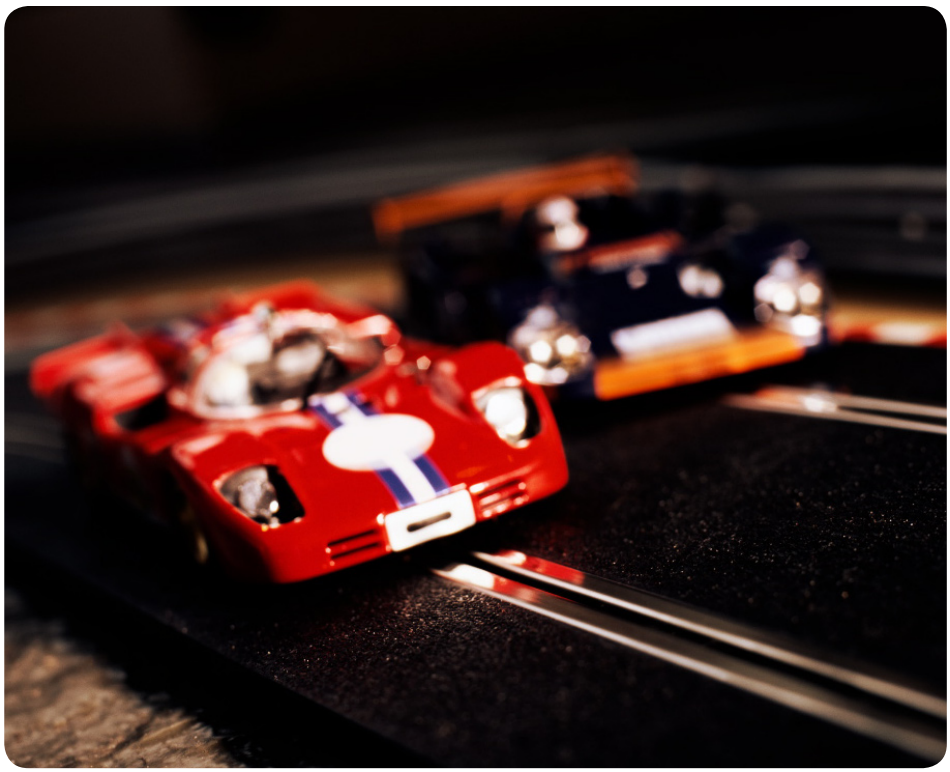
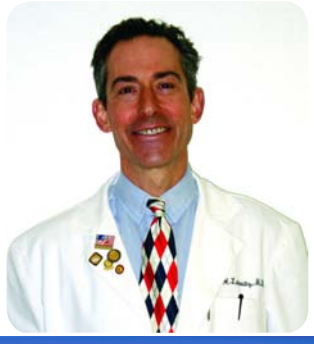
VOLUME 5, ISSUE 13 | APRIL 21, 2009

Orthopedics This Week

week in review



the picture of success



breaking news

For all the news that is Ortho, read on.

Announcing the newest arrival in biomaterial solutions

The Change is **Natural**™

The same material that provided him protection in the womb, provides protection to your patients as well—AmnioClear is an in-vivo wound covering that utilizes the natural protective function of Amnion, delivering a defensive barrier at the site of surgery. In choosing between a biological wrap and a synthetic, the decision is clear. Natural material, natural choice.

