKO	$9.05	$227	3.3%
6	Stryker	SYK	$46.00	$18,290	1.3%
7	Smith & Nephew	SNN	$44.23	$7,810	-1.1%
8	Synthes	SYST.VX	$119.18	$14,143	-1.2%
9	Zimmer Holdings	ZMH	$52.57	$11,230	-1.6%
10	Medtronic	MDT	$35.70	$39,510	-2.4%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGBO.OB	$0.61	$6	-34.4%
2	CryoLife	CRY	$6.00	$170	-24.7%
3	Symmetry Medical	SMA	$7.97	$285	-23.1%
4	Orthovita	VITA	$3.50	$267	-20.3%
5	TranS1	TSON	$3.97	$82	-17.5%
6	Kensey Nash	KNSY	$23.91	$266	-17.4%
7	Capstone Therapeutics	CAPS	$0.68	$28	-13.9%
8	NuVasive	NUVA	$36.29	$1,370	-13.1%
9	Integra LifeSciences	IART	$30.54	$868	-10.6%
10	RTI Biologics Inc	RTIX	$3.92	$213	-9.9%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Symmetry Medical	SMA	$7.97	$285	7.27
2	ArthroCare	ARTC	$19.00	$509	11.24
3	Medtronic	MDT	$35.70	$39,510	11.87
4	Johnson & Johnson	JNJ	$59.05	$162,730	12.96
5	Zimmer Holdings	ZMH	$52.57	$11,230	13.45

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	I Flow Corp	IFLO	$12.62	$309	121.13
2	Smith & Nephew	SNN	$44.23	$7,810	77.36
3	RTI Biologics Inc	RTIX	$3.92	$213	48.02
4	Synthes	SYST.VX	$119.18	$14,143	37.06
5	NuVasive	NUVA	$36.29	$1,370	33.22

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	ArthroCare	ARTC	$19.00	$509	0.45
2	CryoLife	CRY	$6.00	$170	0.75
3	Symmetry Medical	SMA	$7.97	$285	0.87
4	Exactech	EXAC	$15.00	$192	0.89
5	Integra LifeSciences	IART	$30.54	$868	1.01

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$36.29	$1,370	3.29
2	CONMED	CNMD	$21.19	$616	3.04
3	RTI Biologics Inc	RTIX	$3.92	$213	1.75
4	Johnson & Johnson	JNJ	$59.05	$162,730	1.74
5	***Average***			***$10,030***	***1.59***

Lowest Price to Sales Ratio (TTM)

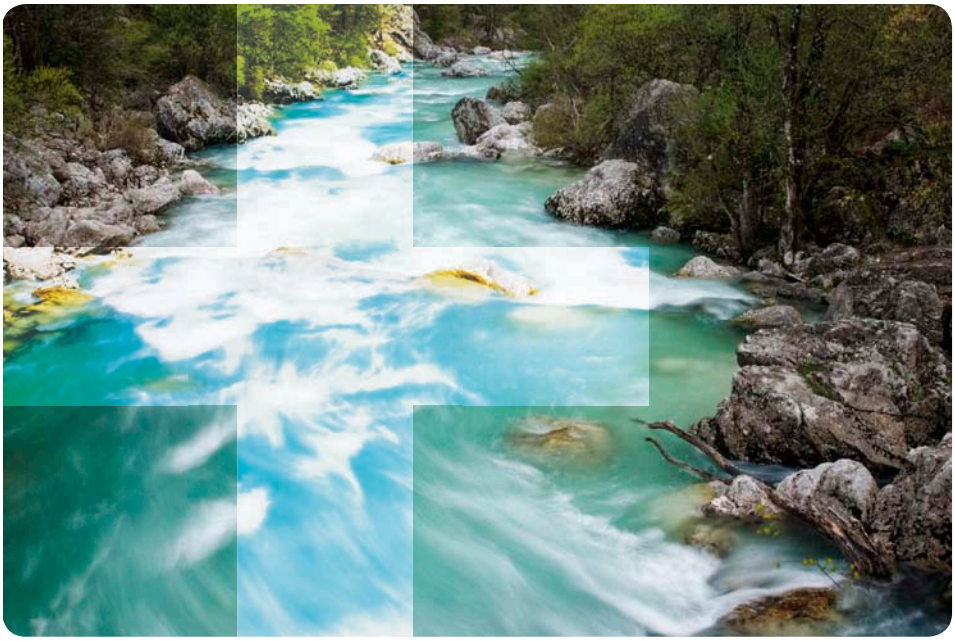
	Company	Symbol	Price	Mkt Cap	PSR
1	Symmetry Medical	SMA	$7.97	$285	0.70
2	Osteotech	OSTE	$4.32	$78	0.81
3	CONMED	CNMD	$21.19	$616	0.91
4	Orthofix	OFIX	$32.00	$549	1.06
5	Exactech	EXAC	$15.00	$192	1.18

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$5.83	$143	200.28
2	Mako Surgical	MAKO	$9.05	$227	11.44
3	Synthes	SYST.VX	$119.18	$14,143	8.65
4	NuVasive	NUVA	$36.29	$1,370	4.14
5	Regen Biologics	RGBO.OB	$0.61	$6	4.10

Risk Flows Downhill

By Robin Young



At $63,413 California has the highest average Medicare charge in the United States. The national average Medicare charge is $34,399. New Jersey is #2. Interestingly, the Army Post Office AP is #3. Four years ago New Jersey was higher than California. Between 2004 and the first half of 2008, California's average Medicare charge has increased 29.7% (from $48,894).

But that is **not** what California received. In 2007, California sent 844,905 claims up to Medicare and received $9.763 billion or an average of ***$11,555 per claim.*** While the average charge was $63,413 in California, the average reimbursement was $11,555.

That's a big financial gap for someone (the state of California, the hospital, surgeon, surgery center or patient) to cover.

California has another distinction; it is probably bankrupt. California's public purse broke some months (or years) back and the headlines today are about how much to cut costs and how much to increase fees. Tuition at the University of California college system, for example, will rise 9.3% this year—higher, incidentally, than the expected rise in Medicare charges.

Medicare BENEFITS

Medicare actually spends more in California than it does in the rest of the country—about two-thirds more than the national average per enrollee. Yet that spending doesn't even cover 20% of the average amount California requests of Medicare.

If California's Medicare charges rise 29.7% between 2008 and 2012, the

same rate as the last four years, then the Medicare charges in California will rise to $82,000 per enrollee. Unfortunately, Medicare is not planning to increase its payments to California.

Funding Medicare in an environment where claims are rising 30% every four years, as in California, is risky business. In an era of record deficits and looming state insolvencies, Medicare desperately needs to manage this risk.

Private health insurance companies manage risk. They are, actually, risk managers. Risk is what insurance companies calibrate, charge for and protect their customers from.

Risk management is different from providing health care. Washington policy makers and a fair percentage, we suspect, of the general public equate payers and insurance companies with health care. In this paradigm, if health care is not available then it is the fault of the insurance company. But, they are wrong. **Insuring health care is not the same as providing health care.**

The average health insurance premium for a family in 2008 was $12,680 a year. That's a fair amount of money. What if a family decided to save it instead of buying health insurance? That model actually works pretty well for routine office visits plus a couple or three emergency room visits per year. But add in ambulance trips, specialists, follow-up visits, MRIs, and medications, and the costs can jump to $30,000 or more. Then there's the cost of heart disease, arthritis or cancer.

Insurance replaces large unpredictable risks with small but known payments by distributing the small risk over a large pool of insured policies.

To illustrate this further: here are some events that are NOT appropriate for insurance coverage since they entail NO risk, they are 100% certain—a f at tire, an empty refrigerator, snow or rain or a dropped pass in the big football game. A policy that covers predictable and recurring events would have to charge at least as much as the event itself ***plus*** more for the cost of claims processing.

Predictable events that cost a lot require a savings account or a term loan—not an insurance policy. Like an auto purchase. Residential property destruction, auto-related (liability for injury; theft) catastrophes, and accidental death or permanent disability are classic insurable events because they are unpredictable and comparatively rare events. Insurance works when it is used as a hedge against a contingent loss and that loss can be spread out over many policyholders.

So, in health care there are certain events that are unpredictable and lend themselves to insurance as a risk management tool. There are other events—cut fingers, cold and f u, cavities or pregnancies—that are not risky items in need of insurance. They are more suited to savings accounts or loans.

Some of the techniques that healthcare insurance companies (aka payers) have relied upon to manage healthcare risk are going away. Pricing for risk by risk-adjusting each patient (i.e., not paying for pre-existing conditions) is probably going away. An aging population with rising rates of chronic conditions like diabetes, obesity, arthritis, and heart disease puts more health events into the routine category.

This process of adjusting for new and shifting levels of risk means, we think, that systemic healthcare reform is happening **regardless of any bills in Washington.** What is, in effect, passing for organic reform is really risk shifting from the insurance companies to hospitals and from hospitals to patients and manufacturers.

For example:

1. Risks that shift to the hospital

   a. Medicare will no longer pay for the additional cost of hospitalization if the condition

was hospital-acquired and "reasonably preventable" (CMS quotes). That is, if a condition is not present upon admission, but is subsequently acquired during the hospital stay, Medicare will no longer pay the additional cost of the hospitalization.

b. Medicare has identified eight preventable conditions for which it will no longer reimburse, such as:

i. Surgical site infections following certain elective procedures, including certain orthopedic surgeries, and bariatric surgery for obesity

ii. Certain manifestations of poor control of blood sugar levels

iii. Deep vein thrombosis or pulmonary embolism following total knee replacement and hip replacement procedures

c. Medicare will also no longer pay for the following mistakes:

i. A mistaken surgery or other invasive procedures performed on a patient

ii. A surgery or other invasive procedures performed on the wrong body part

iii. A surgery or other invasive procedures performed on the wrong patient

2. Tools that push decisions down to the patient level

a. Health Savings Accounts (HSA). Eight million people have these in the United States. In two years, experts estimate, the number will rise to more than 12 million. HSAs were put in place in 2003 to help encourage the use of savings to pay for healthcare costs. HSAs are tax advantaged medical savings accounts where the funds are used by patients to pay for their own medical expenses. The patient makes the purchase decisions. Furthermore, the purchases are made with cash. In theory at least, cash purchases should lower healthcare prices because the consumer is making the choices and providers compete for that business.

b. Cost comparison tools for patients to use when spending their cash / HSAs on health care.

