VOLUME 5, ISSUE 26 | AUGUST 25, 2009

Orthopedics This Week

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Orthopedics This Week

VOLUME 5, ISSUE 26 | AUGUST 25, 2009

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Orthopedic stocks continue to show preternatural strength. Three reasons, we think, are fueling the buying interest. Low P/Es and PSRs. Comparatively high profit margins (20%-30% of sales!). A powerful demographic tail wind. In the market, as in life, all things move in cycles. We're on an upswing.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	7.65%	25.94%	Wall Street's growth expectations are lagging the reality at OFIX. Conditions are improving rapidly.
2	4	Stryker	23.28	5.35	Simple equation at SYK. Will MedSurg be stronger one year from now? We're confident it will be.
3	2	Medtronic	31.37	7.97	Wall Street doesn't think very much of MDT's future earnings. It's paying only 12x. Don't paper mills get a higher P/E?
4	3	Integra LifeSciences	12.32	25.40	Occasionally a stock hits equilibrium. It's rare, but IART's market pendulum appears to be at the mid-point.
5	7	ArthroCare	16.87	36.06	The recent equity raise put P&Ls into someone's hands. And the stock has buyers all over. What does that tell you?
6	8	Alphatec	(8.51)	41.54	Wall Street's expectations are pretty high for ATEC. Analyst consensus is a profit in Q4.
7	6	CONMED	8.28	7.75	CNMD has the same binary equation as SYK—will hospital spending rebound in the next 12 months. We think so.
8	5	Symmetry	10.80	36.85	We agree with Wall Street consensus that future growth is not likely to be as high as past growth. Still SMA is cheap.
9	9	Zimmer	29.31	12.29	Upgrade by Raj Denhoy at Thomas Wiesel. Smart move. Not much downside here.
10	10	Johnson & Johnson	26.29	3.42	Low P/E. Low growth. At least the dividend yield is 3.20%.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	CryoLife	CRY	$7.95	$226	51.1%
2	Alphatec Holdings	ATEC	$4.60	$241	41.5%
3	Symmetry Medical	SMA	$11.03	$395	36.8%
4	ArthroCare	ARTC	$18.30	$487	36.1%
5	Orthofix	OFIX	$27.92	$479	25.9%
6	Integra LifeSciences	IART	$35.25	$1,000	25.4%
7	I Flow Corp	IFLO	$8.17	$200	23.4%
8	Wright Medical	WMGI	$16.60	$641	22.1%
9	RTI Biologics Inc	RTIX	$4.85	$263	17.7%
10	Synthes	SYST.VX	$116.81	$13,862	14.3%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Orthovita	VITA	$4.73	$361	-15.4%
2	Mako Surgical	MAKO	$7.50	$189	-15.1%
3	TranS1	TSON	$5.73	$118	-7.9%
4	Kensey Nash	KNSY	$25.13	$285	-4.3%
5	Osteotech	OSTE	$4.60	$83	-3.4%
6	Regen Biologics	RGBO.OB	$2.20	$22	-2.2%
7	TiGenix	TIG.BR	$6.25	$152	-1.9%
8	NuVasive	NUVA	$41.40	$1,560	2.1%
9	Johnson & Johnson	JNJ	$61.03	168,190	3.4%
10	Stryker	SYK	$41.76	$16,600	5.3%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Symmetry Medical	SMA	$11.03	$395	10.06
2	ArthroCare	ARTC	$18.30	$487	10.75
3	Zimmer Holdings	ZMH	$47.24	$10,120	11.52
4	Medtronic	MDT	$37.80	$42,050	12.89
5	Johnson & Johnson	JNJ	$61.03	$168,190	13.53

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	RTI Biologics Inc	RTIX	$4.85	$263	83.70
2	I Flow Corp	IFLO	$8.17	$200	78.41
3	Smith & Nephew	SNN	$41.18	$7,270	72.02
4	NuVasive	NUVA	$41.40	$1,560	39.88
5	Synthes	SYST.VX	$116.81	$13,862	36.32

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	ArthroCare	ARTC	$18.30	$487	0.43
2	Orthofix	OFIX	$27.92	$479	0.89
3	CryoLife	CRY	$7.95	$226	0.96
4	Symmetry Medical	SMA	$11.03	$395	0.97
5	Exactech	EXAC	$15.55	$199	1.07

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$41.40	$1,560	4.36
2	RTI Biologics Inc	RTIX	$4.85	$263	2.36
3	Johnson & Johnson	JNJ	$61.03	$168,190	1.66
4	CONMED	CNMD	$18.21	$530	1.63
5	***Average***			***$10,213***	***1.52***

Lowest Price to Sales Ratio (TTM)

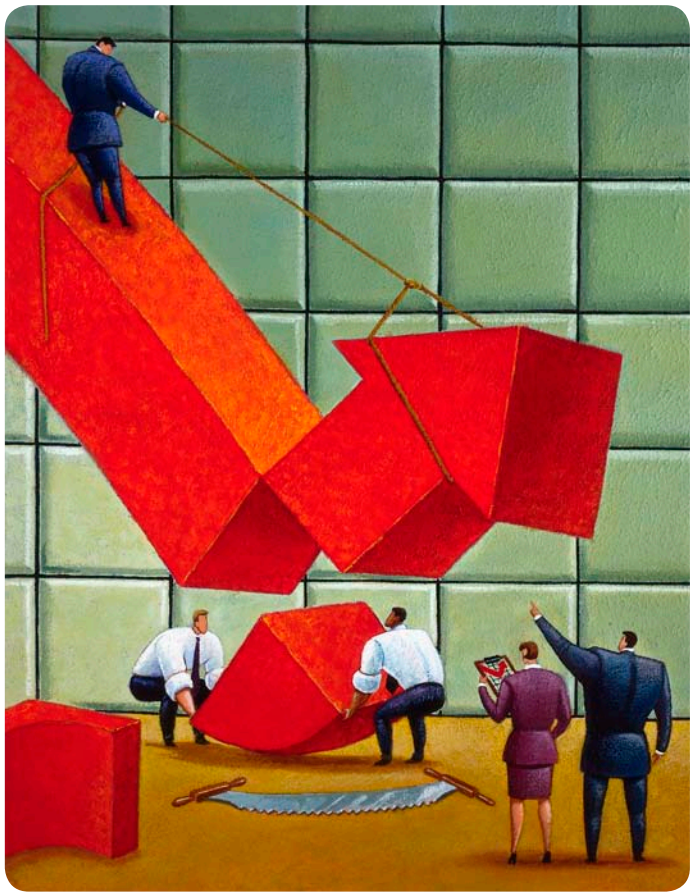
	Company	Symbol	Price	Mkt Cap	PSR
1	CONMED	CNMD	$18.21	$530	0.76
2	Osteotech	OSTE	$4.60	$83	0.87
3	Orthofix	OFIX	$27.92	$479	0.90
4	Symmetry Medical	SMA	$11.03	$395	0.94
5	Exactech	EXAC	$15.55	$199	1.18

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$6.25	$152	345.06
2	Regen Biologics	RGBO.OB	$2.20	$22	14.33
3	Mako Surgical	MAKO	$7.50	$189	9.13
4	Synthes	SYST.VX	$116.81	$13,862	8.47
5	NuVasive	NUVA	$41.40	$1,560	4.96

Orthofix's Gritty Rebound

By Robin Young



In ways large and small, Orthofix's management team has been beating expectations for the last 10 months. Here's the record:

- Quarterly cash flows have risen sharply and consistently since early 2008.
- Debt, which was high following the purchase of Blackstone Medical, has begun to decline precipitously.
- A determined vulture capital attack (Ramius) was dismantled with surprising vengeance and effectiveness.
- New senior managers (a president of North American operations and a new chief financial officer) have not only melded well, but have already had an impact on operations.

Creating a Wealth-Producing Engine

One year ago, Orthofix was struggling with an underperforming spine division that had cost the firm $333 million ($330 million of which was debt) in 2006, a shrinking stock price, and bankers who had their own set of historically difficult problems.

In one of those "when you're up to your ass in alligators, it's hard to remember that your goal was to drain the swamp" moments, management didn't talk much about creating a wealth-producing engine on its conference calls. Rather, managers talked about their Blackstone Spine division; the new Group President of North America and head of Blackstone Medical, Brad Mason; and negotiations with bankers.

From a high of $60 per share (about $1 billion in market value) in 2007, the value of Orthofix had hit bottom at $9 per share.

Then something very interesting happened. Orthofix's management made a series of changes beginning late last year that today, 10 months later, looks like the emergence of a new Orthofix—one that increasingly resembles a wealth-producing engine.

Of course, most investors couldn't spot a "wealth engine" if it walked up and said "howdy." In the early 1980s Eugene Fama, Burton Malkiel and a group of brilliant economists from the Universities of Chicago, Pennsylvania (Wharton), Columbia and elsewhere tackled this question of defining and characterizing corporate wealth engines.

They were looking for the quantitative fingerprint of that most elusive corporate animal. Was it sales, earnings, book value, technology, intellectual property, growth rates, cash on hand, debt levels? Then as now, the predominant tool used by Wall Street investors to find wealth engines was earnings or accounting income.

So Fama, in particular, put the earnings paradigm to the test. He measured the statistical link between company market values (stock prices) and all of these measures of corporate economic activity—earnings, sales, book value, you name it.

Earnings, he found, had a weak statistical connection to the value of a company (as measured by stock price movement). But cash flows (which were earnings but with all of the accounting accruals added back in) could predict reasonably well the direction of stock prices and company values.

Of course, boiled down to a simple truism, Fama's observation was essentially that managers couldn't spend accounting income, but they could spend cash flow. So cash flow trends were better statistical measures of managerial performance than reported income.

Recently Fama's research was put to an updated test by a group of researchers from various universities around the world. In a paper titled "Earnings Quality and Stock Returns" (Chan K, Chan LKC, Jegadeesh N, Lakonishok J. *Journal of Business*. 2006;79(3):1041-1082. Available at http://www.fbe.hku.hk/~konanchan/research/JB_2006.pdf), the researchers looked at every company listed on the NYSE, AMEX and NASDAQ for the period from 1995 to 2005 and, in effect, repeated Fama's research.

The results were the same. Cash flows are a stronger and more reliable measure of both the economic value of a company and the skills of the company's managers.

Indeed, the researchers criticized Wall Street's near obsession with earnings and accounting income, which led many investors to a consistent pattern of poor stock picks (the authors specifically cited investor enthusiasm for, at certain times, Enron, Tyco and Xerox).