www.afcellmedical.com

7235 Vicksburg Pike, Fort Wayne, IN 46804

AFcell™
The Change is Natural™

Orthopedics This Week

VOLUME 5, ISSUE 13 | APRIL 21, 2009

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Sales of large joints and spinal implants from DePuy and Biomet were higher than expected and signal potentially strong results from Stryker, Zimmer, Synthes and Medtronic. Growth rates are still down, but these reports are clearly good news. This bounce looks like the real deal.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Stryker	23.13%	13.19%	Stryker's 1Q sales performance underwhelming—excepting spine, which rose 8%. SYK is still 45% below its 52-week high.
2	2	Zimmer	29.96	17.38	Consensus is forecasting a 5% decline in sales this quarter. Really? The Zimmer Franchise may surprise—on the upside.
3	5	Symmetry	9.92	35.12	Rock n roll! SMA is in the right place at the right time. Serving a recovering orthopedic industry.
4	3	Medtronic	31.68	14.17	MDT is cheap, but we worry that spine surgery is more delay-able than large joint recon. The fifth least expensive stock in ortho.
5	6	ArthroCare	16.87	156.13	Up 156%—and STILL third least expensive company in orthopedics at just 0.83x annual sales.
6	8	Exactech	13.08	20.24	New Optetrak knee due in 2H09—and with procedure volume's stabilizing, timing could not be better.
7	4	Integra LifeSciences	12.37	8.54	How strong is this recover? IART's 8.54% increase in 30 days ranks 17th best.
8	7	Johnson & Johnson	25.36	4.59	DePuy's numbers were great. But, again, hidden in Pa JNJ reminds us again how much better DePuy would look on its own.
9	NR	CONMED	10.82	23.80	With a recovery in ortho, demand for drills, saws, and the tools of MIS should return as well.
10	9	Synthes	33.70	5.52	Attention is now moving to beaten but recovering stocks. When the credit markets were frozen, Synthes's cash = safety. Now it's a burden.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	ArthroCare	ARTC	$10.45	$278	156.1%
2	I Flow Corp	IFLO	$4.95	$122	57.6%
3	Alphatec Holdings	ATEC	$1.82	$86	55.6%
4	Regen Biologics	RGBO.OB	$2.90	$28	38.1%
5	Capstone Therapeutics	CAPS	$0.65	$27	35.4%
6	Symmetry Medical	SMA	$7.81	$280	35.1%
7	Kensey Nash	KNSY	$22.70	$261	34.5%
8	TranS1	TSON	$7.12	$146	24.9%
9	CONMED	CNMD	$16.44	$477	23.8%
10	Wright Medical	WMGI	$15.85	$602	23.1%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	RTI Biologics Inc	RTIX	$2.67	$145	-17.8%
2	CryoLife	CRY	$4.74	$133	-10.6%
3	Mako Surgical	MAKO	$7.01	$175	-6.7%
4	Orthovita	VITA	$2.95	$224	-6.3%
5	Smith & Nephew	SNN	$34.41	$6,070	2.3%
6	Johnson & Johnson	JNJ	$53.05	$146,730	4.6%
7	Synthes	SYST.VX	$113.29	$13,450	5.5%
8	**Average**			**$8,939**	**7.3%**
9	NuVasive	NUVA	$30.36	$1,100	8.0%
10	Integra LifeSciences	IART	$24.14	$679	8.5%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	CryoLife	CRY	$4.74	$133	4.17
2	ArthroCare	ARTC	$10.45	$278	6.14
3	Symmetry Medical	SMA	$7.81	$280	6.89
4	Orthofix	OFIX	$17.62	$301	7.52
5	Zimmer Holdings	ZMH	$42.96	$9,570	10.26

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	I Flow Corp	IFLO	$4.95	$122	54.90
2	NuVasive	NUVA	$30.36	$1,100	41.48
3	RTI Biologics Inc	RTIX	$2.67	$145	21.66
4	Osteotech	OSTE	$3.37	$60	19.18
5	Synthes	SYST.VX	$113.29	$13,450	18.30

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	ArthroCare	ARTC	$10.45	$278	0.25
2	Integra LifeSciences	IART	$24.14	$679	0.66
3	Symmetry Medical	SMA	$7.81	$280	0.74
4	CryoLife	CRY	$4.74	$133	0.79
5	Stryker	SYK	$37.94	$15,040	0.83

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$30.36	$1,100	29.99
2	RTI Biologics Inc	RTIX	$2.67	$145	1.60
3	Johnson & Johnson	JNJ	$53.05	$146,730	1.48
4	**Average**			**$8,939**	**1.46**
5	Exactech	EXAC	$13.90	$177	1.23