3. Less money to pay for healthcare products and services—thereby forcing routine care expenses to be paid for outside of Medicare or the private insurance programs. Medicare and Medicaid funding will be cut by hundreds of billions of dollars (The House version has cuts totaling $400 billion over 10 years).

The professional risk managers, the insurance companies, are preparing for an era where insurance will be more explicitly separated from healthcare services. So, for example, hospitals—not insurance companies—will begin to risk-adjust their patients and start to charge varying amounts for products and services depending on the risk profile of patients.

Patients will begin to shop around for routine services that are not well

suited for classic insurance coverage and use their HSA or other savings or term loan payments to pay for those services.

Where might this affect suppliers and manufacturers of medical products?

We suspect that it will hit under the rubric of comparative effectiveness or the discipline of justifying the cost of a product with the patient outcome. Comparative effectiveness will be the reasoning, we think, behind hospitals, Medicare and others to move at least part of the payment risk to manufacturers.

The concept of a third-party payer that will provide unlimited health care at minimal or no cost to the patient, if it ever really existed, is likely dead.

The concept of the hospital, the patient and the manufacturer shouldering more and more of the payment risks is very much alive and will, we expect, become the mechanism whereby the current healthcare system discontinuities are reconciled. Regardless of what happens in Washington.

As for California, nothing focuses the mind like no money in the bank. It differs from the rest of the country only in magnitude. In its extremes of cost and budget strife, California highlights exactly the problems that are pushing risk managers (the private insurers and, increasingly, Medicare) to narrow their focus and move payment and other risks downstream.

Orthopedics This Week

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A Little Bundle of…Pediatric Emergencies

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

If you're the spine specialist on call at 2 a.m. and hear, "Doctor, there's an infant in room five who's crying and can't move his leg," you may feel a bit panicky. Naturally so, given that the majority of orthopedists do not work with children and thus are not familiar with the conditions that they fall prey to.

Dr. James McCarthy, Associate Professor of Orthopedics and Rehabilitation at the University of Wisconsin School of Medicine and Public Health, explains, "Many of my non-pediatric colleagues do not frequently see many of the unusual and often serious orthopedic issues that befall children, and they get nervous when a child shows up in the ER and needs orthopedic care. It is important, however, that those who take call develop the skills to assess what are often emergency situations that can result in loss of a limb or in some cases, a life."

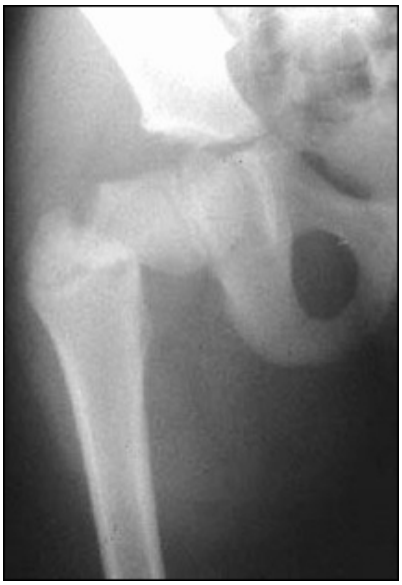
Tracking Down Killer Bacteria

One of the most serious conditions sounds like it belongs in a macabre film. Dr. McCarthy: "Necrotizing fasciitis, an infection that can evolve from a simple scrape to the knee, is often called 'flesh eating bacteria.' This is actually a misnomer because the bacteria is not the problem…it's the toxins they produce. A child can scrape his knee and the next day or two have pain that is significantly out of proportion to the minor injury. A fever comes on fast, and the child's blood pressure is unstable. If the doctor on call can't quickly diagnose the condition, then the fascia will be affected, and the child may lose his or her limb or life."

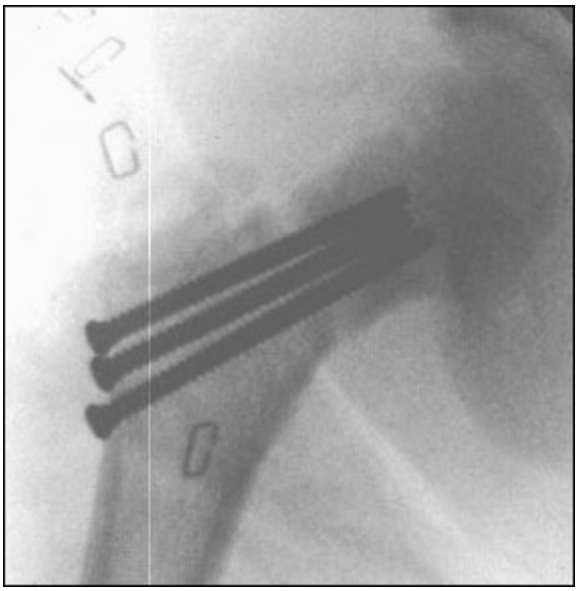
What else should the doctor be on the lookout for? "Keep an eye out for a rash that looks like cellulitis, but is more tender," recommends Dr. McCarthy. "Ultimately you can't diagnose this condition unless you do an MRI or a biopsy. The main thing to remember is that the condition progresses so quickly that you can't afford to lose any time. An MRI can take 30 to 45 minutes—if you can get one right away. A biopsy can be done at the patient's bedside. A non-pediatric orthopedist may only see this condition once or twice in a lifetime—but you don't want to remember that situation as being one where the child lost a leg or died."

Dr. Peter Pizzutillo, Professor at the Drexel University College of Medicine in Philadelphia, adds, "It is difficult to pinpoint the true incidence of necrotizing fasciitis because the related research often involves both children and adults. We have seen an increase over the last five years, however, with recent literature indicating that there are approximately 1500 cases per year in the U.S. and a 30% mortality rate. Some of the factors involved in mortality are a delay of treatment for more than 24 hours, using the wrong antibiotics and failure to aggressively debride all of the involved tissue."

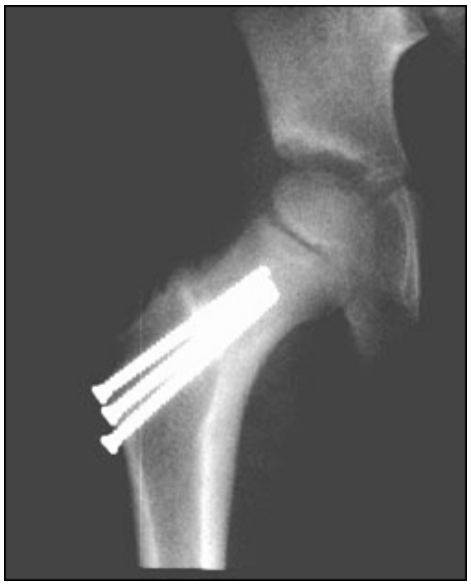
But the old fashioned, simple techniques of observation and palpation can save a limb or life. Dr. Pizzutillo: "The child doesn't necessarily look like they are in bad shape. You will typically find, however, that the skin is warm, red, swollen, and tender. If it is an infection of the fat then the skin is tender if you push on it—but there is not much discomfort. With necrotizing fasciitis, however, there is increasing pain. If you suspect this condition, you should immediately order an MRI because



Hip fracture



Hip fracture after surgery



Hip fracture healed

it will give you multiple facets of information. You will see early bony changes that would not show up on an Xray. You will also be able to see if it is osteomyelitis, myositis, or cellulitis."

Skip the body scan, though, advises Dr. Pizzutillo, and don't use other outmoded diagnostics. "Don't do a CT scan because it will not let you visualize the soft tissue. And, while in the past we would often wait to see if there was gas or air under the skin, we now know that this is a later sign—and it could be dangerous to wait. Let's say you don't do anything and think that it's cellulitis. The area will become more tense and firmer to the touch; then it will look black and blue because there has been some insult to the veins and capillaries. Next you will see large blisters appear, accompanied by a feeling of gas moving under the skin. Then the area will die. Before it gets this far, however, you should be aggressive about removing any tissue that looks unhealthy."

"This is not the time to be fainthearted," continues Dr. Pizzutillo. "You should not make a peephole incision, but one that extends, for example, from the ankle to the groin. Essentially, you have to keep operating until you find normal tissue, along the way making sure that the patient

has fluids and that the blood pressure is monitored frequently. The bacteria can travel up to the abdomen in a matter of days. Once in the abdomen the mortality rate increases to 65%. It's incredible, but it spreads up the fascia—the superhighway of the leg."

Testing for Septic Arthritis

Another pediatric condition in which bacteria is on the prowl is septic arthritis. Dr. McCarthy states, "This condition, which involves an infected joint, is most likely to affect children and the elderly. When the joint gets infected, the cells that fight the infection secrete enzymes that can be harmful to the joint. While it is not life threatening, there is a real risk to long term morbidity due to joint destruction. In some joints septic arthritis is easy to diagnose, but in the hip it is not so clear cut. Children generally won't express pain when they rotate their hips; infants typically start crying and may not be able to move their leg."

The unlucky, say, foot and ankle specialist who pulls the curtain aside and finds such a case needs to know how to test for the bacteria. Dr. McCarthy: "If not treated correctly, this condition destroys the hip. Getting a combination of lab values, as well as fluid from the hip joint will let you know if the joint is infected."