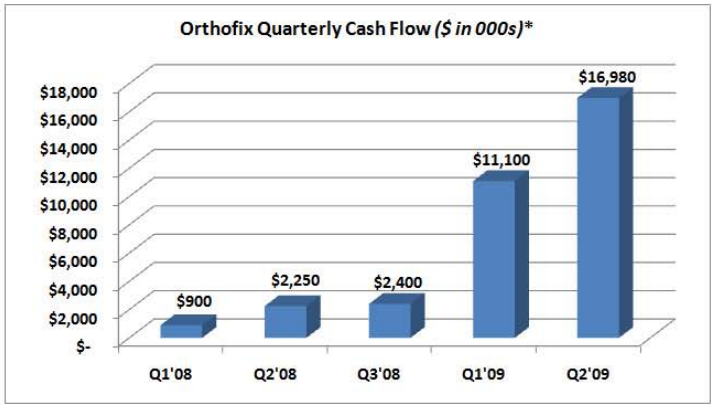
Compared to earnings, said the authors, cash flows are less volatile and deliver greater predictive power to the investor. They asserted that relying on cash flows instead of accounting income gives investors a 2x increase in rates of return. "In one-way sorts by earnings-price ratios, the extreme deciles of stocks have differences in annual returns of about 3.9 percent over the subsequent year (Lakonishok J, Shleifer A, Vishny RW. Contrarian investment, extrapolation, and risk. *Journal of Finance*. 1994;49:1541-1578). When sorted by cash flow to price ratios, the return spreads are about 9.9 percent."

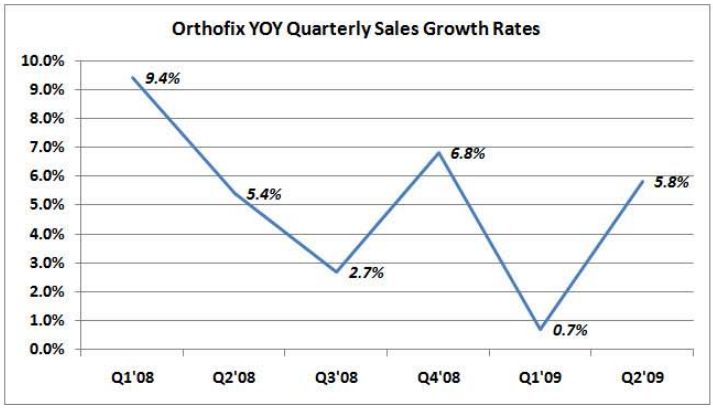
So what does all this have to do with Orthofix?

Look at the two charts below. The first one shows Orthofix's cash flow trend. The second is Orthofix's year-over-year quarterly sales growth pattern.

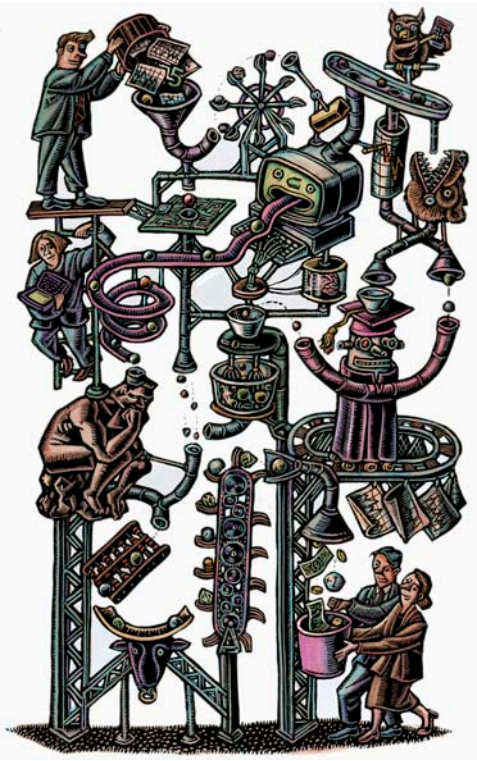
See how the two charts illustrate the diverging trends at Orthofix. Even as sales growth has been choppy at best, cash flows are rising and rising with increasing strength.

Those two diverging trends, lower sales and higher cash flows, are counter-intuitive for many professional investors. But, as Fama argued and as subsequent studies have confirmed, rising cash flows are in fact the single best predictor (better than earnings) of a company's future value.





Source: company documents

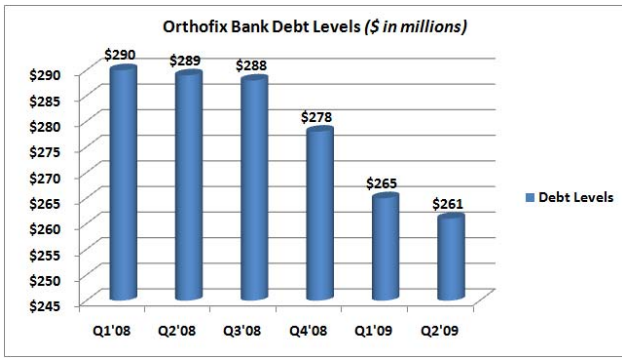


Even choppy sales growth, when combined with rising cash flows, is a strong positive since it is an excellent indicator of a management cleaning house and culling sub-performing businesses or products.

This beautiful pattern is the sign of a company that is getting focused on doing the right things, not just doing things right.

With the bounce in cash flows, debt can be paid down (and, in fact, Orthofix has been accelerating its debt reduction). As debt is paid down and cash keeps building, then management can turn its attention to its profit stars and increase the investment in those businesses.

When this cash flow cylce starts, it can set in motion a wealth-producing cycle.



Source: company documents

The Conditions for Change

Orthofix was always a bit of a diamond in the rough. It has more than 560 direct sales people globally plus 290 distributors, the majority of which are outside the U.S. Orthofix has solid distribution in Europe, Asia, Latin America, the Middle East, and Australia. The only other orthopedic firms with comparable distribution networks have market values of between $8 billion and $15 billion (Orthofix is presently trading at under $500 million). But with a headquarters in the Netherlands Antilles and no particular stars or brand names in the product line, OFIX was a platform waiting for something.

Blackstone Medical's spinal implant product line and its Trinity brand stem cell product line were the "something."

The purchase of Blackstone Medical in 2006 for $330 million put Orthofix's stock on an upward trajectory—for a while. Unfortunately, the promise of Blackstone did not meet up with reality. Doing the right thing, in this case, was not backed up with doing things right. Within one year, most of the key managers who'd built Blackstone were gone. The replacements left a year later.

When sales didn't meet pre-acquisition expectations, the debt incurred to pay for Blackstone began to drag Orthofix down. When the overall credit crisis hit in 2008, banks began to pressure Orthofix in new and painful ways. A new CFO came and went. Orthofix's stock price finally hit bottom the week of October 20, 2008.

The conditions for either a change or capitulation were in place. More than one institutional analyst was questioning the ability of the company to survive without divesting Blackstone—even at a discount.

But no towel came from the OFIX corner.

Instead a gentleman named Brad Mason, the founder of DJ Orthopedics and later Breg (one of Orthofix's divisions) took over as President of North American Operations and President of the troubled Blackstone Spine division.


Robert Vaters

A couple of months later, Robert Vaters joined Orthofix as the firm's new Chief Financial Officer and Executive Vice President.

A month later, in mid-December while the market was trying to forget an awful 2008 and look ahead to, hopefully, a rebounding market under a new U.S. president, this announcement was made: "Orthofix International to Make Partial Debt Repayment Ahead of Schedule." The company's new CFO was quoted as saying that he thought it was probably a good time to start deleveraging the balance sheet. That was unexpected.

Then Blackstone's offices in New Jersey and Massachusetts were closed and consolidated in the McKinney, Texas, operation.

On December 2, a letter arrived at Orthofix from well-known corporate raider and vulture capitalist hedge fund, Ramius Corporation. In a nutshell, the letter accused Orthofix's board of directors and management of failing to build shareholder value, recommended that certain members of the board be replaced, and suggested that the assets of the company be reviewed for possible divestiture or re-organization.

Orthofix responded with a vengeance. One press release after another attacked Ramius, its principals and its board nominees…again and again and again.

January 20, 2009: Orthofix issues a press release accusing Ramius of using misleading and inaccurate information.

January 28, 2009: Orthofix accuses Ramius of nominating unqualified candidates for the board.

February 9, 2009: Orthofix attacks the qualifications of yet another Ramius board candidate.

February 19, 2009: Former Orthofix Chairman, Robert Gaines Cooper, writes an open letter opposing Ramius.

March 2, 9, 11, and 21: Orthofix sends four sharply worded letters opposing Ramius to its shareholders.

March 18: An independent proxy advisor rejects Ramius's bid.

March 19: Orthofix accuses Ramius of egregious errors in its shareholder letters.

March 31: Orthofix forces Ramius to retract false statements.

At the shareholders' meeting on April 2 the vote wasn't even close. Every Ramius candidate was crushed.

The New Orthofix

Last week Orthofix President and CEO Alan Milinazzo provided a comment about his company's quarter: "I'm very pleased to report a strong quarter. These favorable results were consistent across all of our core business segments. This included our spinal implant business, which continued to gain momentum in the second quarter as sales grew 12% led by the recent launches of our Firebird pedicle screw system, Pillar SA interbody device and Trinity Evolution stem cell-based allograft. Additionally, our improved cash flow has allowed us to make a total of $20 million in debt payments ahead of their scheduled maturities so far this year, including a $5 million payment this month. Based on our results for the first half of 2009 we are reaffirming our full year guidance."

While there is no discernible swagger among Orthofix's managers, there is gritty determination. This team has been through the valley of the shadow and emerged stronger than perhaps

President and CEO Alan Milinazzo

even they expected. From where we sit, and after more than 25 years analyzing companies, we recognize this pattern. We see a wealth-producing engine in the making. The future for Orthofix is so bright right now that both managers and shareholders will need sunglasses.

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1. Data on file at DePuy Orthopaedics, Inc.
2. Orthopaedic Research Society, 2007, P1784.

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Alone in the Woods? Rural Orthopedics

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

Mountain blizzards, the lack of available beds, and declining skill sets…all are issues for orthopedists who work in rural areas. And while these surgeons are masters at getting what they need to treat patients, sometimes things go awry.

Taos, New Mexico

Dr. James Lubowitz, Founder of the Taos Orthpaedic Institute and a team doctor for the U.S. Ski and Snowboard Team, wants to make orthopedic treatment in rural areas easier on his patients. "Fifteen years ago I left 'the city' and moved to Taos, New Mexico. One of the first obvious differences between the two areas was in the transportation realm. Because a typical patient was driving two to three hours—even to remove stitches or get a new drug recommendation—one of my first steps was to establish satellite clinics throughout the area. It only seemed fair that if they were going to do all that driving, then we could get in the car once a month and drive two hours to a clinic."