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$3.37	$60	0.54
2	CONMED	CNMD	$16.44	$477	0.62
3	Symmetry Medical	SMA	$7.81	$280	0.64
4	Orthofix	OFIX	$17.62	$301	0.65
5	ArthroCare	ARTC	$10.45	$278	0.83

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$4.53	$110	249.98
2	Mako Surgical	MAKO	$7.01	$175	59.49
3	Regen Biologics	RGBO.OB	$2.90	$28	20.62
4	TranS1	TSON	$7.12	$146	5.57
5	NuVasive	NUVA	$30.36	$1,100	4.46

Extremity Implant Markets Revving Up

By Dev Joshi, PearlDiver Extremities Analyst

Extremities are like orthopedics NASCAR. Not only is it the fastest growing sector but it is also, we think, the most competitive. Companies selling extremity repair products posted the highest rates of sales growth of all the major orthopedic product sectors in the fourth quarter of 2008. The 12.1% year-over-year (YOY) growth for 4Q08 brought the market for extremity implants to an annual growth of 15% for the year. By contrast, sales of products for large joint repair struggled with a declining rate of growth. Knee implants, for example, grew just 3% in 4Q08. Demand for spinal implant and biologic products grew less than 10% in 4Q08. Finally, sales of trauma products rose at roughly half the rate of extremities coming in at 6% year-over-year. Though the revenue growth rate of extremities exceeded that of other markets in 2008, it did show a slight decline in the fourth quarter from the 15% rate it achieved over the previous three quarters in 2008.

Reviewing individual company performance for 2008, Wright Medical, we estimate, ended the year with the largest share of the foot and ankle implant market while Tornier led in sales of shoulder implants and instruments. We estimate, DePuy holds the largest overall market share and reported approximately a 10% rate of YOY sales growth. DePuy's total sales of extremity implants and instruments for 2008 were $214 million, making it the first company to pass the $200 million milestone in extremity sales. By contrast, Zimmer, we estimate, was the worst performer among the major extremity product suppliers reporting less than a 3% rate of sales growth.

Table 1 shows the extremity companies with their fourth quarter earnings and future estimates.

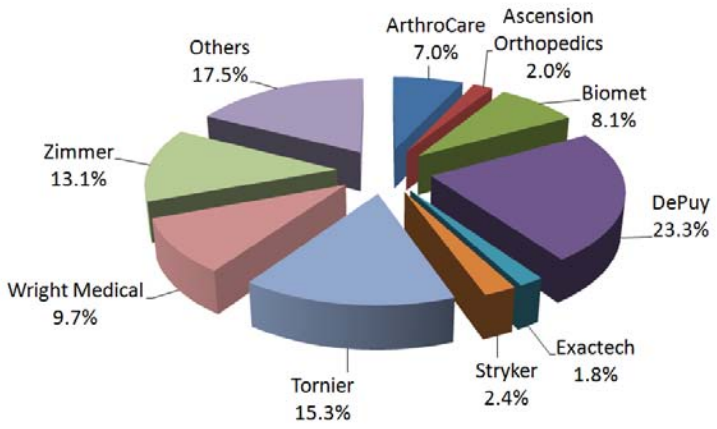
Table 1: Worldwide Extremity Product Shipments by Company (2008-2010E)

Companies	4Q08	2008A	1Q09E	2Q09E	2009E	2010E
ArthroCare	$16.7	$64.1	$16.2	$17.5	$70.2	$78.7
Ascension Orthopedics	$5.3	$18.2	$5.4	$5.1	$23.1	$30.2
Biomet	$18.4	$74.3	$20.3	$22.6	$85.7	$99.1
DePuy	$57.0	$214.0	$64.6	$48.4	$230.8	$262.6
Exactech	$5.0	$16.8	$5.1	$5.2	$22.7	$30.1
Stryker	$6.2	$21.8	$5.5	$5.2	$23.1	$25.2
Tornier	$39.4	$140.6	$38.6	$36.0	$157.4	$184.8
Wright Medical	$24.8	$88.9	$25.0	$26.8	$109.4	$132.2
Zimmer	$30.0	$121.0	$33.2	$32.7	$128.0	$139.5
Others	*$45.2*	*$160.7*	*$43.2*	*$39.6*	*$174.5*	*$195.8*
Total	*$248.0*	*$920.4*	*$257.1*	*$239.1*	*$1,024.9*	*$1,178.2*
Year-Over Year Growth	*12.1%*	*15.0%*	*9.1%*	*10.3%*	*11.4%*	*15.0%*

Source: SEC filings, PearlDiver estimates and press releases. ArthroCare has not reported sales since 1Q07. Stryker sales represent just their shoulder sales. Ascension and Tornier represent estimates.