Dr. Pizzutillo adds, "If you suspect septic arthritis, I recommend getting an ultrasound of the hip early on. If you don't act quickly, this condition can destroy not only the cartilage, but the growth plate. The child can end up with a 30% loss of the thigh bone and a difference in leg length of six or seven inches. Once the hip dislocates the blood supply to the hip dies and the child is essentially left without a hip."

Having an immediate conversation with the parent(s) can yield information that can point the attending orthopedist in the right direction. Dr. Pizzutillo advises, "If the child is a toddler the first thing the parents usually notice is a limp—the child is walking normally one day and the next day he or she starts limping. Actually, depending on the bacteria they may not want to bear weight on it at all."

"Infants who are still crawling will show no signs of this condition except that they stop eating," continues Dr. Pizzutillo. "At our facility if we have a baby who is not eating we then look for infection *everywhere*. If we can't come up with a problem in other systems, such as the bladder or kidney, then the physical exam will usually show some limitation of joint motion. Also note that the child will not necessarily have a fever. I would recommend consulting with a pediatrician on these cases as they usually have a high index of suspicion for septic arthritis."

Fixing Fractures in Children

The hip is also prone to other grave "mischief," namely, fractures. "These are not very common in children," explains Dr. McCarthy, "but they are difficult to treat, with estimates of complication rates up to 60%. If not treated within 24 hours there is an increased chance of avascular necrosis of the femoral head, as well as long term disability. Fortunately, hip fractures are usually easy to diagnose via Xray and a careful (hip) exam."

And what might the imaging show? Dr. McCarthy: "There are four kinds of hip fractures, transepiphyseal, transcervical (the most common), cervicotrochanteric, and intertrochanteric. Treatment for each of these will involve some degree of reduction, joint decompression, and stable fixation. The managing orthopedist should aim for *gentle* traction, abduction, and internal rotation."

Going into detail, Dr. McCarthy notes, "It is preferable to avoid crossing the physis with the fixation device, but stability is ultimately more important. If the child is less than three years old you would use smooth pins, and perhaps cannulated screws for older children."

An attending orthopedist might also meet a youngster who has taken a spill

from a jungle gym or come crashing down after a pillow fight, and landed on her elbow. Dr. Pizzutillo explains, "Supracondylar fractures of the elbow are the most common elbow fracture in children. Doctors dread seeing this condition because of the potential for compartment syndrome. Approximately 2% of these patients have major blood supply issues, while 7% have neurologic problems such as injury to the anterior interosseus nerve (leaving them unable to pinch with the thumb and index finger). With compartment syndrome, it is a direct trauma that makes the muscles swell, and that swelling is occuring in a rigid environment. Because the compartment is made of a tough material and doesn't stretch, any swelling adds a lot of pressure and prevents blood from going into the muscle and draining…so the muscle and nerve dies."

As for treatment of compartment syndrome, Dr. McCarthy recommends, "first make the diagnosis, then get the patient to the OR urgently (within six to eight hours of the injury)."

Open fractures, says Dr. Martin Herman, a pediatric orthopedic surgeon at St. Christopher's Hospital for Children in Philadelphia and Associate Professor of orthopaedic surgery at Drexel University College of Medicine, are particularly dicey. "When the bone is exposed to air there is a particular risk of infection. To address this possibility, the child should be given antibiotics as soon as he arrives in the ER, along with a tetanus shot update if necessary. Inspect it, noting its size, contamination, bone exposure, and

level of hemorrhage. You should also perform a careful neurovascular assessment, ideally prior to the administration of pain medication or intubation. Then you apply a sterile dressing, grossly realign the limb and splint, and take radiographs of the entire bone."

Sharing his OR experience, Dr. Herman adds, "Only debride tissue that is obviously non-viable, and leave questionable tissue for a second look later. Consider releasing compartments in severe injuries or in a child with a head injury, regardless of the pre-operative neurovascular assessment. A VAC (Vacuum Assisted Closure) dressing may be applied to large open wounds, and fasciotomy wounds. Fractures associated with small open wounds with minimal swelling and that are stable after reduction may be treated with cast immobilization and not fixation. Fracture stabilization, however, is indicated for most open fractures. And while the ideal duration is undetermined, it is generally thought that IV antibiotics should be administered for 48 hours after surgery. Several debridements may be necessary, and should occur at 24-48 hour intervals. And depending on the degree of soft tissue injury, you may want to call in a plastic surgeon for a consult."

Treating Multiple Injuries

When do you really need to pull out all the stops (and pull in all the specialists)? When a child has multisystem trauma. Dr. Herman: "What often appears to be an isolated injury can actually be a number of injuries all at once, including head and thoracoabdominal injuries. The mantra here is: don't expect the orthopedic surgeon to be the only person involved—you will need a neurosurgeon and a general surgeon. You might have, for example, a closed head injury, liver laceration, displaced supracondylar elbow fracture, right femoral shaft fracture and a fracture of the distal femur. In such a situation

you would immediately do damage control orthopedics—manage any hemorrhaging, attend to soft tissue problems, and do external fixation or splinting to limit the amount of initial surgery. When the child is more stable, other procedures can be done to definitively manage fractures and other injuries, usually within several days."

Dr. Herman continues, "After the initial assessment for life or limb threatening injuries, get the initial imaging to include radiographs and CT scans of the head, neck, thorax, and abdomen. Then do a more thorough orthopedic evaluation by examining not just the obvious sites of injury but all extremities and the spine. You should, among other things, look for swelling of the extremities, deformity, crepitus, and limited range of motion."

Some of the most important things to consider in a multisystem trauma situation, says Dr. Herman, are continual reassessment and having enough resources. "We get better outcomes with these patients when they are assessed frequently and when the trauma team is able to accurately anticipate possible complications. And you've got to have enough of a team to get the job done. Don't be scared to enlist the help of an attending or two if necessary."

Even after listening to the sage advice of these three doctors, there is still much more to learn. That is why, say Drs. Herman, Pizzutillo, and McCarthy, it is important to attend instructional courses in pediatric orthopedics at venues such as the annual meeting of the American Academy of Orthopaedic Surgeons, as well as the specialty societies. After all…more training, less trepidation.

Stryker Biotech Indicted

By Walter Eisner

Bone growth products like Stryker's OP-1 and Medtronic's InFuse have been shown to create new bone in humans. The products have also created significant adverse events for the companies that produce them.

The most recent adverse event involving Stryker's OP-1 is an October 28 federal grand jury indictment in Boston. The indictment accused the company's biotech division and four current and former executives of promoting the product without approval and lying to the FDA about the number of patients treated under a Humanitarian Device Exemption (HDE) program.

Michael Loucks, acting U.S. attorney in Boston, also accuses the company and its senior managers of participating in a fraudulent marketing scheme to pump up sales of OP-1 by lying to doctors, providers and payers about FDA approval.

Cigars, Tootsie Rolls and Vienna Sausages

Specifically, the government says the company promoted OP-1, "in a manner that was different from its FDA approved use; namely they promoted a combination of the devices with a bone void filler, called Calstrux, and in furtherance of that promotion provided 'recipes' to surgeons, medical technicians and others as to how to mix the OP-1 products with Calstrux."

The government says the reason the company promoted a combination of the products was to overcome a competitive disadvantage with other legal products, such as InFuse.

It is alleged that some of these "recipes" called for medical personnel to mold the combined product into "cigars," "tootsie rolls" or "Vienna sausages." The indictment charges that the defendants knew that such a combination had never been studied in a clinical trial and had never been presented to or approved by the FDA.

More on those recipes later.

Stryker's Response

Following the announcement of the indictments, Stryker made three announcements of its own.

First, the company issued this statement on the day of the indictment:

> "The Company is disappointed with this action and still hopes to be able to reach a fair and just resolution of this matter. Conviction of these charges could result in significant monetary fines and Stryker Biotech's exclusion from participating in federal and state health care programs, which could have a material affect on Stryker Biotech's business. As a matter of Company policy Stryker will not have any further comment on these allegations."

Two days later, Stryker announced that John Brown will be retiring

as Chairman of the Board as of December 31, 2009, and that he would be replaced by current company President and CEO Stephen MacMillan. The company then announced that it will be paying shareholders their dividends quarterly instead of annually.

Polly Exoneration?

The indictment may also become an adverse event for Iowa Senator Chuck Grassley.

Senator Grassley recently accused University of Minnesota Spine Chief and InFuse consultant David Polly, MD, of lying to his IRB (Institutional Review Board) about his choice of InFuse for a clinical study. OK; the senator didn't actually call Dr. Polly a liar. He said Dr. Polly was being "less then truthful," when the physician told his IRB that InFuse was the only commercial off-the-shelf product available for his study.

Dr. Polly's lawyer, John Lundquist, being a good fellow Midwesterner, didn't actually call the senator "ignorant," but told *OTW* after the announcement of the Stryker indictment:

> "As Dr. Polly and the Department of Justice agree, OP-1 had not been approved for marketing, but could be used only pursuant to the "highly restrictive" Humanitarian Device Exemption (HDE). The events today thus confirm that Dr. Polly spoke entirely accurately about OP-1…. It is now possible to understand how the senator had been mistaken in his earlier pronouncements."

Senator Grassley's office did not respond to repeated inquiries from *OTW* asking if the senator had changed his mind about accusations against Dr. Polly.

Stryker's OP-1 Drama

This latest chapter of the OP-1 drama follows an FDA warning letter last year to the company's biotech unit. That letter included the charge of falsification of hospital-approved documents which allowed limited use of the product. It was followed by an FDA orthopedic panel recommendation earlier in the year that OP-1 should not be approved by the FDA as a device that promotes fusion.

The OP-1 warning, among three other FDA warning letters at other Stryker facilities, has caused Stryker to undergo a massive $200 million quality control overhaul as well as appointing a new quality chief.