Dr. Lubowitz advocates for no excuses. "It is my philosophy that regardless of whether someone is being treated in an urban or rural setting, that person should receive the same standard of care. You may not have as many resources in 'the country,' but dedicated orthopedists will do their best to get the appropriate care for their patients. For example, we don't have an M.D. anesthesiologist at my hospital; instead, we use the services of well trained RN anesthetists. But, we have to consider the possibility that the sickest patients may be better served by an M.D. anesthesiologist. If someone comes in with severe problems, we transfer or refer the patient to a center with a higher level of care."

Because you can't see an X-ray through the phone (although this is rapidly changing in our electronic age), Dr. Lubowitz and colleagues must sometimes rely on long distance specialists for input. "We have no pulmonologists or intensivists and often must consult these individuals via telephone. There are also no traumatologists here, but even in urban centers you may not have an orthopedic traumatologist at every single hospital."

The orthopedic juggling act involved in caring for rural patients may remind some of a Hollywood film… except it's planes, ambulances, and

helicopters. Dr. Lubowitz explains, "Albuquerque is about 2.5 hours away. If the hospital there—the University of New Mexico—says they have no available resources, then we've got to get the patient in an ambulance, on an airplane or in a helicopter for the trip to Denver. While the University of New Mexico is usually happy to help us out, they may have no available beds. In fact, my understanding from several parties is that they may also not have enough nurses. We are fortunate that two years ago a couple of the hospitals in Denver stepped up and said, 'We are never closed.' But it's a real nail biter in the winter when we have huge snowstorms. In those instances the planes can't fly, and we just stabilize the patients and treat them to the best of our ability."

So they work with what they have. "While there are certain things that all orthopedists should be able to do," says Dr. Lubowitz, "there are many complex fractures (acetabular, for example) that only a few specialists can do. And it's not just the surgeon's ability, but having a team with experience, as well as the right equipment, that makes the difference. Fortunately most fractures can wait 24/48 hours to be treated, i.e., until the snowstorm clears."

Even when the skies are clear, however, the logistics of transporting patients are anything but simple. "Taos Hospital has a helipad, but sometimes for reasons of safety or availability, fixed wing planes are preferred. Then, we start by putting the patient in an ambulance and taking him or her to the Taos airport, where they are moved onto a helicopter or fixed wing plane that has come in from Colorado. If it's a fixed wing plane, however, they can't land at the medical center in Denver, so another ambulance has to meet them at the airport in Colorado. All of this can cost more than $10,000."

With these extra difficulties, how to do you attract and retain talent? Market forces and call schedules are big parts of the equation. "You don't want too many orthopedists because then they can't make a reasonable living. If there are only 60,000 people (or 6,000) instead of millions, you may not have enough elective surgery to build a practice. And if they're going to be asked to be on call every night, that's not a real draw. If someone is in a large urban hospital and all the orthopedists are taking call one night a month then that is very manageable. But if you're in a small town where there is only enough elective work for one or two orthopedists can you reasonably ask someone to be on call 15 or 30 nights out of the month? I did it when I first graduated from residency and was 30 years old. Fifteen years later, however, I'm older, busier, and need more sleep—not to mention that I'm further in time away from residency where I did a lot of trauma."

But Dr. Lubowitz has developed a model that works. "We have been successful in bringing in partners and fellows who help with call while they train in sports medicine. The fact that Taos is a destination resort makes this possible. We use our four satellite clinics to increase the volume of elective surgery in sports medicine so that we can have enough work to attract doctors to cover the ER."

Detailing the behind the scenes struggle to cover all the specialties in a rural area, Dr. Lubowtiz says, "When I first moved to Taos 15 years ago as a fellowship trained surgeon there was one other orthopedist and he wasn't very busy. I did general orthopedics, along with my specialty, sports medicine. However, a sophisticated patient didn't want to see me for a hip replacement because there was a guy in Albuquerque whose entire focus was hip. I did my best and achieved good outcomes, but, as is always the case with being a jack of all trades, the volume is not very high…and the more volume the better the outcomes."

"I realized," states Dr. Lubowitz, "that not only did I like ACL reconstruction more than bunion work, but that my ACL results were better than my bunion results. An increasing number of patients came to me as they began to realize that I was a specialist. Over the years, I restricted my elective practice to knee surgery, and just this year I stopped doing total knee replacement surgery and now only do knee arthroscopy and ligament reconstruction. Other doctors on the hospital staff, such as those in primary care and emergency medicine, are frustrated because our community needs a foot and ankle specialist; they think that if I'm an orthopedic surgeon then that should be good enough. However, my opinion is that best outcomes for patients are the primary priority, and if the community requires and can support a foot and ankle subspecialist, we should recruit such an individual."

"I have brought in a partner who does upper extremity work, along with basic hand surgery," adds Dr. Lubowitz. "We must refer complex hand problems to Santa Fe, however,

meaning that the hospital loses these economically productive cases. There is not much to be done, however, if there is not enough work to support a full time foot and hand specialist. And if you have only generalists in rural areas then the outcomes won't be as good. There is also a real risk of creating two standards of care, with moneyed patients traveling out of town to larger centers and those without means having no choice but to see a generalist. The 'least best' option is to say, 'I'm sorry, but we don't provide these services.'"

When asked why the average urban/suburban orthopedist should care about rural orthopedics, Dr. Lubowitz says, "Rural orthopedists need to rely on their colleagues in larger centers to help them take care of problems outside the scope of their practice or comfort level. By and large, if a hand specialist in an urban setting is consulted by a rural orthopedist about a hand patient, he or she is very appreciative because it may increase business. Sorting out the issues in rural orthopedics can also benefit our urban colleagues by preventing patient 'dumping.' Overworked city orthopedists who are approached to help rural colleagues may say, 'Why can't you do it yourself?' The upshot is that rural surgeons often don't feel supported, while urban surgeons feel dumped on. The federal Emergency Medical Treatment and Active Labor Act (EMTALA), the law that regulates patient transfers, contains anti dumping provisions. But of course it doesn't address misunderstandings and poor communication between orthopedists."

Shining further light on the back-and-forth that goes on between urban and rural orthopedists, Dr. Lubowitz says, "We sometimes feel that when we send a trauma patient to Albuquerque they feel dumped on. But the urban orthopedists may not be aware of the denominator…they're paying attention to how many patients we ***transfer*** not how many we ***keep***. For example, a patient had fractures of both femurs—major trauma. It wasn't that the orthopedists in Taos couldn't put rods down the femurs, but this is a much sicker patient who requires a bigger team and greater resources. However, the 'receiving' doctor in Albuquerque might not appreciate that while we're sending them ***that*** patient we're keeping people with unilateral femoral fractures, hand fractures, and hip fractures. Unfortunately, I think there is tendency for our urban colleagues to think, 'They're being lazy. They should be doing this.' But, alas, it is human nature to remember the one time someone did something that frustrated you—even if it was three or four years ago—and not remember the other 364 days that they didn't need your help."

Ontario, Canada

A primary concern for Dr. Mohit Bhandari, the Research Chair in Musculoskeletal Trauma at McMaster

University in Canada, is the issue of skill drop-off in rural areas. "Those individuals who choose to work in rural settings will likely find that the communities can't sustain them; so, they lose their skills. Then they will get to a point where they start referring patients because they haven't seen xyz problem in three years. The well-regarded epidemiologist, Ellen McKenzie, Ph.D., has done research involving large hospital database registries in which she asks, 'Does the number of patients seen in a given hospital affect the outcomes?' She has found that in fact the more patients seen, the better the outcomes you have, meaning that in general, rural areas suffer."

Using technology to link orthopedists is especially important in more remote areas. Dr. Bhandari: "At McMaster we are increasingly trying to give rural orthopedic surgeons access to experts via telemedicine. We have also found it helpful to build ties with tertiary care referral centers. That way, X-rays are easily sent to specialists on call."

Dr. Bhandari: "McMaster, encouraged (and pressured) by outlying populations, came to realize that there was an increasingly urgent need for rural healthcare. Thus, the university created a medical school in the extreme north of Canada…one that only accepts individuals from the north. It has been a raging success."

Trauma patients rolling into an urban ER can be relatively confident that the hospital will have the resources to treat them. Dr. Bhandari discovered firsthand how untrue this is for rural areas. "Twelve years ago I was teaching in a town of 500 whose hospital had an ER department that was lacking in staff. I was doing a talk on the resuscitation of trauma patients when the ER coordinator approached me and said, 'We could use your help right now.'"

"Along with the audience, I ran out and found a patient who had been hit by a car and had multisystem trauma. There were three or four family physicians on hand but no surgeons—most everyone was frozen with fear. I had no privileges at the hospital but was granted immediate permission because the patient would have died had a surgeon not stepped in. In five minutes, the patient went from being on his deathbed to having a chance for survival. It's very frightening, but this can happen anywhere. Since then, every time I've been more than 100 miles from a major city I think, 'Boy, if I'm in a serious accident, I just may not make it.' The randomness of it all was quite an awakening."

Educated as to the significance of certain kinds of training, Dr. Bhandari says, "In extremely remote areas, orthopedics is handled by family physicians or technicians. These are people accustomed to seeing tumors, something that is not going to kill anyone in five minutes. What we need is a certificate program for training healthcare professionals on resuscitation. The bottom line is that the volume of patients is low. One orthopedist actually told me, 'I can't remember the last time I saw a multisystem trauma.'"

"The reality," says a philosophical Dr. Bhandari, "is that in many countries rural populations make up the majority of the population. The specialized needs and infrastructure of these areas deserve our attention."

Central Louisiana

Dr. Steven Kautz, an L.A. orthopedist who chose "the other" LA—Louisiana—speaks firsthand of being, well, alone in the woods. "Several

years ago I left the hectic pace of Los Angles behind and accepted a staff position at Natchitoches Regional Medical Center in central Louisiana. While the relaxed lifestyle is definitely an improvement, having a solo practice in a rural area is head spinning at times. With regard to call, the hospital staff knows that if I am in town they can call me and I will come."

And that is much more available than many orthopedists want to be. Dr. Kautz: "For some people such work is not attractive because you have to be available most of the time. I do have exceptional support, however, as my colleagues in the ER know how to do most of the initial treatment and workups. Unfortunately I have no resources along the lines of plastic surgeons or vascular surgeons. If we get any pelvic trauma or life threatening injuries, our general surgeons are not going to care for these patients. We send them to Louisiana State University. The good news is that we have a helicopter pad."