In 2008 DePuy sold more extremity implants and instruments than any other company but coming up strongly are Tornier and Wright Medical. For the full year, Tornier and Wright ended with 15.3% and 9.7% market shares, respectively. Currently, DePuy, Wright Medical, Tornier, Zimmer, and Biomet make up 70% of the total extremity market. Chart 1 illustrates the market share by company for the fiscal year 2008.

Chart 1: 2008 Extremities Market Share



Source: Company's SEC filings and press releases

DePuy

For the fourth quarter ending December 31, 2008, Johnson & Johnson's DePuy, the leading extremity company worldwide, reported 9.6% year-over-year growth with $57 million in product shipments. The growth rate was lower than we expected due to increased shoulder product competition from Tornier and Biomet and from Wright Medical's INbone product in the foot and ankle sector. DePuy's 4Q08 extremity sales growth was much less than the growth rates reported in 4Q07, when the company reported that extremity product sales grew by more than 67%. Of course the major cause of that growth rate was last year's purchase of new product lines. Domestic extremity sales were 65% of the total reported for the fourth quarter.

DePuy's share of the extremities market, we estimate, is now 23.3% —down slightly from the prior year's 24%. DePuy's 9.6% rate of extremity revenue growth for the fourth quarter fell short of our forecast by about 300 basis points. Given the increasingly competitive extremity market, the overall economic recession, we are reducing our 1Q09 sales growth estimate for DePuy from 8.2% to 6%.

Overall, for 2008, DePuy's extremity business grew at an annual rate of 11.5%. The company's two product spotlights are the Agility Ankle System and the Delta Shoulder System, which contributed significantly to DePuy's extremity sales. DePuy still reigns as the shoulder division leader with over 25% market share. Tornier, Biomet, and Zimmer are, however, closing the gap, we think, and make this market one of the most intensely competitive. Tornier's reverse shoulder system and Wright Medical's ankle system will certainly keep DePuy on their toes in the coming years.

Zimmer Holdings

Zimmer Holdings reported minimal growth in its extremity sales for the quarter and was the slowest growing major extremity company. Fourth quarter extremity sales only grew 3%—a staggering drop from the 36% rate reported for the same period last year. Zimmer's fourth quarter extremities revenue contributed $30 million to overall Zimmer sales of $1.03 billion and account for 3.0% of Zimmer's total revenues which, although small, is still higher than the 2.6% reported for all of 2007. For the full year 2008, Zimmer's extremity product sales rose 15.2% YOY bringing total extremity sales to $121 million.

In 2008, 73% of Zimmer's extremity sales were from the domestic market which grew by 19.2% YOY. Zimmer's European extremity sales increased 11.2% compared to a mere 2.9% increase in Asia. European sales represented 21% and Asia Pacific accounted for 6% total of total extremity sales.

Even with a weak fourth quarter, Zimmer held on to its #3 rank in the extremity market with 13.2% market share. A strong line of leading products certainly helped them keep their position. Zimmer's Bigliani/ Flatow Shoulder Solution and the Zimmer Trabecular Metal Reverse Shoulder System lead their extremities sales in the North America division. The Anatomical Shoulder System and the Coonrad/Morrey Total Elbow lead extremities sales in Europe, while the Coonrad/Morrey Total Elbow lead in the Asian market.