There is some good news, however, for Stryker on the FDA front. During a recent quarterly conference call with Wall Street analysts, the company announced that the OP-1 FDA warning letter had been lifted. Vice President for Strategy and Investor Relations Katherine Owens told analysts, "Not surprisingly, we've received numerous inquiries regarding the plant in this program going forward, following the disappointing FDA panel outcome earlier in the year. Given the extent of development that we have done to date and potential applications for OP-1 in other indications such as soft tissue, we are undergoing an intense review on our various strategic options."

Inside the Indictments

But back to the indictments.

There are three products at issue in this case: OP-1 Implant, used to promote growth in long bone non-unions; OP-1 Putty, used to promote bone growth in certain, very limited spinal fusions; and Calstrux, a bone-void filler for surgically created bone defects or bone defects resulting from traumatic injury.

Stryker had various levels of FDA blessing to use each of these products separately for their narrowly intended purposes. What the company did not have was permission from the FDA to use the OP-1 products mixed together with the bone-void filler.

OP-1 Humanitarian Approvals

The FDA granted Stryker HDEs for the OP-1 Implant in October 2001 and the OP-1 Putty in April 2004.

David Polly

Senator Charles Grassley

An HDE is similar to a PMA (Premarket Approval) application, but it is exempt from the effectiveness requirements of the PMA. The product must demonstrate that it is safe, has no comparable competitors in the market, treats a condition that affects fewer than 4,000 individuals in the U.S., and is approved by an IRB.

According to the indictment, shortly after the introduction of the products, surgeons complained to the company that OP-1 handled poorly (like wet sand) and did not provide enough product volume.

Calstrux Filler

In response to these complaints, prosecutors say Stryker developed Calstrux (TCP Putty), a product with a malleable, Silly Putty-type consistency that the company intended to be mixed with OP-1 products as a "carrier" or extender to increase volume and improve handling qualities of OP-1.

The government alleges that Stryker, despite intending to use Calstrux as a mixture with OP-1, only applied to the FDA for 510(k) clearance for Calstrux as a bone-void filler. Clearance was granted by the FDA on August 26, 2004, with no provision for allowing it to be mixed with any bone growth products.

After the Calstrux clearance, Stryker never conducted any clinical trial in a human to determine whether the mixture of the bone-void filler with OP-1 was safe and effective for humans, and no labeling for that use was ever developed.

The government says the defendants, former Stryker Biotech President Mark Philip and current sales managers William Heppner, David Ard and Jeff Whitaker, all knew this.

OP-1/Calstrux Launch

In early 2005, despite knowing there was no FDA approval for mixing the products, the defendants, in a company-wide launch, allegedly presented Calstrux to the sales force as a "carrier" or "extender" for the OP-1 products, and Philip noted the availability of Calstrux should "accelerate" the sales of OP-1.

Stryker allegedly promoted the products to surgeons and surgical staffs in the same manner, and the vast majority of Calstrux sales were for mixing with OP-1 products.

The defendants allegedly promoted "recipes" on how to mix the products that recommended forming the combination into "cigars," "tootsie rolls," "logs," "bricks," or "Vienna sausages" among other shapes.

Adverse Events

By mid 2005, the company began receiving reports of adverse events arising from the combination. One sales rep, according to the indictment, wrote senior management:

> "Like any product, if we have 30+ people doing something different with regard to mixing, dosing, etc., we are going to see different results."

Some of the results included inflammation, drainage and impaired wound healing. Some of the patients needed revision surgery where surgeons observed that the mixture had migrated from the site and looked like "oatmeal," "grits" or "white sesame seeds." Some patients suffered from unwanted bone growth and had to have the growths removed.

Stryker asked a surgeon using OP-1 in early 2006 to prepare an analysis of the patients who had been treated with the mixed product. That report allegedly concluded that patients with the mixed product had an adverse event rate "higher than the norm." Later in the year, the same surgeon, according to the indictment, told the company that the mixture of OP-1 and Calstrux was not effective.

Internal Warnings Ignored

At around the same time in early 2006, prosecutors say a senior manager at the biotech division sent a memo about the mixture to Philip expressing concerns over adverse events, the wide variety of "recipes" and improper promotion of the products. He recommended that the company send out a "dear doctor" letter advising surgeons about the adverse effects.

Heppner and Whitaker are accused of arguing against this because such disclosure would "harm sales, anger surgeons who had been misled because 'many surgeons are just handed the product prior to implantation and think its all OP-1' and cause IRBs to cease all OP-1 usage," according to the indictment.

The government says that despite knowing this, Philip, the company and the sales managers continued to promote the allegedy illegal mixture for two more years until February 2008, without informing surgeons of the side effects, to keep sales rolling.

Financial Scheme

The purpose of this scheme, according to the indictment, was to "obtain millions of dollars in sales from OP-1 and Calstrux."

Hospitals paid approximately $5,000 for each unit of OP-1 Implant and $5,250 for the OP-1 Putty (the putty's higher cost was for a vial of carboxymethylcellulose).
To meet increased sales quotas, outlined in the indictment, prosecutors say the defendants had to lie to the FDA about the number of patients being treated under the HDE approvals.

The company was obligated to submit annual reports regarding OP-1 Putty to the FDA on the number of devices that had been shipped or sold and, if the number shipped exceeded 4,000 in any year, provide an explanation and estimate of the number of devices used per patient, and the number of patients treated.

Stryker reported that each revisionary posterolateral spine fusion surgery (the HDE approved use) involved use of two units of OP-1 Putty per patient, one for each side of the patient's spine.

However, says the indictment, in part owing to the cost, two units were rarely used and most sales were of one unit per patient per surgery.

Stryker concluded in a 2005 analysis that it was selling approximately 1.3 units of Putty per patient. Based on that usage, prosecutors say Stryker could only sell approximately 5,000 units of the Putty per year (4,000 patients x 1.3 units/patient = 5,200 units). However, the indictment says that Stryker undertook to sell more than the allowed amount. Selling an additional 1,000 units of the Putty would generate additional annual revenues of $5 million.

In 2007, Stryker reported to the FDA that it sold 6,234 units of the Putty. "Since 2 units of OP-1 Putty are used per patient, it is estimated that 3,117 patients have been treated," said the Stryker report. In fact, say prosecutors, the company knew that less than two units were used per patient and that more than 4,000 patients had been treated during the year.

The government says that Philip attempted to conceal the actual number of patients treated by trying to get a law firm to issue a "bogus" legal opinion and allegedly asking a colleague to say that the company had no way to track the per patient use of OP-1 Putty in a conference call with management at the parent Stryker Corporation.

Aftermath

Mark Philip self-surrendered on October 28 and appeared in court. He was released on standard conditions and surrendered his British passport.

His arraignment was set for Friday, October 30 in front of Chief Magistrate Judge Judith Dein.

If convicted of the charges, Stryker Biotech faces fines of $500,000 or more and possible exclusion from public healthcare programs. Philip, Heppner, Ard, and Whitaker each face up to 20 years imprisonment and a $250,000 fine.

Whether or not this indictment is the last adverse event for Stryker and OP-1 is hard to know. But bone growth products like InFuse and OP-1, have shown themselves be able to grow controversy for their makers as they have shown themselves able to grow bone in humans.

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Spine Procedure U.S. Market Reports	Code
Spine Fusion	
Anterior cervical fusion	81.02
Posterior cervical fusion	81.03
Anterior dorsal and dorsolumbar fusion	81.04
Posterior dorsal and dorsolumbar fusion	81.05
Anterior lumbar fusion	81.06
Lateral lumbar fusion	81.07
Posterior lumbar fusion	81.08
Spine Refusion	
Posterior lumbar refusion	81.38
Other Spine Procedure	
Discectomy	80.51
Decompression	03.09

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

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

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

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NuVasive Takes More Market Share

NuVasive's quarterly conference calls with Wall Street analysts reviewing the company's past quarter aren't so much about revenues and earnings, as they are about how much market share the company took from competitors in the last three months.

Company Chairman and CEO Alex Lukianov told the analysts on October 22, that while the overall spine market will continue to grow in excess of 10%, NuVasive expects to generate revenue growth in the 30% to 35% range in 2010.

For the third quarter of 2009, NuVasive's total revenues rose 41.8% over last year to $95 million, causing the company to increase its 2009 revenue guidance range to $365 million – $367 million from $360 million – $365 million.

Said Lukianov:

> "Our third quarter results confirm that NuVasive's exclusive approach to spine fusion has gained market share by improving the safety and reproducibility of spine surgery. Our sales force continues to educate the spine surgeon community on the benefits of excellence in all of our unique products, which cover the lumbar and thoracic, and cervical spine, as well as biologics and motion preservation."

Lukianov cites a market that is shifting away from open procedures as the driver for the company's strategy to become the number four global spine company. "As we advance adoptions of the XLIF procedure and improve the utilization of our entire product offerings, we continue to anticipate generating increasing levels of profitability."

NuVasive's development efforts will be on full display at NASS, where the company plans to launch several new products which expand the reach of XLIF to new areas of the spine and to treat more pathology. "These launches include a host of new products that represents comprehensive solutions for the thoracic spine and are designed to be performed through our minimally disruptive lateral approach," said Lukianov.

Clinical Projects Update

The company also provided an update on some of their clinical projects. Lukianov said the latest lateral XL TDR clinical IDE (investigational device exemption) study began enrollment during the third quarter and is expected to complete enrollment in late 2010. Studies for the Osteocel Plus biologic in both the lumbar and cervical spine are also underway with data expected to come in late 2010 through 2011. Additionally, the company is on track to file for PMA (premarket approval) submission for the PCM cervical disc replacement device in early 2010 as planned.