Exemplifying the flexibility required of rural orthopedists, Dr. Kautz notes, "I have had patients who required plastic surgeons to do soft tissue coverage work. I sent one patient to Texas and on another occasion I tried to send the person to a doctor in Baton Rouge, but the hospital couldn't guarantee me a bed for five days. As fate would have it, the majority of plastic surgeons in the area are now doing non trauma (beautification) plastic surgery."

So what's unusual and superb about practicing in a rural area? "When I had a patient tell me that rubbing pig fat on a wound would prevent an infection, I was a bit skeptical. Oddly, it seemed to work. As for lifestyle, there is no orthopedic ivory tower. You should know that you're going to run into your patients at the grocery store. Ideally, you would welcome such a sense of community. On one occasion my aunt was visiting from Los Angeles, and when we went to Walmart, a patient of mine approached me excitedly and told my aunt how happy she was with her operation and that her scar was barely visible. Such intimacy is not the norm for city people…like my aunt."

As it's unlikely that spine specialists or shoulder savants will soon be flocking to the far corners of Arizona or the mountaintops of Georgia, it is important to bring creative thinking to play in addressing the orthopedic needs of rural populations. Dr. Urban, Dr. Rural…conference anyone?

Surgeon in the Crosshairs – Part 2

By Walter Eisner

In part one of "Surgeon in the Crosshairs," David Polly, M.D., Chief of Spine Surgery at the University of Minnesota, talked to OTW readers about his experience as an industry consultant and the role of surgeons in an increasingly complicated relationship with industry and universities.

David Polly, M.D.

It was one of the most refreshing conversations we've had with a leading spine surgeon on the topic. The discussion shed light on an issue that goes to the heart of collaboration and innovation in orthopedics. Dr. Polly's experience of media and political scrutiny offered lessons for his colleagues and led us to seek out guidelines for physicians looking to enter into collaborations with industry and academia.

In this week's part two of "Surgeon in the Crosshairs," Dr. Polly continues his discussion with *OTW* and describes the pitfalls of disclosure in light of his congressional testimony on behalf of the American Academy of Orthopaedic Surgeons (AAOS). Finally, industry attorney Mark DuVal offers his "Polly-Approved" checklist for physicians to use in taking charge of their own compliance management.

Public Disclosures

Last week we outlined how Senator Chuck Grassley's release of detailed billing records of Dr. Polly's work as a Medtronic consultant thrust Polly into the public spotlight. There were no allegations of improper payments, no charges of undue industry influence on clinical studies, or any accusations that patients did not receive the best care.

There was, however, one criticism of Dr. Polly's actions as an industry consultant the he admits was valid.

In May 2006, Dr. Polly testified on behalf of AAOS in front of a congressional committee. He was urging Congress to fund orthopedic research for soldiers. He didn't tell the committee that Medtronic had paid his expenses for the trip.

We asked him about the disclosure oversight.

"Yeah...if I had that to do over again, I would do it differently," said Polly.

"I can't tell you the specifics behind it. What I can tell you is that anytime I've had a disclosure form on which I had the opportunity to disclose that I have a consulting relationship with Medtronic, I've done that.

"In the testimony before Congress, people were typically saying I'm representing, you know, breast cancer, prostate cancer, etc. So that's how that played through.

"There was no intent to mislead or deceive, but there is a perception that full transparency wasn't achieved.

"So I accept that criticism and that's appropriate. The fix, I think, is to provide disclosure sheets to people testifying before Congress and allow them to, beforehand, provide appropriate disclosures.

"I am delighted to comply with that anytime or anyplace. Anytime I am given a disclosure statement, my

tendency is to over disclose. I'm still disclosing that I received Department of Defense research support that finished about a year ago.

"I think that the best way for people to get what they want is to ask for it.

"It never occurred to me in the limited testimony time to [disclose the Medtronic connection]. Perhaps I should have, I don't know. But if I am asked in any format to disclose who I get paid by, it's easy: the University of Minnesota, consultant for Medtronic, U.S. Army retiree, Department of Defense research support, and whatever else is appropriate."

The fact that an experienced professor like Dr. Polly was caught off-guard about disclosure speaks volumes for the need for clear and widely accepted guidelines for physicians to follow when they enter into a relationship with industry and universities.

Times Have Changed

"Times have changed. Get over it," said Mark DuVal in interviews with OTW. DuVal is President of DuVal & Associates, a Twin Cities law firm specializing in FDA and regulatory issues.

We asked DuVal: What can physicians do to protect themselves before they get into industry/university relationships?

Most importantly, DuVal said, always ask yourself: Have your financial relationships compromised or biased your [medical] decisions and the care of your patient?

Mark DuVal

And then, look out for yourself and take charge of your own compliance management.

"Make your own personal compliance your objective. Don't rely on your institution or the company with whom you've worked to protect you if times get tough—they may be loyal, they may not be. It depends on how bad the publicity is and the pressure gets." – Mark DuVal.

He offered up the following guidelines. After reviewing the list, Dr. Polly called them "spot-on." (Bolded headings are our.)

1. Consider Adverse Publicity

Begin your consulting relationship with potential adverse publicity in mind. Ask yourself, how would my relationship look if it were on the front page of the newspaper or on the nightly news? Are you viewed as a product evangelist or prostitute for one company or product? It's acceptable to be an enthusiastic user/prescriber, but try to maintain some sense of balance.

2. Documentation and "Fair Market Value"

Document your relationship with the Company—the agreement must be in writing to qualify for protection from government prosecution under the Personal Services Safe Harbor to the Anti-kickback Statute. Also document all that you bill a company with detail—the matter, time spent, work performed, and mention names of people with whom you've dealt and/or products on which you've worked. Would the rate you are being paid meet an outsider's view of "fair market value" or is it a reflection of your ego?

3. Go Beyond Disclosure Requirements

Be scrupulous about meeting your institution's guidelines—go above and beyond disclosure requirements if necessary. The more you can demonstrate transparency and openness, the better off and less subject to criticism you'll be. Consider disclosing all the money and other remuneration (stock, stock options) you receive and making your time sheets available to your institution even if it does not require them to be disclosed. Remember to disclose on other occasions as well, such as in a journal article or speaking in front of a professional audience. Many organizations have disclosure guidelines and, if they don't, disclose anyway.

4. Independent Perspective

Use a third party (friend, mentor, colleague, institutional ethics officer) as a sounding board for your financial relationships. They don't need to have veto power, but they should be able to provide an independent perspective. It will make you think of things you might do along the way to protect your reputation.

5. Don't Get Greedy

Don't be greedy or too attached to one company. Be wary of doing business with companies that seem overly desperate for your assistance and sales of their product to you, your practice and/or any affiliated institutions. You are entitled to be paid for your time, but make sure that the time you bill does not appear to deprive your employer of your services during a work day. Also, be careful when the cumulative hours billed in a day seem to be more than a normal human can bill in a day. Ensure that you do not appear to bill for every conceivable second and/or overbill for time spent on tasks that could be done in far less time than you've billed.

6. Know Existing Standards

Know the AdvaMed Code of Ethics, PhRMA Code, and the company's guidelines on interactions with healthcare professionals so you know the rules. Also abide by the AMA Code and your medical specialty society's rules if you are a member.

7. Take Charge of Compliance

Don't rely on your institution or the company with whom you've worked to protect you if times get tough—they may be loyal, they may not be. It depends on how bad the publicity is and the pressure gets. Make your own personal compliance your objective.

8. Times Have Changed

Remember that the world has changed—it's no longer how it used to be. Get over it.

9. Know the Risks

You are entitled to be paid for all the time you legitimately work. Don't be an apologist for it, but view the public's perspective independently of your freedom to work and to be paid at fair market value. You may decide to take the risk of criticism, but do it knowingly and protecting yourself the best you can.

10. Know Your Biases

Most importantly, ask yourself always: Have my financial relationships compromised or biased my [medical] decisions and the care of my patient?

Finally, we asked DuVal how physicians can protect themselves if their industry client gets in the crosshairs of the media or government.

DuVal suggested that in addition to following the guidelines above, physicians should ensure that they've had an open and honest dialog with the company about the boundaries of their relationship and how that relationship might be perceived by the public. He also suggests that physicians keep a written record, like emails, of those conversations.

We wondered what Medtronic thought of these recommendations.

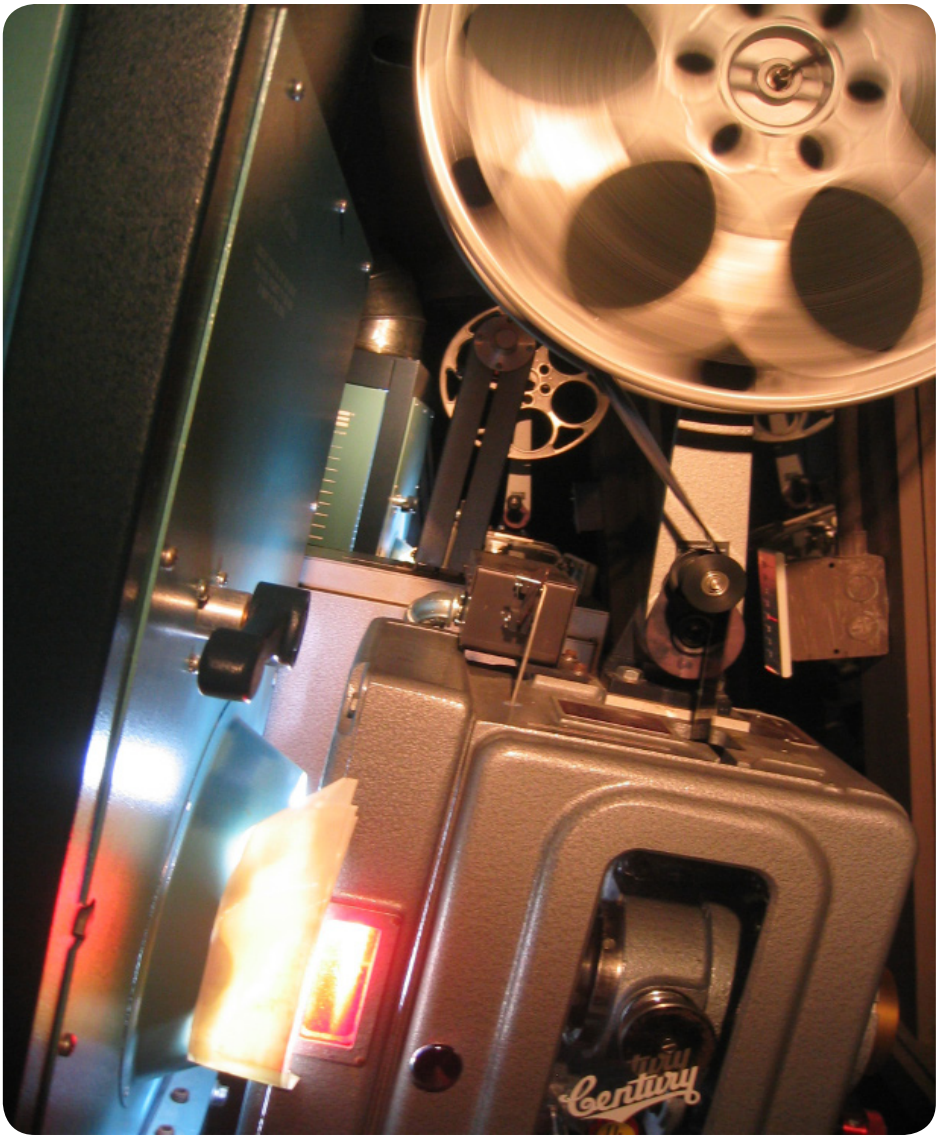
Marybeth Thorsgaard, a Medtronic spokesperson, told us: "Our intent in the coming weeks is to announce a new standard for clarity and transparency in these relationships that will build on our previous work in crafting the AdvaMed Code of Ethics and our strong support for the Physician Payments Sunshine Act, currently pending in Congress."