Given the recent decline in Zimmer's growth in large joints and extremities, PearlDiver estimates Zimmer's 2009 first quarter sales growth to be around 4%, a much slower growth rate than 1Q08, when the company reported 28% year-over-year growth. A key factor in Zimmer's decline in market share, we believe, is stiff competition from Tornier and Biomet. Lower extremity companies are quickly gaining market share in areas where Zimmer does not have products. Looking ahead to 2009, we are forecasting that Zimmer extremity sales growth will likely come in between 5% to 7% YOY— barring, of course, any merger or acquisitions activity.

Wright Medical Technologies

Wright Medical Technologies' strong extremity sales performance in 2008 is in part due to the company's strong commitment to innovation as demonstrated, we think, by the its CHARLOTTE line of foot and ankle products and the 2008

STAY AHEAD OF THE CURVE.

Attending SAS 09 in London?

Come a day early and learn about exciting, new advances in anular reconstruction technology and techniques. Hear the facts about an innovative, new approach to lumbar disc herniation repair that lets you ***Close with Confidence.***™

Anular Reconstruction

Greg Lambrecht, President and CEO, Intrinsic Therapeutics, Inc.

Monday, April 27 10:00 AM
East Wintergarden at Canary Wharf Convention Center, London

SPINE Technology Summit
Separate Registration is Required

The Barricaid, an endo-prosthesis used for Anular Reconstruction, offers an innovative, new alternative for addressing the challenge of reherniation following discectomy.

Come see us at the SAS Ninth Annual Global Symposium on Motion Preservation Technology

Booth #100

Don't miss these informative talks on anular repair:

Barricaid® ARD in the Treatment of Lumbar Disc Herniations: A Prospective Study

Speaker: Prof. Darko Ledic

Friday, May 1 11:48 to 11:53 AM
General Session

The Anulus: Damage and Repair

This moderated discussion will explore the biomechanics, biology, and clinical implications of anular deficiencies, as well as novel surgical strategies.

Tuesday, April 28 8:00 to 9:00 AM
General Session

Intrinsic Therapeutics

Science Driven Spine Care™

acquisition of INbone Technologies and A & M Surgical's foot and ankle products. Wright Medical's management has stated that its goal is to become the market leader in foot and ankle product sales and, based on reported sales results for 2008 is, we think, closing the gap with overall market leader DePuy. Wright's market share in total extremities sales spiked to 9.7% in 2008 from 7.7% in 2007. At this rate of growth, it may be just be a matter of time, we think, before Wright Medical, with its steady stream of innovative product launches, becomes the #1 foot and ankle product supplier.

For 4Q08 Wright Medical reported that sales of extremity products grew 30.5%—bringing quarterly revenues to $24.8 million. For all of 2008, Wright Medical reported a 42.7% annual growth which was higher than its previous year's growth of 38%. Sales of extremity products now represent 19% of Wright Medical's product sales. Wright's U.S. extremity business grew on the strength of rising shipments of the DARCO and CHARLOTTE product lines and product sales from its April 2008 acquisition of INbone Technologies. International sales were driven primarily by Wright's DARCO plating systems.

Wright Medical's strong performance in 2008 sets the company up, we think, to become the leader in the foot and ankle market by the end of 2009. We estimate that revenue for the first quarter of 2009 will grow by 22% year-over-year, and we predict that sales for the full year 2009 will rise 23%. One year ago, in 4Q07, the company reported that its extremity product sales (off a low base) rose 61% to almost $19 million. By the end of 2009, we are predicting Wright Medical will surpass the $100 million mark in extremity product revenues and become the fourth largest supplier behind DePuy, Tornier, and Zimmer.

Biomet

Biomet's fiscal year starts on June 1st and ends on May 30th. For the calendar year 2008 fourth quarter, (September 2008 to November 2008) Biomet had, we estimate,$18.4 million in extremity sales and almost all of those sales were from shipments of implants and instruments for the upper extremity. The total extremity sales for the calendar year 2008 were, we estimate, $74.3 million —which is a 12.4% rate of YOY growth. Biomet, which became a private company in 2007, now holds, we estimate, 8.1% of the global extremity market, which is a slight decrease in share from 2007.