When asked about healthcare reform, Lukianov told analysts that regardless of what happens, the overwhelming benefits of minimally invasive

company news

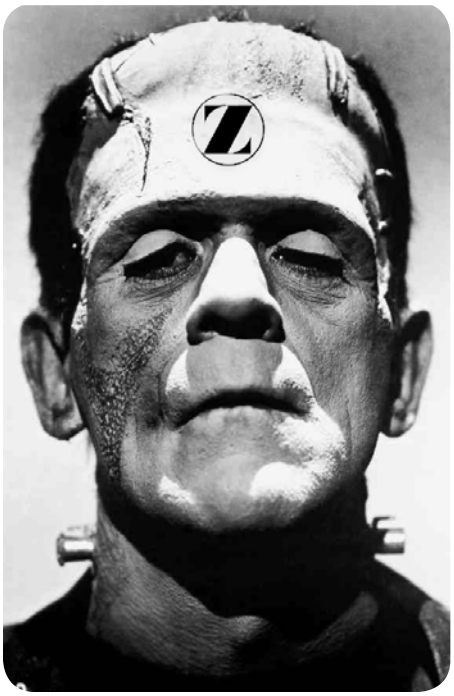
approaches like XLIF will continue to drive market growth, because surgeons are increasingly shifting toward less disruptive techniques.

Finally, it was announced on the call that Michael Lambert will be replacing Kevin O'Boyle as the company's new Chief Financial Officer. Lambert was most recently the CFO of American Medical Optics, a publicly traded medical device company with over $1 billion in revenue.

—WE (October 27, 2009)

Zimmer Awakens

"It's alive," wrote Joanne Wuensch of BMO Capital Markets, referring to the orthopedic market. But she may just as well have been writing about Zimmer.



It's been a long road to stability for Zimmer and CEO David Dvorak after a period of customer disruption from deferred prosecution agreements and Durom cup hip problems.

> On October 22, Zimmer reported that its revenues rose for the third quarter of 2009 by 2.4% to $976 million, beating expectations by $22 million. The company's reported reconstructive business was up 1%, with knees rising 2% and hips dropping 1%. Extremity revenues rose 19% and spine was up 24%.

Hip and Spine Expectations

When asked about the decline of sales in hips, Dvorak noted that he didn't believe the company was losing customers at this point, but may be losing some cases due to a gap in their product line. With new product launches underway outside the U.S., those gaps are being filled before clearances comes through in the U.S. "We have some very differentiated technology built into the Acetabular Cups, for instance, and so we're really optimistic about the future there and then of course to get after those same opportunities within the U.S. market is going to require these clearances coming through," added Dvorak.

"During the quarter we saw positive uptick with our new stems; including the ML taper with connective technology and the bone conserving fit more family of stems as well as solid results with our Trabecular Metal Modular Cups. We are in the initial phases of launching our new Acetabular Cup Systems outside the U.S. And early surgeon feedback on the new cup systems has been very positive," said Dvorak.

The company attributed the strong growth in spine revenues to, "solid sales of the acquired fusion devices as well as legacy interbody devices and bone graft substitutes partly offset a decline in Dynesys revenue in the quarter," according to Dvorak.

The company was hopeful of improved sales performance of the Dynesys dynamic stabilization device which is heading for an FDA ortho panel review on November 4. Zimmer is seeking broader indications for the device. "That's going to be telling to the future of that product line," said Dvorak.

Recovery and Stabilization

Zimmer's revenues are finally stabilizing and the quarter showed positive signs, said PearlDiver senior large joint analyst Scott Ellison. He noted that even the decline in hips was a marked improvement over the past two quarters when sales were down 10% and 9%. The growth in knees compared to declines in the previous two quarters of 6.2% and 5.5%

Dvorak told analysts that after watching procedure rates dip three to four percentage points earlier this year it looks like there was a one-point recovery in the third quarter.

company news

"We think that over time you're just going to see a continued progression towards a more normalized procedure rate."

Canaccord analyst Bill Plovanic said he believed the tide has turned for Zimmer and with easy comps, favorable FX (foreign currency) impacts and stabilizing procedure volumes the company is positioned for positive growth rates going forward.

—WE (October 27, 2009)

Ambitious ApaTech Collects Awards

British orthobiologics company ApaTech, has won the bronze award in the Deloitte Technology Fast 50 as a result of an 8,000% five-year sales growth rate.

Just last month the company came in second in the Sunday Times Fast Track and remained Britain's fastest growing medical technology company for the third successive year. In March, the company won the Frost & Sullivan award as North American Device Biologics Firm of the Year.

The company's fast growth is based on its Actifuse product, a silicate substitute calcium phosphate bone graft material which ApaTech manufactures and supplies globally. The Actifuse scaffold, according to the company, mimics the body's natural boney structure and accelerates the growth of high quality bone.

ApaTech has operations in London, England; Foxborough, Massachusetts; and Berlin, Germany, and is backed by international investors, Encore Ventures and Healthcor. Since its founding in 2001, the company has raised more than $60 million from investors.

Simon Cartmell, Chief Executive Officer of ApaTech commented:

> "Winning awards such as this is always a great testament to the company's success. One of our core values is ambition and we've now completed a new $13 million production facility which will enable us to meet $300 million of sales annually, which shows where our ambition lies. So hopefully we will continue to be 'ever-present' in the Deloitte Fast 50 awards for some time to come."

Clinical Data

This past April, the company presented new clinical data for Actifuse, suggesting that it can provide an alternative to Iliac Crest Bone Graft (ICBG), in the treatment of patients with degenerative lumbar spine disease. According to the company, two new studies presented at the North American Spine Society Spring Break Meeting showed that Actifuse has the potential to be as clinically effective as ICBG.

"These data provide further evidence that Actifuse is an excellent alternative to ICBG for physicians and patients offering comparable efficacy to ICBG without the need to take bone from the patient's own skeleton" commented Brad G. Prybis, M.D., Carrollton Orthopaedic Clinic, Carrollton, Georgia.

—WE (October 28, 2009)

Biomet Buys ChonDux

The major orthopedic device companies are in a competition to win the market for repairing and regenerating cartilage with biomaterials.

company

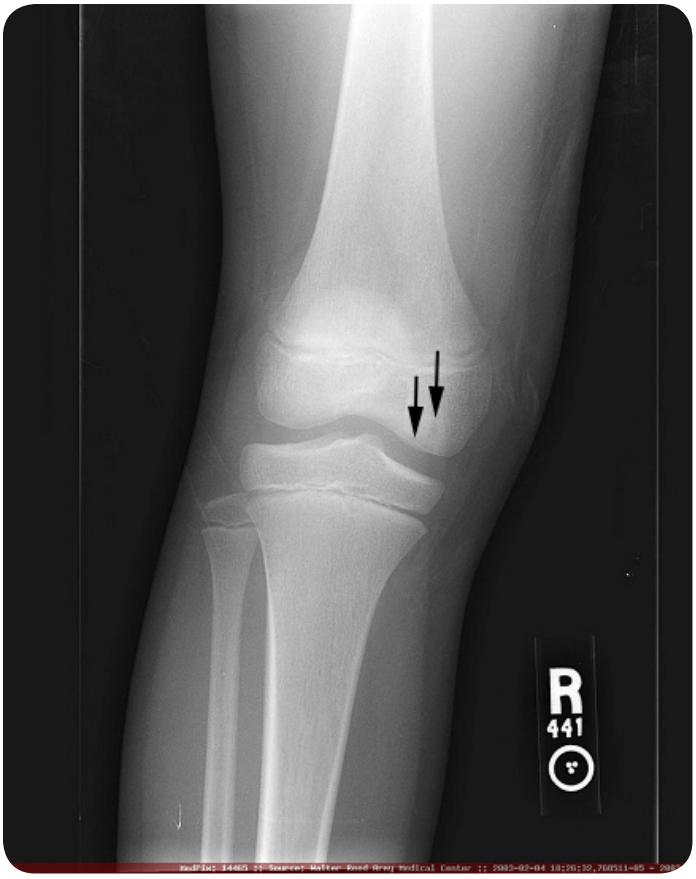


Photo: Human Cartilage

Seeing an opportunity for earlier intervention in pre-arthritic patients, Biomet announced on October 20 that it had acquired a proprietary cartilage repair technology called ChonDux, from Cartilix, Inc.

Cartilix was founded in 2004 by Frank Huerta, Jennifer Elisseeff, Ph.D., and orthopedic surgeon Norman Marcus, M.D., to develop novel biomaterials to repair damaged tissue in articular joints and other applications. The company then developed ChonDux for repair of knee cartilage. ChonDux technology uses a biological adhesive and hydrogel to fill articular cartilage lesions.

The product is not available commercially, but the company says clinical trials are scheduled to begin in Europe during the first half of 2010, followed by the U.S. shortly thereafter.

"We believe that Cartilix's technology platform is a great fit for Biomet's continuum of solutions for knee disorders," said Biomet President and CEO, Jeff Binder. "Biomet has a rapidly-growing sports medicine franchise, the world's leading partial knee replacement system, and the most comprehensive total knee replacement system on the market, allowing us to provide a broad spectrum of solutions for varying degrees of knee disorders. The Cartilix technology provides Biomet with an opportunity to facilitate earlier intervention in pre-arthritic patients."

In 2003, Cartilix cofounder and Chief Science Officer, Jennifer Elisseeff was highlighted in *Technology Review's* "10 Emerging Technologies That Will Change the World." As a biomedical engineer at Johns Hopkins University, she and her colleagues developed a way to inject joints with specially designed mixtures of polymers, cells, and growth stimulators that solidify and form healthy tissue. "We're not just trying to improve the current therapy," says Elisseeff. "We're really trying to change it completely."

No information was provided on the purchase price for the assets.

The *Ft. Wayne Journal Gazette* reported that Biomet didn't say whether the acquisition would create any jobs.