Getting into the crosshairs of public scrutiny is a price physicians now have to pay if they want to collaborate with industry and universities to develop innovative new devices for patients. As Dr. Polly pointed out in part one of this two-part story, the price of compliance may not be worth it for a university physician, and industry may find itself dealing with more physicians in private practice in the future.

Hopefully Dr. Polly's experience and candid discussion about the future of these collaborative relationships, along with Mark DuVal's guidelines, will offer physicians a framework to take charge of their own compliance management.

New Film Educates Spine Patients

By Daniel Knowlton



Orthopedists are well aware of the various causes of and treatments for spinal problems, but what about their patients? When severe back pain hits, it can often mean the start of a long and confusing path toward recovery. Some patients find their active lifestyles reduced to a constant focus on pain management, and in the midst of this life-changing struggle, finding the right doctor and the right treatment can be a daunting task.

Fortunately, these are just the sort of people who stepped up to help educate other patients in Richard Longland's new film, Getting Back on Their Feet. The film is the first of its kind in the world of spinal arthroplasty, and who better to put this project together than someone who intimately knows the struggles of living through spine surgery.

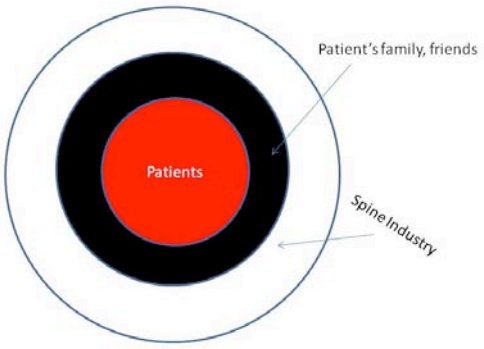
"I was inspired to make this film because I was a patient myself," explains Longland. "Even though the Internet provides a wealth of information at our fingertips, I had to do a lot of research. When I say research, as a layman, I mean I had to spend hours and hours online, and I complemented that by reaching out to patients through discussion boards, by e-mail and eventually by phone. And it struck me then, and unfortunately now, that patients must look in so many places to put the pieces of the puzzle together. So there's a tremendous amount of information in the film as it attempts to organize all the information that patients need and put it in a logical presentation that is easy to watch."

Through candid interviews, Getting Back on Their Feet follows seven spine patients from their initial realization of their spine problems through diagnosis, surgery, recovery, and all the important research and decisions that happen in between. When spine problems caught up to Ken, a police officer and active athlete, it felt like "taking a race car and putting it up on blocks." He tells the camera, "I was miserable being me," while he describes how pain management became his daily routine. Jim, another patient in the film, says, "My kids joke about it now, but I was always on the floor…and that's where they remember me being for a large portion of my life." Eileen also points out the difficulty of helping friends and

co-workers understand the problem: "people don't necessarily understand pain unless they see blood and guts."

Starting with these difficult realizations and life changes, the patients recall their paths to recovery in an effort to educate future patients about spine surgery. Most of the people in the film decided to undergo artificial disc replacement (ADR), a procedure approved by the FDA in October 2004 for the lumbar region of the spine. Although most of the interviewees preferred ADR over spinal fusion procedures, the film is careful to point out the risks and potential complications of ADR, and one patient urges viewers to exhaust all pain management options before considering surgery. Thus, the end result is an objective, 75-minute, high definition film which feels like the visual equivalent of a "how to" manual for recovering from spine problems. A DVD copy of the film can be obtained through a suggested donation to Richard's Arthroplasty Patient Foundation of $50 for ADRSupport patients, and slightly more for doctors and organizations.

Longland describes his intended audience for the film in terms of a target: "at the very center, it would be spine patients who are considering spinal surgery of some kind. The next circle from the bull's-eye would be loved ones, family members and

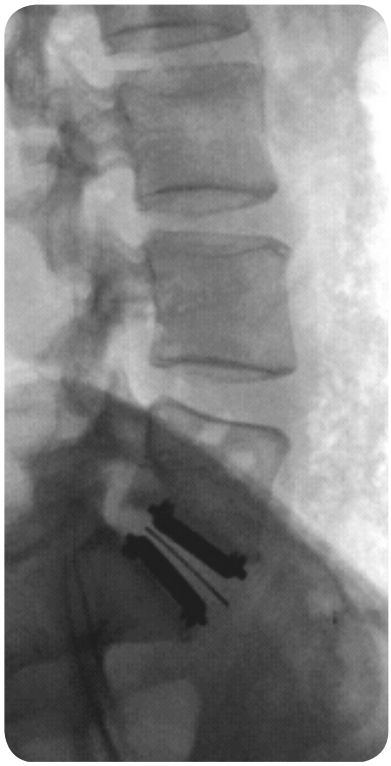


friends. And the last circle would be people in the spine industry, whether it's medical professionals or people who read orthopedic publications."

The Making of the Film

But how did one ADR surgery patient with no background in film put together this comprehensive documentary? "Everything started with surgery on June 24th, 2004, over five years ago," says Longland, when he underwent a single-level (L5-S1) ADR surgery. "When I was recovering, I felt great, and I decided to use that energy to launch a website: ADRSupport. But it wasn't until 2006 that I realized my obligation and clear path to do more to help spine patients. I looked at how patients were struggling to get reliable information to support their decision making while battling insurance, getting a diagnosis, managing pain, and researching new spine treatments like disc replacement. I decided the best thing to do was to start a nonprofit organization. That way, I knew I could offer the transparency of providing all the financial reports online, while aspiring to lead a credible, helpful, and patient-centered organization."

Longland applied for nonprofit status in 2006 and received his 501(c)(3) approval in 2007 for The Arthroplasty Patient Foundation. Today, the foundation's "seed organization," ADRSupport, has grown into an online community that brings together people of all walks of life from over 70 countries. And it's not solely for ordinary patients; doctors, radiologists, dentists and researchers have all contributed as members in the community.



X-Ray image of Richard Longland's spine post-surgery with artificial disc in place at L5-S1

However, in addition to this online support forum, Longland sensed that film would be a great medium for delivering information to spine patients and decided to make the documentary at the same time he applied for nonprofit status. "Patient selection was a big part of this," explains Richard. "Initially when I announced my intention to do this film, way back in 2006, I got some enthusiastic responses from the member community at ADRSupport, and I narrowed down the candidates to 12 people."

Unfortunately, that entire list of 12 patients didn't make it into the final version of the film. "I wanted to include patients that did not have good outcomes as well, and it was awkward for me to think about interviewing people who were still suffering greatly," says Richard. "But they wanted to help the cause and contribute to the overall educational aspects of the film. One patient had to cancel. I think his pain was just too severe." Other cancellations followed

for fear that insurance companies would ask for patients' money back if insurance executives saw the film. Despite these setbacks, Richard still found a group of interviewees who were able see the project through to the end.

He also had the help of one amazing partner. "There is no way that I could have accomplished this feat without Moki Goyal," says Longland. "I actually worked with him many years ago at an Internet firm when he was a web developer and programmer. Then Moki moved to New York and worked at a video production company while attending graduate school in video production. In 2004, he helped me launch ADRSupport and its online community, now a global family of thoughtful and supportive spine patients. I found Moki easy to work with and extraordinarily talented. So when I told him about the film opportunity, he was happy to help the cause while furthering his technical skills in HD production."

Richard Longland returning to his active lifestyle post-surgery.

Richard then took a kind of crash course in video production through making the film. He learned technical aspects of video production, including camera and audio setup and proper framing of his subjects. "I really wanted to shoot in high-definition for maximum picture quality. What I realized is that in HD, things such as focus and lighting are much more critical than in standard definition production."

Candid Stories and Useful Advice

Besides the technical challenges inherent in filmmaking, Richard also learned about how the medium of film can change the expected content. "I actually used the same script for each patient interview," he explains. "But as you can see from the film, there are a lot of different kinds of thoughtful responses. When you're face to face you'll hear more details that you won't learn about anywhere else. There's a level of intimacy there that enables that kind of honest candor that is raw, unexpected but usually of interest and utility to other spine patients."

For example, another interviewee named Jim gives his own scale for measuring progress during post-op recovery. It isn't the normal bit of advice you might hear in a book or from a doctor, but it's a useful way for patients to imagine and work through the healing process. "When you're in the bathroom," says Jim, "there are so many things that happen that you need to do with your body, such as washing your hands, shaving your face, getting in and out of the shower, putting on your pants without a grabber or without somebody helping you, putting on your socks. These are the things to watch to determine what your rate of progress is. Forget about the numbers and forget about everything that everybody talks about. What you can do in the bathroom tells you how much better you're getting."

In order to get this sort of candid advice for patients, Richard had to continually improve his interviewing skills. "You have to ask the right question," he says, "and sometimes ask the same question in several different ways in order to glean information that maybe the patient hasn't even thought about. One of those things I focused on was how much responsibility the patient placed on themselves to research and get information as compared to a more traditional patient role of relying completely on the doctor for everything. That's a really interesting 'thread' that I looked for in the interviews, and you'll see subtle differences in how empowered patients allow themselves to be."

Projects on the Horizon

Longland believes that his film and his nonprofit organization can encourage patients to empower themselves with research and decision-making. "Many spine patients are literally at the end of their rope, and they're thinking 'just fix me, just fix me.' They're thinking very mechanically, and that's not always good, because they might not do the due diligence on their potential contra-indications. This is potentially a tricky issue. For example, if the patient presents with a long list of health complaints and defers solely to an orthopedic surgeon, the "surgeon-patient" team may not have the expertise to address all the cause(s) of chronic pain afflicting the patient. This is not a finger-pointing exercise; it is simply recognizing the terrible complexities now facing the modern spine patient."