Biomet's upper extremity division has been engaged in fierce competition with strong product offerings from Tornier, DePuy, and Zimmer. The company's new Comprehensive reverse shoulder system is a next generation's reverse shoulder prosthesis that offers intra operative flexibility. Biomet's most prominent extremity products include the Bio Modular shoulder system and the Copeland Humeral system.

As part of Biomet's third fiscal quarter (February 2009 quarter) sales results, management announced that the company had posted good double-digit extremity sales growth rates which were stronger than the overall market growth rate. We are therefore estimating Biomet's extremity business grew just over 12% year-over-year in the quarter. We are also estimating that Biomet's current development in upper extremity product lines will deliver a solid 15% rate of sales growth for the year ending May 30, 2009.

Exactech Inc.

Exactech Inc., represents less than 2% of the extremity market worldwide, yet is reporting rapid revenue growth off an admittedly low base. For the fourth quarter Exactech reported that extremity product shipments reached $5.0 million, a 56% annual year-over-year growth rate, which easily surpassed our estimate of 35%. Total

sales for fiscal year 2008 amounted to $16.8 million. We estimate that extremity sales will continue to grow at strong double-digit rates at Exactech on the strength of the increasingly popular Equinoxe shoulder system (which doctors use for total shoulder replacement, reverse shoulder replacement, and other shoulder-related procedures). We are now estimating that Exactech's extremity sales will grow 37% for 1Q09 and can rise to $23 million by the end of 2009.

Tornier

For 2008, Tornier's sales rose 13% to $141 million, which was actually a slower rate growth than management had originally forecast. Again, strong competition from Biomet and Exactech, we think, played a role in keeping Tornier's 2008 growth rate at a still respectable 13%. Tornier's lead products are the Aequalis Shoulder System and the NexFix MTP Fusion System.We estimate the company will likely increase sales by less than 12% in 2009—again, under management's expectations. This slower-than-expected rate of growth is due to, we think, the strong competition in the foot and ankle market from Wright Medical and the product offerings from Biomet and Exactech in the shoulder sector. Overall, DePuy still holds the biggest shoulder implant market share at between 25%-28%, but Tornier is closing the gap and accounts for, we estimate, 20% to 22% of the total shoulder market.

Tornier, the second largest extremity product supplier, was founded in France but, due to a private equity buy-out in 2006, is now based in Minneapolis, Minnesota. Tornier's product sales include some large joint sales in Europe and, of course, extremity product repair implants and instruments.

Other Extremity Companies

The remaining companies that serve the extremity markets are mostly privately held companies or public companies which do not report extremity sales separately, but there are some with potential for fast growth. Ascension Orthopedics, based in Austin, Texas, is an extremity company that reported revenues in 2007 of $14 million. We estimate its 2008 sales exceeded $18 million and we are estimating that sales in 2009 will rise 25% to 30%. Small Bone Innovation (SBi), Arthrex, Integra LifeSciences, Orthofix, Smith & Nephew, and Acumed are other companies that have established a good foundation in the extremities division. SBi, we estimate, grew sales at a 16% resulting in $12 million in revenue for 2008. Integra LifeSciences reported in excess of 20% year-over-year sales growth for the year 2008. Stryker does not play a big part in the extremities area, but it does have a small segment in the shoulder division, and reported 2008 sales reached $21.8 million.

For the quarter ending December 31, 2008, extremity product shipments increased 15% year over year to $920 million. In the fourth quarter of 2008, growth rates slowed considerably to a still strong 12.1%. For the first quarter of 2009, an overall dismal economic environment will, we expect, keep extremity product sales growth rates at 10% YOY—which is down by about 200 basis points from our previous 1Q09 growth rate estimate of 12%. For the full year 2009, we are estimating that sales will grow by 12%.

Shoulder, foot and ankle products dominate the extremity market with well over 65% of the total product shipments. Tornier and Exactech, we expect, will continue to perform well with their shoulder products while Biomet and Exactech will definitely grow at a rapid rate on the strength of their new reverse shoulder devices (Biomet's rolls out in May 2009). Wright Medical will, we think, continue to dominate the foot and ankle market and might even surpass DePuy in terms of overall extremity sales by the end of 2009. Zimmer will struggle in its extremity sales as the upper extremity market is facing stiff competition. Even though the extremities market is only a small slice of the orthopedics industry, we estimate that it will reach new heights in 2009 with global product sales of more than $1 billion dollars. The increasing competition and strong growth rates promise to make 2009 an exciting one for extremities.