—WE (October 29, 2009)

legal & regulatory

Kuklo Exonerated – Sort Of

A Washington University investigative panel issued a report on October 14 regarding allegations that Timothy Kuklo, M.D., falsified data in a study published in the August 2008 *Journal of Bone and Joint Surgery.*

According to a letter sent by Kuklo's attorney to U.S. Senator Chuck Grassley, the University concluded that, "Dr. Kuklo presented adequate evidence to question the accuracy of the number of patients contained in the [Walter Reed Medical Center's data base]." In other words, the Army kept bad records and Dr. Kuklo can't be found guilty of fabricating data if the data base is f awed.

The Wash U panel "unanimously concluded that the allegations of fabrication and/or falsification of data in the Manuscript is not supported by the preponderance of evidence...and determined that the allegations must be dismissed," wrote Kuklo's attorney, Henry Dane.

Not Complete Exoneration

However, according to a *St. Louis Post-Dispatch* story on October 15, the university said the report was not a complete exoneration. "This is akin to a finding of insufficient evidence, and should not be characterized as a complete exoneration," the university's statement said.

Regarding the Army investigation which concluded that Dr. Kuklo had falsified data, Dane wrote, "The Army investigation was based on the largely unsubstantiated allegations made by Lt. Col. [Romney] Andersen, a junior colleague of Dr. Kuklo's. The Army accepted the allegations at face value and did not afford Dr. Kuklo the necessary time to defend himself."

Research Misconduct

Finally, addressing the issue of Dr. Kuklo signing colleagues' names to the study without their permission, Dane wrote, "The co-authors were of far lesser stature in the realm of academic medicine" and Dr. Kuklo was simply "attempting to give his colleagues some (perhaps undeserved) recognition."

"Although his actions may have been misguided, there is no evidence that they were anything other than well intended," concluded Dane.

The Wall Street Journal reported that the panel found the listing of doctors as co-authors without their permission to amount to "research misconduct."

Washington University said that Dr. Kuklo's resignation was not being reconsidered.

—WE (October 28, 2009)

large joints

Biospace med: Expansion and Prestigious Award

The words "expanding radiation" usually aren't a good thing. But in the case of the innovators at Biospace med, they are. The company has announced that it is delving deeper into the U.S. market with its FDA-cleared EOS X-ray imager—the world's first ultra-low-dose X-ray technology. In other exciting news, Professor Georges Charpak, inventor of the EOS technology, has received the Centenary Medal from the French Radiological Society (SFR), the organization's highest honor.

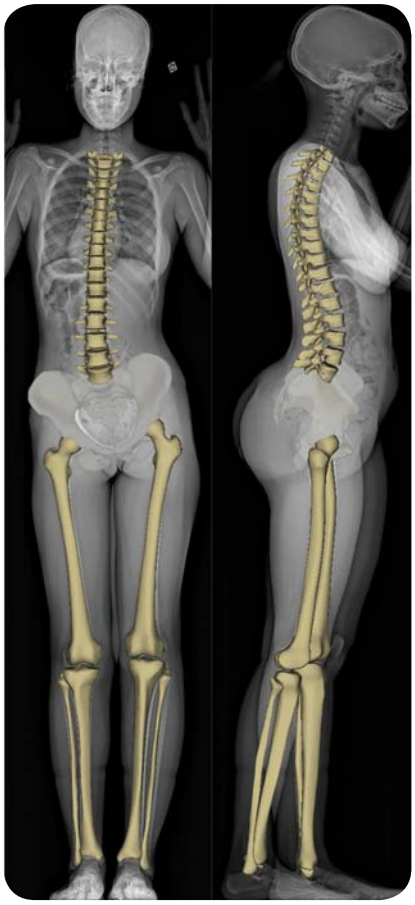
Biospace med, which has recently added new customers in the Midwest and Southeast regions of the U.S., indicates that EOS can capture head-to-toe images of patients in a standing, weight-bearing position with a dramatic reduction in radiation dose—up to 10 times less than a conventional X-ray and up to 1000 times less than a CT (computed tomography) scan. The company also notes that the EOS images are designed to provide sharp detail and to empower physicians to better diagnose and plan an appropriate course of treatment.

EOS System/Biospace med

"We are very pleased to announce additional installations of our ultra-low-dose EOS X-ray imager in new markets across the United States," said Marie Meynadier, Ph.D., CEO of Biospace med, in the news release. "Now that we have a beachhead in two new regions of the United States, we look forward to meeting the numerous healthcare institutions in these new markets that are still imaging patients with a conventional digital X-ray, as they are in the front rank of candidates to adopt EOS.

"In addition, because EOS uses significantly less radiation than a conventional X-ray or CT scan, it represents a remarkable advance for children with pediatric scoliosis, a condition involving a curvature of the spine that virtually always requires recurring X-ray examinations, possibly as many as two dozen over the duration of their clinical follow-up," added Dr. Meynadier.

"Further, we are extremely proud that Professor Charpak has been recognized for his seminal contribution to low-dose X-ray imaging," said Dr. Meynardier.



"EOS is a major breakthrough in the safe and effective imaging of patients. It is especially beneficial in situations where patients want to restrict their exposure to radiation when long-length, weight-bearing images are required. Professor Charpak is most certainly deserving of the SFR's highest award."

When asked if the company envisions any obstacles to the adoption of EOS over traditional imaging, Dr. Meynadier told *OTW,* "Our recent site installations across the world and product-usage adoption are clearly proving that EOS is fully responding to orthopedist and patient requests

large joints

for non-irradiating, high-quality and high-throughput images. We have no doubt that EOS will become in the future the 'gold standard' for osteo-articular imaging as our expansion continues."

Regarding the company's future plans for EOS in the U.S. market, Dr. Meynadier told *OTW,* "Biospace med started in 2008 to install EOS in strategic sites across the U.S. to learn about this market, and we continue in 2009 our expansion across the country on selected sites. Our growth in the future can be accelerated by strategic partnerships, and we're starting discussions for potential alliances."

She added, "In addition, because EOS uses significantly less radiation than a conventional X-ray or CT scan, it represents a remarkable advance in musculoskeletal imaging, as all other technologies deliver a substantial dose of radiation to the patient."

—EH (October 27, 2009)

Genetic Study: RA in African-Americans

Cogitating on chromosomes… The University of Alabama at Birmingham (UAB) is set to lead a multi-site study of genetic factors in rheumatoid arthritis (RA) in African-Americans. With a five-year $4.4 million grant from the National Institute of Arthritis, Musculoskeletal, and Skin Diseases (NIAMS), part of the NIH (National of Health), the consortium will perform the first large-scale genetic analysis of African-American RA patients.

S. Louis Bridges Jr., M.D., Ph.D./UAB

RA is the most common form of inflammatory arthritis among African-Americans. While its cause is unknown, genetic and environmental factors are involved, and there is evidence that genetic variants associated with RA differ by race and ethnicity. The study will include 3,200 African-Americans, and will look throughout the human genome to see which specific genetic regions confer susceptibility to RA.

"We will use this genetic information to gain new insights into the cause of RA in African-Americans," said, S. Louis Bridges Jr., M.D., Ph.D., in the news release. Dr. Bridges, Director of the UAB Division of Clinical Immunology and Rheumatology and principal investigator of the study, added, "We also will be looking at genetic factors that affect damage of joints and osteoporosis in African-Americans with RA, as well as genetic factors that turn on or off expression of genes in blood cells from these subjects."

Because there are existing relationships in place, says Dr. Bridges, the multi-site study is uniquely positioned to gather and analyze this information. These collaborations are a result of the NIH-sponsored CLEAR Registry (Consortium for the Longitudinal Evaluation of African-Americans

large joints

with Early Rheumatoid Arthritis), which Dr. Bridges directs, and other data-collection efforts. Dr. Bridges names the key collaborators as Richard Myers, Ph.D, and Devin Absher, Ph.D, of the Huntsville-based HudsonAlpha Institute of Biotechnology, which will perform genetic testing and collaborate with data analysis.

"We believe this work will provide advances in clinical rheumatology, improve diagnostic strategies and develop targeted therapies for RA in African-Americans," Dr. Bridges added.

Dr. Bridges told *OTW,* "The great thing about this approach is that we will examine the entire genome and will likely discover new genetic associations that we would not have anticipated."

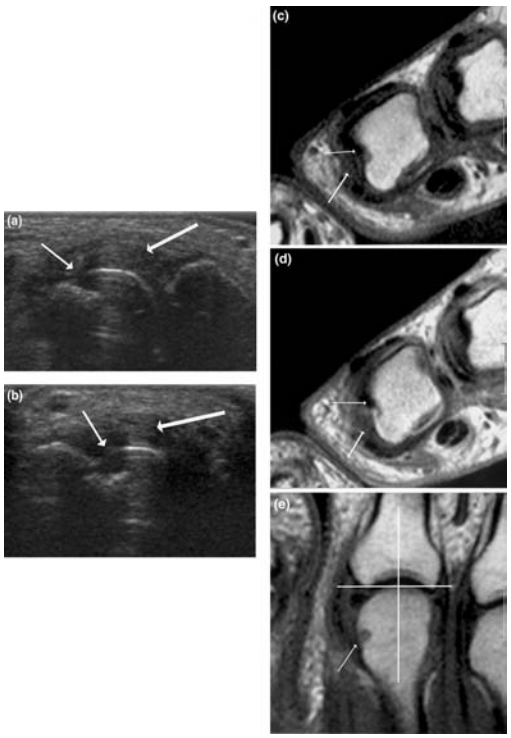
Participating sites are UAB; HudsonAlpha Institute for Biotechnology; Kaiser Foundation Health Plan of Georgia, Inc.; John Hopkins University; Little Rock Diagnostic Clinic; Medical College of Georgia; University of Mississippi Medical Center; Louisiana State University Medical Center; Howard University College of Medicine; Wake Forest University; Brigham and Women's Hospital; University of Nebraska; and University of Chicago.