Richard's commitment to educating patients like himself is one of the main reasons why he wants to continue making films. "Any issues in spine are inherently complex," he says. "Film is a great format to crunch down, distill and convey information into one place in a fairly balanced manner that will help other patients. Many spine patients do much better after surgery, compared to their pre-op pain levels, but there's still a tremendous amount of research and support that is needed to help these spine patients even after surgery. This is the challenge that fueled the formation of our foundation mission statement. We try to help people get back on their feet by providing surgical information and naturopathic information. We keep a close eye on some of the biological discoveries as well. It takes more than one tool in the tool bag, as patients and doctors know."

Among the interviewees in Getting Back on Their Feet, "one common thread is insurance and the cost of these surgeries being a nightmare for almost everybody," says Richard. "And it hasn't improved much, unfortunately. The thing I really wanted to delve into was the contra-indications for surgery because several patients interviewed (though it's not discussed explicitly) had arthritis and autoimmune conditions not comfortably dealt with between doctors and patients. I'd like to do another whole video on that topic."

Richard Longland plans to continue bringing patients together and helping them to share their stories. As for the patients in *Getting Back on Their Feet,* the film does have a happy ending. Jim's wife tells the camera, "he's wiser, he has survived a nightmare, and now he can help others. Our sons are seeing a whole new guy…kids are very forgiving, and they can forget that this person who just laid on the floor is now this interesting, thriving human being who has a new lease on life." And as for Jim, he's not looking back.

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DePuy's Pinnacle Recommended for Approval

DePuy's new ceramic-on-metal is safe and effective.

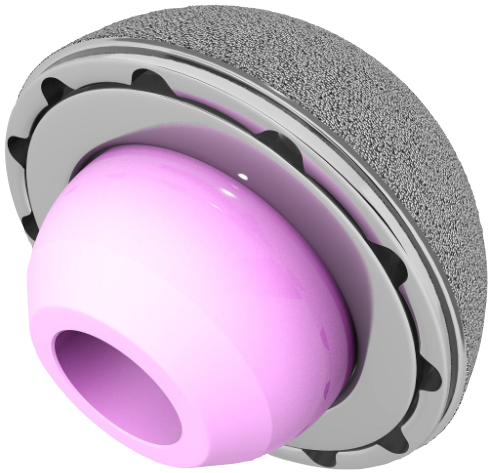
That's the unanimous conclusion reached by the FDA's Orthopaedic and Rehabilitation Devices Advisory Committee on August 18.

The panel voted 5-0 to recommend approval for DePuy's Pinnacle CoMplete Acetabular Hip System, the first ceramic-on-metal (COM) hip bearing to be considered for approval in the United States. This is the first time ceramic and metal bearing surfaces were combined in a hip replacement system in the United States, which requires FDA approval.

"If [ultimately] approved by the FDA, the Pinnacle CoMplete System would represent an important innovation for hip replacement in the United States," said Pamela Plouhar, Ph.D., Vice President, Worldwide Clinical Affairs, DePuy Orthopaedics. Unanimous recommendations from the advisory panel are rarely, if ever, ignored by the FDA.

The Pinnacle would be used in adult patients who suffer from severe pain and disability due to osteoarthritis or post-traumatic arthritis. Conditions for approval recommended by the panel include refinements to the proposed product labeling and a 10-year post-approval study.

There was only one meaningful point of discussion with FDA reviewers in DePuy's approval application.



Pinnacle CoMplete Acetabular Hip System

DePuy had hoped to show that COM would produce fewer metal ions than produced by metal-on-metal (MOM). There are concerns that ion accumulation may cause autoimmune reactions or other health problems over the long term.

DePuy's Pinnacle would presumably allow a decrease in wear induced osteolysis and failure and allow use in younger, more active patients. This benefit would allow extension of use of this bearing surface for those patients restricted from using a MOM bearing surface (women of child-bearing age, patients with renal failure or other kidney problems, etc.).

However, based upon the metal ion analysis, there was no statistical difference in the metal ion release between the COM group and the MOM groups. The FDA reviewers said the Pinnacle did work as well as a MOM hip in a company study that measured pain, functioning and complications after the implant.

The company said laboratory testing on the Pinnacle showed a greater than 90% reduction in wear compared to the MOM system under normal gait conditions and a more than 80% reduction in wear under adverse conditions.

—WE (August 18, 2009)

FDA Panel Nixes Durolane

One day after saying "yes" to DePuy's hip, the FDA Ortho Panel said "no" on August 19 to Q-Med AB/Smith & Nephew's Durolane knee injection.

Panel members were convinced that Q-Med's studies had not proven Durolane to be effective. The panel then voted 6-1 to not recommend approval of the product by the FDA.

Source: Wikipedia Commons

Smith & Nephew immediately put out a statement after the vote stating: "The FDA Advisory Committee did not recommend Durolane for immediate approval, requesting further information as part of the Premarket Approval (PMA) process for the product. Smith & Nephew plans to work with Q-Med and the FDA to provide the data required."

Q-Med's Durolane, to be distributed by Smith & Nephew, is a single injection

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hyaluronic acid (HA). The company says Durolane is currently sold in 32 countries and has been used to treat the symptoms of osteoarthritis (OA) in more than 350,000 patients worldwide.

Q-Med CEO and Founder Bengt Agerup said the company would continue to work to provide satisfactory clinical evidence for Durolane. "We remain committed to our goal of providing U.S. physicians and patients access to a non-animal single injection product."

Smith & Nephew currently distributes Supartz in the United States. Supartz reportedly requires three or five injections with pain relief lasting three months and six months respectively.

Wells Fargo senior analyst Mike Matson wrote on August 19 that he believes that Smith & Nephew has been losing market share to Genzyme's Synvisc-One in the United States. Requiring only one injection for six months, Synvisc-One was approved by the FDA this past February.

Matson describes Q-Med's "data gymnastics."

First, the company compared Durolane to saline at six months. Not finding statistically meaningful results, they ran another trial at six weeks. Again nothing meaningful.

The company then ran a subgroup analysis and excluded certain patients and identified a statistically significant difference. After checking with the FDA, the company ran another trial with the patient population identified in the subgroup. Those patients compared Durolane to the corticosteroid methylprednisolone at 12 weeks. Here the trial showed Durolane to be non-inferior to methylprednisolone and superior to the saline groups in the previous trials.

If the FDA follows the advice of their panel (they almost always do), the winner in all this may be Zimmer.

Matson noted that Zimmer has announced an exclusive ten year distribution agreement with Seikagaku for its single-injection HA product. Seikagaku submitted a PMA application for approval of its product about a year ago. Matson says Zimmer expects approval of the product later this year or early 2010.

It looks as if we'll be hearing more about Durolane and the FDA in the near future.

—WE (August 20, 2009)

Dr. Schultz Quits FDA

Daniel Schultz, M.D., has resigned after 15 years at the FDA.

Dr. Schultz was the head of the FDA's Center for Devices and Radiological Health. Getting one's medical device approved meant going through him.

On August 18 it was announced that Dr. Schultz was resigning

Daniel Schultz, M.D.

immediately by "mutual agreement" with the FDA Commissioner, Margaret Hamburg, M.D.

An FDA spokesman reportedly said Schultz's decision came as the result of talks with the Commissioner and had nothing to do with any specific issue related to a device's approval process. In a letter to agency staffers obtained by the AP, Dr. Schultz said he and the Commissioner agreed his resignation "would be in the best interest of the center and the agency."

Reaction

"A small piece of good news," is how the Project on Government Oversight described the event. The group says improper influence by manufacturers and from Congress continues to undermine the FDA's independence.

On the other hand, AdvaMed credited him with securing stable FDA funding through industry user fees.

Dr. Schultz may be the first to fall on the sword for an agency that has been at war internally between scientists and agency leaders.

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Scientists within the agency have charged that its leaders were ignoring their scientific and medical advice in favoring speed over safety. They said industry had an undue influence in that policy.

"[T]hey've been embarrassed," Morningstar analyst Debbie Wang told Reuters. "[W]hether there's truth behind it or not, there certainly is the perception that some things happened on his watch that were negative. ... You're going to have to reach a higher bar [now] in order to get approval."

Two years ago Senator Grassley held hearings on the approval of a nerve stimulation device.

Orthopedics

Recently a ReGen Biologics knee device, approved through the 510(k) clearance process by Dr. Schultz, caused the political infighting and policy debate to spill over into orthopedics.

Dr. Schultz gave his approval for clearance for the device after the FDA's Orthopaedic and Radiological Panel told him they considered the device "effective" with some hesitation. Schultz's approval caused the chair of the panel to publicly question the integrity of the FDA approval process.

The agency recently announced it was reviewing its approval procedure for that device. Will the FDA take a closer look at other medical devices approved during his five year tenure as Director of the Center?

Politics and Policy

There is a much larger story to tell here about politics and policy debates within the FDA, including a debate over the effectiveness of the 510(k) process.

In the meantime Dr. Schultz presided over an unprecedented era of scientific growth. There is a tension between getting a safe and effective product out to the market in a timely manner and waiting for another piece of evidence to assure its safety. That's a fair and honest debate. Dr. Schultz was a symbol of that debate and the new leadership at the FDA is now making its mark.

The Commissioner had something nice to say about Dr. Schultz. In a prepared statement, she said he left a strong legacy and helped the division enhance understanding of medical-device use in children.

Some of the first policy reviews, such as the review of the knee device, are working their way through the agency. Watching their outcome may tell industry leaders something about a new era at the FDA.

—WE (August 20, 2009)

Kuklo Resigns From Wash U

Former Army surgeon Tim Kuklo, M.D., is resigning from Washington University and putting his house up for sale.

According to *The New York Times*, a spokesperson for the University said in an email message on August 18, "Dr. Kuklo has agreed to voluntarily resign from the university, effective September 30, 2009. Dr. Kuklo will have no clinical, research, or educational duties for the University between now and that date."


Dr. Timothy R. Kuklo

legal & regulatory

Dr. Kuklo tendered his resignation on July 30, according to University officials who declined further comment.

Dr. Kuklo took a teaching position at Washington University after he left the Walter Reed Medical Center in August 2006. He was also working as a consultant to Medtronic at the time.

A story in the *St. Louis Business Journal* on August 20, stated that Washington University said Dr. Kuklo didn't disclose his relationship with Medtronic until May 2007. At that time, the school's Disclosure Review Committee reviewed two previously approved research projects involving a Medtronic product and determined there was a conflict of interest.