Grants: Now More Than Ever

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

In today's economic climate, grant writing has become a dog-eat-dog world (read: researcher eat researcher).

Dr. Javad Parvizi, an orthopedic surgeon and researcher at The Rothman Institute at Thomas Jefferson University Hospital in Philadelphia, has been awarded twelve grants during his career. He says, "Knowing how to properly approach a grant application is much more of a necessity now. High caliber scientists are losing their jobs and exciting projects that would have enabled us to better care for patients have been discontinued. While the new administration in Washington is looking to reverse these trends with an infusion of $7.9 billion to the National Institutes of Health (NIH), the grant arena remains extraordinarily competitive."

Dr. Parvizi elaborates, "Balancing the demands of being a clinician scientist is a major challenge. The person who has a serious interest in research should dedicate a significant portion of his or her time to clinical or basic science research—ideally 50%. Also, to be successful in a scientific field one needs to have a primary area of interest, generate sufficient data, and be peer reviewed."

Getting inside bone can be hard… getting inside the NIH funding stream is harder. Dr. Parvizi: "The major source of funding for clinical research is still the NIH. To obtain their funding you must have a topic of research that appeals to the study section related to your area of interest. There is typically a primary reviewer, two or three secondary reviewers and then a tertiary reviewer. Aside from the benefit of having lots of experienced eyes 'on the case,' employing so many reviewers avoids even the hint of bias…no one can say, 'I didn't get the grant because such-and-such reviewer didn't like me.'"

"After these individuals have completed their tasks," says Dr. Parvizi, "another meeting takes place

in which the applications are scored by a large number of people. Who obtains funding also depends on the availability of funds in that particular year. There is an annual funding line, meaning, for example, that in a certain year the top 10% of projects get funded…anyone in the 11% category is not funded."

Those on the right side of that line, however, will now have a better chance than ever of having a clinical impact. "The NIH has made it an objective to move more towards translational research," says Dr. Parvizi, "something that will obviously benefit patients. As for researchers, we can focus on the clinical problem and design around it."

NIH's job could be described as risk management. Dr. Parvizi: "In essence, the study section is charged with funding proposals that have the least amount of risk with the greatest chance of success. One of the most significant challenges is to have enough preclinical or clinical data or supporting material to convince the study section that the project is doable. They are also going to ensure that your background includes experience in the appropriate areas…they want to know that *you* are the one who can get the project done right."

Dr. Parvizi continues, "There are different grades of funding, including high risk grants which only allot a small amount of money for a relatively short period of time (usually one or two years). For example, let's say I have a new product to inject into the knee that I say will reverse cartilage degeneration. Although I may have lab research to support it, the fact remains that it's a very challenging field and it is unlikely that my product is going to be effective. Yet, the study section would likely see it as an area of interest due to the disability it causes in so many patients…and they would likely fund it as high risk."

"Then there are the R01 grants," explains Dr. Parvizi, "which last from four to five years, have one principal investigator, and are milestone-based. Using my R01 grant as an example, we have looked at the issue of infection. If bone has eroded, you have the option of using cadaveric bone, which, although it works fine most of the time, can get infected. This is particularly true in cancer surgery where the immune system is depleted and the risk of infection is high. Working with allograft provided by the Musculoskeletal Transplant Foundation, my team and I are doing chemical modification of bone allograft and implants, something the NIH study section found sufficiently promising to fund."

If you're not ready to climb "Mount NIH" just yet, there are other sources of funding that can help propel your hypotheses testing and data. Dr. Parvizi explains, "Other options are the Small Business Innovation Research Program and the Small Business Technology Transfer Program, both administered by the U.S. Small Business Administration Office of Technology. These programs are structured such that researchers partner with small business to develop a proposal for producing products."