As far as next steps, Dr. Bridges told *OTW,* "We currently have DNA and clinical data on about 1,000 African-Americans with rheumatoid arthritis for the first part of the study, the genome-wide association study. We need to collect DNA and clinical data from an additional 800-1,000 African-American patients to validate our findings in an independent set of subjects."

—EH (October 30, 2009)

No Increase in Cancer Risk for RA Patients

Nordic news flash… According to *Health Day News,* (October 29, 2009, "Rheumatoid Arthritis Treatment Doesn't Promote Cancer"), researchers from Sweden have found that being treated with tumor necrosis factor (TNF) blockers does not increase rheumatoid arthritis (RA) patients' risk of cancer.



RA Ultrasound/Wikimedia Commons

TNF, secreted by immune cells, regulates the immune system and plays a role in inflammation. TNF blockers are immunosuppressants that reduce inflammation in RA patients, but there are concerns that long-term use of the drugs may increase the risk of infections and cancer.

In the current study, the researchers analyzed data from 6,366 rheumatoid arthritis patients who started anti-TNF therapy with infliximab (Remicade), adalimumab (Humira) or etanercept (Enbrel) between January 1999 and July 2006. Those individuals were compared with other groups of RA, including 61,160 not taking medications, 4,015 taking methotrexate (the gold standard) and 4,105 taking combinations of disease-modifying anti-rheumatic drugs (other than TNF blockers).

The investigators reported that 240 first cancers were diagnosed during follow-up among patients who had no history of cancer when they began anti-TNF treatment. Compared to RA patients who didn't take anti-TNF drugs or those with no history of cancer, the relative cancer risk of anti-TNF therapy was 1.00 and remained unchanged for those taking immunosuppressant drugs for up to six years.

As quoted in the article, Dr. Johan Askling of the Karolinska University Hospital in Stockholm, and the team

large joints

leader, stated, "Our research indicates the overall cancer risk is the same for rheumatoid arthritis patients on immunosuppressant therapies and those not taking medications for the disease." He added, "Given several uncertainties, continued vigilance remains prudent."

Commenting on his plans for future research, Dr. Askling told *OTW,* "This is one of several attempts to assess the potential risk for cancer associated with TNF-inhibitors. As such, and since cancer is a long-term outcome, this analysis is but an interim assessment and clearly doesn't 'close the case.' Also, an unaltered overall risk is not the same as saying no increased risk for any specific type of cancer. So, we're preparing for a further update, hopefully with sample size enough to be able to address risks for particular cancer sites."

—EH (October 30, 2009)

Henry Moore - Large Vertebrae/commons.wikimedia

spine

OREF: DePuy Spine Funding Fellowships

A victory for the vertebrae of the future…The Orthopaedic Research and Education Foundation (OREF) has announced that DePuy Spine will provide funding for up to 25 graduate medical education (GME) fellowships in spine care. The funds will be awarded for the 2010-2011 academic year through the OREF Clinician Development Program (CDP).

According to OREF, DePuy Spine is the first company focusing exclusively on spine-related products and services to join this program, and was attracted by the success the CDP had in its first year and by its unbiased method of selecting recipient institutions.

Commenting on the program's first year was Gene Wurth, OREF President and CEO, who told OTW, "In its first year, OREF's Clinician Development Program secured support from seven corporate partners, including three commitments of $1 million or more. As a result, OREF was able to fund 50 fellowship grants, 110 residency enhancement grants and 11 CME for 2009-2010. We are completing the second grant-making cycle with a $2.1 million

spine

commitment from DePuy Spine and are on track to sustain the growth of the program going forward. We're deeply grateful for the response from industry."

As indicated by OREF, its CDP program is an independent grant-making system free of donor bias that facilitates industry support for orthopedic education and research while maintaining compliance with best practices. The program was reviewed and endorsed by U.S. Department of Justice monitors assigned to three device manufacturers by federal mandate. For the 2009-2010 academic year, the program's first year, OREF awarded $3.9 million in fellowship, residency enhancement, and CME grants.

"We are extremely pleased to welcome DePuy Spine to this very successful new program for facilitating industry support of education." said OREF Board Chair William P. Cooney, III, M.D., in the news release. "DePuy Spine's commitment sends a strong signal that all areas of orthopaedic care can benefit from OREF's Clinician Development Program, and demonstrates that other companies, in addition to those specializing in adult reconstruction, see the benefits of supporting fellowships through this system. OREF appreciates DePuy Spine's past support for OREF-funded research and education programs, and the company's decision to renew and broaden participation."
Providing details on the selection process was Frank B. Kelly, Jr., M.D., Chair, OREF Educational Grants Board, who told *OTW,* "OREF has multiple safeguards in place to ensure both oversight and the selection process for CDP fellowship grants are free of bias. Orthopaedic surgeons on the OREF Educational Grants Board must establish they have had no industry ties for a minimum of two years prior to their term of service. All applications that meet ACGME criteria or equivalent requirements for non-ACGME-accredited programs constitute the qualified candidate pool from which recipients are randomly selected. The number of recipients selected is determined by the funding pool: the total dollars committed by all participating industry partners. With this system, OREF is able to ensure that every qualified applicant has an equal opportunity to receive funding, that no donor bias enters the process and that no organization is favored over another."

—EH (October 26, 2009)

trauma

Study: Skiing Safer Than You Think

Downhill danger? Perhaps not, say researchers from the University of Vermont. Their work, published in the November/December issue of *Sports Health: A Multidisciplinary Approach,* set out to look into 12 common skiing myths… call them "alpinisms."

Downhill Skiier/Wikimedia Commons

"There are many common misperceptions about skiing safety and equipment needs," said lead author, Robert J. Johnson, M.D., Emeritus Professor of Orthopaedics at the University of Vermont, in the news release. "Our study reviewed the literature concerning 12 of the most common topics related to skiing and determined that all or at least part of each of the myths could not be substantiated."

The myths investigated?

- *Skiing is among the most dangerous of activities.* **Truth:** The approximate annual fatality rate per million hours of exposure associated with cars and bicycles is essentially the same as that for skiing.

- *Broken legs have been traded for blownout knees.* **Truth:** The increase in anterior cruciate ligament (ACL) injuries came later than did the decrease in lower leg injuries; the two groups involve completely different mechanisms of injury.

- *All you need to know is your DIN (release indicator value) number and you can adjust your bindings.*

trauma

Truth: Inspection and calibration of ski bindings is a complex process that requires specialized tools, equipment and properly trained technicians.

- *Toe and heel pieces must be set to the same release indicator value or the bindings won't function properly.* **Truth:** Today's standards allow for personalized release/retention settings that may result in different indicator values at the toe and the heel.

- *Formal ski instructions will make you safer.* **Truth:** In most studies done in North America and Europe, skiing lessons did not decrease the risk of injury and have not been shown to be an effective method for injury prevention.

- *The shorter the ski, the less torque is applied to the leg in a fall–short skis don't need release bindings.* **Truth:** Several case control studies have demonstrated a three to twentyfold increase in the incidence of ankle and tibia fractures for persons using skiboarders compared to traditional alpine skis. Release bindings should be a requirement for skis of any length.

- *Young bones bend rather than break, so there is no point in spending a lot of money on children's equipment.* **Truth:** Children are at highest risk for potential equipment related injuries, and therefore require properly functioning equipment if that risk is to be minimized.

- *When buying boots for children, leave plenty of room for fast growing feet.* **Truth:** Poor fitting boots are a major factor leading to lower leg fractures and sprains in young children. If the foot can easily move within the boot, the binding release function is compromised.

- *If you think you are going to fall, just relax and let it happen.* **Truth:** Skiers should assume the posture of a parachutist just before landing and keep joints f exed moderately. Muscles of the extremities and trunk should be strongly contracted; this response will stiffen and protect bones and joints.

- *Exercise is the best way to avoid skiing related injuries.* **Truth:** There is no convincing evidence that conditioning of any type can reduce the risk of alpine skiing injuries, however, there is no downside to good physical condition and it may improve the enjoyment of skiing.

- *Tighter standards that mandate lower release settings will reduce the risk of injury to the ACL.* **Truth:** The primary mechanisms for ACL injury is not related to binding function, so any reduction in the binding release values would not reduce the risk of ACL injury but could increase the frequency of inadvertent releases.

- *Buying new ski equipment is safer than renting.* **Truth:** Rental equipment from shops following current standards is inspected for proper function and wear and tear every time it is rented; user owned equipment is normally inspected only at the beginning of each season.

"Anyone who advises skiers on safety issues and medical care should be certain that the advice given is true and accurate. Our review highlights how when many of these myths are propagated, additional harm and injury can come to the skier," said Johnson.

Regarding what led to this research, Dr. Johnson told *OTW,* "We have been evaluating ski injuries epidemiologically with a case control study design since the 197172 ski seasons. At that time and through the ensuing years, our interest in skiing injuries has been because of the perceived and actual high rate of injury sustained by skiers. We have monitored these changes through the years in our study. We are continuing this study into the foreseeable future."

When asked what the researchers we most surprised to learn, Dr. Johnson told *OTW,* "You apparently were amazed to find that formal ski instruction does not help reduce the risk of injury. When you think about it, this is not a surprising issue, because skiers are taught how to ski, not how to recover or avoid injury if they fall; nor are they given instructions on the proper use of equipment such as skis, boots and bindings. Thus, it was not surprising to us from the very beginning in

trauma

the ‘70s to the present that there is little evidence that formal ski instruction helps reduce the risk of injury. We have observed that skiing experience and skier skill is associated with a reduced risk of injury. In response to your question, through the years it became apparent that injuries to knee ligaments and especially to the ACL are not related to the function of presently used ski boot binding systems. In other words, the most common cause of ACL injury does not relate to the dysfunction of the ski boot binding system. In fact, these devices are unable to identify the types of conditions that result in ACL ligament injury. Probably the most important aspect of our findings is that by devising a program of skier education on how to avoid the conditions that lead to the most common type of injury mechanism, we were able to dramatically reduce the risk of injury among ski patrollers and instructors.”