The University said Dr. Kuklo subsequently discontinued his involvement with that research, and the studies were closed in February 2008.

House for Sale

The St. Louis Block Shopper, published a story on August 13 saying, "Dr. Timothy R. Kuklo and his wife, Linda, have listed for sale a four-bedroom, five-bath home for $2.7 million."

The article said that Dr. Kuklo is an orthopedic surgeon with the St. Louis Children's Hospital and is on the medical staff of the Center for Advanced Medicine, Shriners Hospital for Children and Barnes-Jewish Hospital. It also noted him as an associate professor of orthopedic surgery at the Washington University School of Medicine.

Research and Commercialization

The controversy over Dr. Kuklo's alleged falsification of medical data while in the military has been well reported. Various entities are conducting investigations. Dr. Kuklo, also an attorney, has made no public comments surrounding the allegations and investigations.

Being accused of falsifying medical records and not disclosing a relationship with a device company is serious business. When the full details of this saga are made known we hope the results are made public. Perhaps we'll gain more insights into the relationships between physicians, research and the commercialization of new devices.

—WE (August 20, 2009)

biologics

Wooden Legs Make a Comeback

Next season, wood could be the new metal. And like many new fashion designs, this trend comes from Italy.

Wooden legs might sound low-tech when compared with the sleek metal implants and devices on the orthopedics market today, but one group of Italian scientists are working on a high-tech process for turning wood into artificial bone. Anna Tampieri is helping to lead the effort at the Instituto Di Scienza E Techologia Dei Materiali Ceramici (The Institute of Science and Technology for Ceramics) in Italy.

From: Antony Van Corlear Brought Into the Presence of Peter Stuyvesant by John Quidor
Source: Wikimedia commons

According to a report on Discovery News ("New Artificial Bone Made

biologics

of Wood" August 10, 2009), "the researchers chose wood because it closely resembles the physical structure of natural bone," and red oak, rattan and sipo wood work best. The procedure involves heating a block of wood to reduce it to pure carbon, then spraying calcium on the wood to create calcium carbide and finally converting that into carbonated hydroxyapatite through chemical and physical processes. It takes approximately one week and $850 to complete one artificial bone implant, but the researchers are able to produce implants of almost any size or shape.

Wood also holds some advantage over metals and ceramics. The wooden implant is bioactive, and unlike solid metal, its spongy structure allows living bone to grow into the implant. Trying to recreate this porous structure inside a titanium or ceramic implant is more difficult to accomplish because the material often becomes brittle and can cause further bone damage if it breaks inside the body.

The research team plans to test their implants in large animals such as sheep, but according to Tampieri, it could be years before they can clear these wood-derived artificial bone implants for use in humans. Funding for this kind of research may first go toward other technologies which require materials to retain their structure under high temperatures and mechanical stress, such as space vehicles, turbine blades, and catalytic silencers. So it may take some time before the peg leg makes a comeback, but we could still see a return to wood for the next generation of artificial bone implants.

—DK (August 21, 2009)

spine

Spine Tech Award Nominees Submitted

Fifty-two companies have submitted more than 80 spine technologies for consideration of a 2009 Spine Technology Award. The entry deadline was August 15. Any company that produces products for use in spine surgery was eligible to enter.

The Spine Technology Awards are the first of their kind and are intended to bring increased recognition to exemplary and innovative spine surgery products and the engineering teams and inventors who create them.

Companies submitting entries include:

Advanced Biologics LLC
Alpha Med-Surge, Inc.
Alpha Orthopaedics Inc.
Alphatech Spine, Inc.
Amedica Corporation
Applied Spine
ArthroCare Spine
Aspen Medical Products, Inc.
Axial Biotech, Inc.
Bacterin
Biomet, Inc.
BTE Technologies, Inc.
Covidien
CrossCurrent, Inc.
Custom Spine, Inc.
DePuy Spine, Inc.
DFine, Inc.
Disc Motion Technologies
DSM PTG (DSM Biomedical)
ETEX Corporation
Facet Solutions, Inc.
iMDS
Integra (Theken) Spine
Invibio, Inc.
K2M, Inc.
LDR Spine
Mazor Surgical Technologies Ltd.
Medicrea
Nemaris LLC

spine

NovaSurgical, LLC
NuTech Medical
NuVasive, Inc.
Ortho Kinematics, Inc.
Ouroburos Medical
Paradigm Spine, LLC
Pioneer Surgical Technology, Inc.
Spinal Elements, Inc.
Spinal Kinetics, Inc.
Spine Wave, Inc.
Spine21
SpineFrontier, Inc.
SpineMatrix, Inc.
SpineSmith Partners LP
Spinus
Tekmed LP
TranS1, Inc.
US Spine
Vertebral Technologies, Inc.
VertiFlex, Inc.
Vexim
WW Technology
X-Spine

Surgeons at the event will judge each technology on originality, clinical relevance, and the likelihood that it will improve current standards of care. Entries with the most surgeon votes will receive 2009 Spine Technology Awards during the gala banquet on November 9, 2009, at The Palace Hotel in San Francisco.

The Spine Technology Awards are being presented by Orthopedics This Week, the premier online orthopedics newsletter, as a way to recognize the great talents and contributions of spine technology engineers and surgeon-inventors. For information on attending the gala banquet in San Francisco, contact Lisa Carpenter (lisa@ryortho.com) or Tom Bishow (tom@ryortho.com).

—*WE (August 21, 2009)*

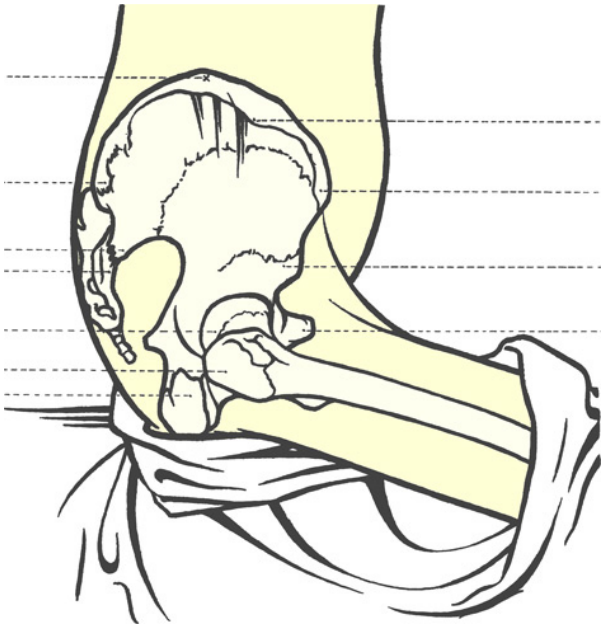
trauma

Hip, Back Breaks Raise Mortality Rates

Some not-so-cheery news out of Canada for the over-50 set. Researchers have found that individuals over 50 who break their hip or back have elevated mortality rates: hip (one in four chance of dying within five years); back (one in six chance of dying within five years).

The study, headed by George Ioannidis, Ph.D., a health research methodologist in the Michael G. DeGroote School of Medicine, was performed in collaboration with scientists from the schools of medicine and nursing at McMaster University, as well as several universities across Canada.

Dr. Ioannidis and his team utilized data from the Canadian Multicentre Osteoporosis Study to examine the relationship between new fractures and mortality over a five year period. Using records from more than 7,750 Canadians aged 50 years and older, the researchers looked at various types of fractures reported by participants, work that differed from previous research in that the study group was representative of the general population.



Source: Wikipedia Commons

"Hip fractures may have long-lasting effects that result in eventual death by signalling or actually inducing a progressive decline in health," said Dr. Ioannidis in the news release. "Our results also showed that vertebral fracture was an independent predictor of death."

The team also determined that all types of bone breaks were more common among women than men, with the exception of rib fractures. In addition, they found that fractures were associated with other negative consequences such as increased pain, immobility and reduced health-related quality of life.

"People should be aware that fractures are a serious problem in osteoporosis," Dr. Ioannidis said in the news release. "They do not just reduce health-related quality of life, they actually cause death. So hip and spinal fractures need be taken very seriously, and prevention should be paramount in treating patients with osteoporosis."

The investigators found that things such as smoking, physical activity and the presence of other diseases increased the risk of death, as did lower educational levels. The authors recommended that interventions—such as osteoporosis medications, fall prevention strategies, hip protectors and enhanced rehabilitation after fracture to improve mobility and strength—be be introduced to reduce the likelihood of fractures.

Commenting to *OTW,* Dr. Ioannidis stated, "The most surprising finding was the significant association between spine fractures and death. In addition, given that spine fractures are common in the general population this type of fracture should be treated seriously. We will be conducting a 10-year study to determine the associations between fractures and death. We will examine fracture types that have not been evaluated such as the upper arm and lower leg. In addition, we should have enough pelvic fractures to determine the impact of these fractures on mortality. Furthermore, we should be able to determine, with greater precision, the impact of fractures on mortality in men."

The research, funded by the Canadian Institutes of Health Research, has been published in the online edition of the *Canadian Medical Association Journal.*

—EH (Aug 18, 2009)

trauma

Cognitive Behavioral Tx for Sleepy OA Patients

While "co-exist" is often a positive term, in this case, not so much. Researchers from the University of Washington in Seattle have found that insomnia is not merely a symptom of osteoarthritis (OA), but rather a co-existing illness. The good news is that the use of cognitive behavioral therapy for insomnia (CBT-I) can be an effective treatment for older patients with osteoarthritis and comorbid insomnia. The research is published in the August 15 issue of the Journal of Clinical Sleep Medicine.

A total of 23 patients with a mean age of 69 years were randomly assigned to CBT-I, while 28 patients with a mean age of 66.5 years were assigned to a stress management and wellness control group. Those in the control group reported no significant improvements in any measure. A majority of the sample was female.

CBT-I consisted of eight weekly, two-hour classes which were spread out over the calendar year. Individuals with sleep apnea were excluded. Sleep and pain were assessed by self-report at baseline, after treatment, and (for CBT-I only) at one-year follow-up. Sleep logs were recorded prior to and after treatment and at the one-year follow-up and included information about sleep latency, wake after sleep onset, and sleep efficiency. Subjects were required to be over the age of 55, have insomnia symptoms that have persisted for at least six months, and have been diagnosed with osteoarthritis.

The researchers found that treatment improved both immediate and long-term self-reported sleep and pain in older patients with OA and comorbid insomnia without directly addressing pain control. Patients who underwent CBT-I reported significantly decreased sleep latency and wake after sleep onset, significantly reduced pain, and increased sleep efficiency. These improvements persisted in CBT-I patients (19 of 23) who were further assessed for sleep quality and perceived pain at a one-year follow-up visit.