—EH (October 30, 2009)

The Picture of Success: Dr. Darrel Brodke

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

His orthopedic siren's song began not with a broken bone, but with, well, sirens.

Dr. Darrel Brodke, Professor and Vice Chairman of the Department of Orthopaedics at the University of Utah School of Medicine, and Director of the Spine Service, explains, "I was raised in Oakland, California, and had a stimulating family life, with a father-dentist and a dental hygienist-mother. I considered medicine in high school, but I also had my sights set on being an astronaut—not only for the adventure, but because I had a substantial interest in achieving that level of education. When I got to college at the University of California, Davis, however, my perspective shifted radically when I began to work at an ambulance company. The drama involved in trauma situations was especially appealing and the more I did this work the more I liked it. I began to see that a surgical subspecialty was somewhere in my future."

Medical Training

Dr. Brodke's medical odyssey officially commenced at the University of California San Francisco in 1985. "When I began medical school I had a strong suspicion that I would choose orthopedics. In fact, as I traversed the subspecialties, I measured everything I did against orthopedics. I kept 'coming back' to this field because I liked the variety of patients, the complexity of the mechanical and biomechanical aspects of orthopedics, and I was drawn to the idea of getting someone back to near normal. In most other specialties you just help manage a patient's disease, but in orthopedics you have a significant effect on his or her quality of life."

Dr. Brodke then met a methodical, talented mentor who would help lay the foundations for his career. "For my residency we returned to Wisconsin, my wife's neck of the woods. My primary mentor at the University of Wisconsin-Madison was Dr. Tom Zdeblick, who gave me an understanding that in addition to being rewarding, spine surgery and research could be fun. Dr. Zdeblick, now Chair of the department at Wisconsin, excelled at the four pillars of academic spine care: patient care, research, education and service work. He established a lab, held weekly lab meetings, set a research path that would cover the next several years, etc. Under his tutelage I discovered a particular interest in the cervical spine, finding this area appealing not only because of the interesting anatomy, but because cervical surgeries tend to be concise. Not to mention that the outcomes are usually good and readily apparent."

But the best approach to the cervical spine can sometimes be quite unusual. Dr. Brodke: "One early spine case I had was a patient with rheumatoid arthritis in which we decompressed the spinal cord through the mouth—a transoral approach. It was very complex, and involved splitting the tongue and jaw. The patient did very well and I was able to be part of an interesting diagnosis, decision-making process, and surgery. Further solidifying my interest in cervical surgery was that in my third year I presented a paper at a meeting of the Cervical Spine Research Society. It was a really stimulating, fun group of people who enjoyed disagreeing and bantering with one another."

Energized, Dr. Brodke went looking for trauma. "My residency gave me broad spine experience, but it did not include much trauma. For that I headed to a fellowship at the University of Washington/Harborview Medical Center and worked under

the guidance of Drs. Jens Chapman and Paul Anderson. Dr. Anderson left to start a private practice as I began my fellowship in 1994. I applied for and got permission to spend a day a week with him as he built his private practice. It was interesting seeing things unfold in a brand new practice for Dr. Anderson. It was also fantastic working with Dr. Chapman; I was alongside him nearly every day for a year, caring for an amazing volume of spine trauma at Harborview and very complex spinal disorders at the university."

Training Others in Academic Medicine

With this practical education under his belt, Dr. Brodke and family set out for Colorado Springs. "I joined a private practice and all was going quite well, including my relationships with my wonderful partners. Then I ran into a friend from the University of Utah who said, 'We need a spine surgeon. Are you interested?' I initially said no, but after some late night discussions with my wife, and a lot of soul searching, we reconsidered. It came down to this: I was two years out of fellowship and thought, 'Well, if I am going to do academic medicine, this could be my last significant opportunity for quite some time.'"

"The department," continues Dr. Brodke, "had two spine surgeons, one who had experienced an aneurism and was unable to work. The other surgeon, who struggled with witnessing his friend's painful situation, decided to leave for his home state in order to be close to family. I interviewed with 14 people over a few hours, and a couple of days later, I was offered the opportunity to run the spine section for the department. It was especially exciting because there were 18 people in the department, half of whom were my age. There was a great deal of camaraderie, and we all skied together and got our families together."

An adventurer and spine specialist, Dr. Brodke would then add "diplomat" to his skillset. "For several years I was the lone spine surgeon in the department. In 1999 I hired a partner and we began to work closely with the neurosurgery spine surgeons. Five years later we developed a combined orthopedics/neurosurgery fellowship, largely because I believed that this approach to training was the wave of the future. As we thought, the benefits of fellows being taught spine surgery from two specialties outweigh the challenges of working across departments. There is naturally a significant amount of loyalty to one's own department, such that when conf icts arise the tendency is to pull back to your own camp. This generates more conf ict, however, rather than a resolution. We approach the fellowship with combined decision making, which works well."

When in the lab, Dr. Brodke also tried to find and combine all the possible angles in a given test. "When I came to Utah I had concrete ideas about how I wanted to develop the spinal biomechanics lab and create certain machinery. Fortunately, our lab director, Kent Bachus, Ph.D., was very willing to do what it took to achieve these goals. Our pièce de résistance was a custom spine simulator that we've used over the last 12 years to test spines. While we originally worked from ideas already in existence, we took the process several steps farther to include software that gave us the ability to test and increase our efficiency."

"This multiaxis simulator allows us to test specimens in a variety of ways. For example, we can load a specimen on the simulator and do pure moment testing (applying the load in one plane or in multiple planes individually or simultaneously). This means that you have very efficient, complex testing of a specimen in multiples directions—all with the aid of an optical tracking device."

"This was all done on a shoestring budget," continues Dr. Brodke, "and created out of parts sitting around the lab. And it was just our Ph.D. student/

software developer, the lab director, and me. We continue to alter the simulator, most recently upgrading the software to improve the stability of the machine as it is testing at higher rates."

Digging for Data

On the research front, Dr. Brodke is curious about many things. One is how certain devices affect their neighbors. "I have studied motion preservation devices and the effects of surgery on adjacent levels in the spine. In one set of studies my colleagues and I looked at the effectiveness of cervical arthroplasty as compared with a fusion on the remainder of the cervical spine. We found that the remainder of the cervical spine was less affected by motion preservation at the operated level than if you fuse the segment. In another series of papers we looked at the effectiveness of two different styles of plating in the cervical spine, namely, a dynamic versus a static plate. We determined that a dynamic plate helps to share the load better than a static plate."

"More recently," states Dr. Brodke, "I have brought in partners, Drs. Mike Daubs and Alpesh Patel, who are interested in clinical research. We have started single center trials and have also joined multicenter studies. One of the latter at present involves looking at cervical spondylotic myelopathy and outcomes of surgery. Thus far we have data from 300 patients around the country. Our results to date show that surgery helps these patients significantly as far as symptomatic relief and spinal cord and neurologic function. The bottom line is that this work helps us understand surgical decision making from a multicenter perspective, which carries quite a lot of weight."

Whether single or multicenter, all in all it's better to rely on data than on conjecture. Dr. Brodke: "We have won several awards for our single center study on the psychological health of 400 patients who have come through the spine clinic. My colleagues and I wanted to see how good we are at using our instincts when it comes to a patient's mental status; we used the Distress Risk Assessment Method test (DRAM), which contains both a depression scale and a somatization scale. Spine surgeons who were 10 years post training, one year post training, and our nonoperative colleagues were all tested to see if they could determine which patients fell into which category: normal, distressed, or at risk."

He continues, "The DRAM has been shown to have validity in surgical outcomes, with worse outcomes among those patients who have higher DRAM scores. Our study found that none of us are particularly good at using our clinical instincts with regard to patients' mental states. We think we know…but we don't."

For this and other groundbreaking work, Dr. Brodke was given a special honor. Last year he was appointed the Louis and Janet Peery Presidential Endowed Chair in recognition of his academic and clinical productivity, teaching efforts, educational activities, and service. Dr. Brodke: "My responsibilities include overseeing all of the fellows in the department, made more challenging because we have seven fellowship programs in all the subspecialties. Because each fellowship was its own individual fiefdom, we brought them all under one umbrella to ensure that they were all being treated/managed the same way with regard to the amount of responsibility, compensation, etc.

"In the end, however we are still primarily a residency program. If we were to find that fellows were taking cases and attention away from the residents, that would be a problem. In our case, the fellows are encouraged, and are told, 'You are part of the faculty and are here to teach as well as learn.' Having a teaching role pushes them to be their very best."

On the Horizon

Dr. Brodke is also glad that the field itself is being pushed to improve. "I

find it particularly exciting that we are increasingly focused on trying to understand our success through clinical outcome measures. That process is evolving in interesting ways, for example the way that we measure outcomes is changing as we better understand patient expectations and needs. The problem is we thought we understood clinical outcomes; in reality we are just entering adolescence as far as understanding what really works for patients. What brought me into spine surgery was the fact that it was evolving quickly—I still feel like that 15 years later."

And if that's not enough change, there has been a huge shift on the home front. "We recently dropped our son off at college. While it is a big change for the family, it's fun in that I get to relive my college years to a certain extent. He is studying to be either a neuroscientist or a physician. Our daughter is still in high school and much of the time can be found on the soccer field (with me in the bleachers). As for my wife, she truly grounds me and the family and keeps everything running smoothly—no small task."

Dr. Darrel Brodke…taming trauma and opening new horizons.

Orthopedics This Week | RRY Publications LLC

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