Dr. Vitiello told *OTW,* "While we were fairly confident that improving sleep would decrease pain in these patients, we were somewhat surprised that the beneficial impact on both sleep and pain persisted a year after treatment."

"The particular strength of CBT-I is that once an individual learns how to improve their sleep, study after study has shown that the improvement persists for a year or more," said Dr. Vitiello in the news release. "What we and others are showing is that CBT-I can not only improve sleep but that improvement of sleep may lead to improvement in co-existing medical or psychiatric illnesses, such as osteoarthritis or depression, and in the case of our study, that these additional benefits can be seen in the long term."

Concerning his next steps, Dr. Vitiello told *OTW,* "We have already begun a large National Institute of Aging funded randomized controlled trial to determine if combining CBT for insomnia with a CBT for pain will provide greater improvement in pain compared to either CBT for pain alone, which is not particularly efficacious, or a control condition."

As for what orthopedists tell their patients regarding these findings, Dr. Vitiello told *OTW,* "Orthopedists can advise their OA patients that there is at least preliminary evidence to suggest that taking steps to improve their sleep, specifically through a CBT-I program, will result in improved sleep and is likely to help control their OA-based pain. It is reasonable to assume that improving sleep may also reduce pain in other pain conditions. Orthopedists should be ready to refer their patients who want to improve their sleep to practitioners, typically clinical psychologists or nurse practitioners who can provide CBT-I."

Information on CBT-I is available at: http://sleepeducation.com/Treatment.aspx?id=5.

—EH (August 20, 2009)

The Picture of Success: Lisa Ferrara, Ph.D.

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

The major manufacturers call upon her expertise, as does the FDA. A biomedical engineer, Lisa Ferrara, Ph.D., founder of OrthoKinetic Technologies and OrthoKinetic Testing Technologies, knows medical device technology.

The Birth of an Engineer

The underpinnings of her success began with two parents who said, "Well, of course you can." Dr. Ferrara: "My two siblings and I grew up south of Boston in a blue collar family. My dad, who came to this country as a laborer at the age of 17, and my mom, an administrative assistant, instilled in us a sense of drive and purpose. They always made us believe we could do whatever we set out to do."

And what she wanted to do was study cells, tissues, and artificial organ systems…. and what could be done with them. "I obtained two undergraduate degrees, one in biology from Bridgewater State University and another in electrical engineering from the University of Lowell, Massachusetts. Although I took the MCAT exams at Harvard University, after sitting through a lecture on myoelectric prosthetics, I was captivated, and switched tracks to bioengineering. I then went to Syracuse University and obtained a masters degree in biomedical engineering and neuroscience. After two years at the university's Institute for Sensory Research, I went to Cleveland State University, where I earned a doctorate in applied biomedical engineering with a concentration in microelectromechanical systems (MEMS) and nanotechnology."

It was in the lab at Syracuse that Lisa Ferrara met a true sage of the medical device world. "I worked alongside Dr. Hansen Yuan, an icon in the field and my greatest mentor. Because he was one of the leading innovators in the field, I was fortunate to learn about the latest in cutting edge spinal technologies and conducted numerous research studies related to novel medical devices. At that time, new technologies in spine implantation were starting to blossom.

"Through my experiences in Syracuse and through Dr. Yuan, I had ample opportunity to learn about the industry and was given the chance to branch into many different areas of research. It was very exciting to take things from the early concept stage to seeing it commercialized. I especially loved the challenge of applying my knowledge of electrical and mechanical systems combined with the basic fundamentals of engineering and applying them to a living system."

Creating Her Own Testing Universe

Having gleaned inside knowledge of what it takes to make a lab run efficiently, Lisa Ferrara then received the opportunity to create her own testing universe. "In the mid-90s I was offered a fellowship and the chance to build and run my own lab at the University of New Mexico (UNM) through Dr. Edward Benzel, an acclaimed neurosurgeon. I decided to take on the challenge. I was given space at the university and the chance to develop new technologies for medical applications, such as MEMS, which was a collaborative effort with Sandia National Laboratories at the time. I was given further collaborative opportunities when I was able to work with Dr. Shahinpoor at UNM on artificial muscles, where we made such progress in the area that we were actually interviewed by ABC News."

They likely made so many leaps and bounds in part because Dr. Ferrara's

vantage point was shifting…and her thinking was expanding. "Because of my position in the Department of Neurosurgery, I had the chance to learn a totally different discipline. I began to look at the spine from a neurosurgical viewpoint and got a better understanding of how orthopedists and neurosurgeons differ in their thought processes, but work well as a team. For example, orthopedists know the physiology and nuances of bone, whereas neurosurgeons are comfortable with the treatment of the neural structures. I was fascinated to watch them work as a team in the treatment of devastating spinal injuries. I got an excellent grounding in the science of the neurological system and how devastating the injuries can be."

Galvanized by this work, when Dr. Benzel left the UNM lab, Dr. Ferrara accompanied him. "Dr. Benzel departed for Cleveland Clinic and asked me to join him and build a research facility there. The effort was a more substantial political and logistical challenge. I was given a computer, but no space to work—just a room the size of a closet. Because they had just built a new research center and had evacuated an older building, I put in a proposal for the entire floor of the old building and subsequently received $1.5 million for renovations. Suddenly I was a construction manager as well, writing budgets and creating a business plan."

But as her parents had assured her long ago, her hard work would pay off. "Out of these efforts I formed Cleveland Clinic's Spine Research Lab. Upon completion I held an open house, which was attended by 300 people, including representatives from NASA, industry executives and the upper echelon of the Clinic. They had fun examining our robotic arm and other interesting equipment that had been generously donated by various companies. My Chairman was so pleased with our success that he wrote me a lovely letter and provided additional funding for the lab."

Some of that funding would go toward mentoring individuals who may not otherwise have had a chance to explore their engineering or medical talents. "During this time I was mentoring a number of young people from the inner city who needed a chance to excel and experience a hands-on approach towards understanding engineering in medicine. The mentees would spend one or two years with me, even getting their names on publications in many cases. I was so proud to have been named Mentor of the Year by John Hay high school in 2002. Even better is when I received letters from my former mentees saying that they had gone on to college and were doing well academically."

Building Her Own Companies

By day she ran the spine lab; by night she worked on completing her dissertation. "I had become increasingly intrigued by the possibilities inherent in the 'micronano' world. Because of this, I wrote my dissertation on MEMS and the development of implantable wireless biosensors that contain a full electronic system on a microsized (1mmx1mm) chip. While it sounds futuristic, we are actually starting to see people using MEMS in certain devices like implantable blood pressure sensors, glucose monitors and for various heart conditions. These biochips emanated from the military, which would have soldiers wear them in the field in order to detect biological and chemical agents. We are moving toward the day when microchip systems can be used diagnostically and therapeutically for long-term implantation into living systems, including drug delivery systems and nano cantilevers for cancer detection."

"Originally, says Dr. Ferrara, "the potential of this technology for medical applications lacked enthusiasm by the medical community, perhaps because it was too futuristic and would take too long to commercialize. Then people began to realize that there are real

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.

Ry Publications

needs that could be met by these novel technologies. For example, if used in the prevention of implant loosening, the microchips will not damage the surrounding areas and can provide early detection of implant failure. They can also be used to map entire diagnostic and therapeutic strategies over time. The initial medical utilization of MEMS technology is in the realm of smart implants, which can detect what's happening with the surrounding tissues, monitor the movement of molecules, or let the surgeon know why the patient's bone isn't fusing."

Homing in on her work with this technology, Dr. Ferrara notes, "I have developed an implantable MEMS that monitors pressure, along with a smart cervical implant to monitor strain. My colleagues and I demonstrated that as the mechanics of fusion changed, the pressure oscillation and strain would change as well, and you could predict when fusion would occur. This was the feasibility, or early stage work that led to the development of the MEMS biosensor and the formation of OrthoMEMS, a company dedicated to developing the technology that can expand the diagnostic and treatment options available to surgeons and patients."

Not only versed in MEMS, Dr. Ferrara also grew comfortable with the business world. "This work provided the background I needed to move forward and develop my own testing center. Although I left Cleveland Clinic to do forensic engineering expert witness work for two years, I quickly realized that there were more suitable opportunities related to the medical device industry. In 2005 I launched OrthoKinetic Technologies LLC, a business aimed at helping companies with their proof of concept and regulatory testing, testing strategies, analysis of the device performance, FDA submissions, publications in peer reviewed journals, creation of marketing materials for industry and due diligence investigation of new technologies."

Dr. Ferrara, named Entrepreneur of the Year for Healthcare in Coastal North Carolina for 2009, notes, "After spending two years as a forensic engineer, I was able to understand the legal thought processes and strategies used to defend or attack a medical device. It was then that I started OrthoKinetic Technologies, a consulting business in which I solely worked with medical device companies to evaluate and validate their implants, and was able to incorporate what I had learned as a forensic engineer into protecting the medical device companies from future liabilities. Within the last year I built a 'one stop shop' testing facility—OrthoKinetic Testing Technologies. I did so because I came to realize that there was no need to outsource testing. We manage a company's entire preclinical package, including the animal studies. I also sit on several clinical and scientific advisory boards for industry and Healthpoint Capital, an activity that lets me focus on the assessment of implant performance, and related engineering or mechanical risks that could affect clinical outcomes."

To share what she has learned thus far, Dr. Ferrara developed a book—Spinal Mechanics for Product Development in the New Millennium—with the help of two wonderful innovators and mentors, Dr. Hansen Yuan and Dr. Vijay Goel, as coeditors. "I felt there was a need to outline the process of innovation from biomechanical theory to the regulatory process."

Living Her Life to the Fullest

Disparate thoughts flow together and click, thus leaving the creator with something new. In addition to experiencing this process at work, Dr. Ferrara has such moments in the garden and at the canvas. "I have a large herb garden, raise orchids, and enjoy jogging, sailing, and painting. My hobbies bring a sense of relaxation and achievement to my life. My husband Jim, who runs the test lab and is an incredible engineer, is my real strength and best friend."

She and her husband use their resources—wisdom, time, love, and money—to impact the lives of those in need. "My husband and I devote what we can to Faith Friendship, a personal care home for mentally challenged individuals. It is a place where folks who need extra care live as one big family; the people who maintain the home and care for everyone are our true heroes. Jim and I hope to eventually donate extra time and money to make the residents' lives more comfortable. I think the greatest lesson learned from our involvement with Faith Friendship is humility."

Dr. Lisa Ferrara… expanding possibilities in medical technology and in life.

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