"In the event that your project may aid those in the military," says Dr. Parvizi, "you may also consider approaching the Department of Defense (DOD). For example, there are studies involving various aspects of trauma care, including treating soldiers in the field, that the DOD may find promising. In addition, you might approach the specialty societies for funding. To do so you need to be a member of the society or be eligible to apply. Begin with inquiring as to how much funding is available for the year and how many grants are being awarded that year. Look at their website to determine what type of studies they have funded in the past. If, for example, the American Society for Surgery of the Hand only gives two grants a year, both of which are $15,000 for tendon repair projects, for you to write an application asking for $17,000 to study hand prosthetics is a waste of time."

Funding may be sexy, but you only need your preliminary data to be suggestive. "You must have enough pilot data to approach these funding sources," explains Dr. Parvizi. "And it should be strong enough to point in the right direction. You could also take such data to the Orthopaedic Research and Education Foundation (OREF). While they have a variety of grants, like many others, they have cut back in this economic downturn. If your work is on arthritis or a related condition, you might approach the Arthritis Foundation. And despite the Department of Justice investigations, you shouldn't give up on industry funding. The companies are becoming a little more active now, but are still primarily interested in projects with more immediate commercialization. Regardless of the entity you approach, I recommend that you contact the previous grantees to discuss their experiences and ask questions."

And how to acquire good pilot data? First and foremost, advises Dr. Parvizi, adopt a good mentor. "Find someone who has a long track record of being awarded grants in your area of interest. The second thing is that you must have a clear idea that you know you will be able to address. For example, a researcher may think that by injecting stem cells into the knee he can regenerate cartilage. In the beginning this is just an idea swirling around in his head. To prove it he must undertake an in vitro study and show that chondrocytes like stem cells and will proliferate. The next step would be to design an animal model for osteoarthritis and inject the stem cells into the animals and show a reverse of osteoarthritis. You want to hone it down and be very clear that you are the one who can get the project done."

Dr. Parvizi continues, "Let's say there is a collagen polymer that delivers antibiotics and anticancer drugs and can be utilized in tumor surgery (leaving a stent behind to deliver the drugs). The researchers have preliminary data showing that they can make the collagen polymer. They are tumor surgeons with a busy practice and all they need is an animal model to prove the concept works. The researchers approach the funders saying, 'The collagen polymer can be engineered in our lab; we can put antibiotic and anticancer drugs on it; we have preliminary data indicating that when a collagen polymer is used in an animal model the outcome is better than when a collagen polymer is not used; we have the infrastructure in place to execute a pilot study.' This kind of strategy and organization is what funders are looking for."

But you had better know how to write all of this up. "Grantsmanship is a different animal than writing a scientific paper or review article," says Dr. Parvizi. "It is very difficult as you must anticipate problems and offer strategies to troubleshoot if and when those problems arise. Grants tend to be scored on scientific flow, ease of reading, and organization. I recommend sending your grant proposal to individuals who have obtained grants in your research area in order to get their input and critique. Then there is your mentor and his or her contribution. Although, to begin with, one should probably take a course on grantwriting."

Yet despite your best efforts, you may end up staring at a 'We regret to inform you letter.' Dr. Parvizi: "Don't be disappointed if your first grant proposal does not get funded. It's actually quite rare that someone's first application receives an award of funding. The process is to go back, rewrite, and incorporate the critiques into a revised application."

"And remember that the pilot data must be solid," says Dr. Parvizi, "*not* just a single observation that won't withstand the test of time. If I say that allograft bone is capable of eradicating infection, but I have only seen that in one of two cases (n=2), then I'm way off base. Verify that your writing is clear and simple with no 'razzle dazzle.' Do not contact the NIH study section members—this is seen as highly unprofessional and is in fact illegal. Also, ensure that you have declared any conflicts of interests…

or *potential* conflicts. You don't want to leave anything out, and then later something comes to light. It may affect not only the grant, but your career."

So approach the grant process like you would approach the research process. Be focused, strategic, thorough… and patient.

What Insiders Are Buying AND Selling!

By Robin Young

Insiders buy on the basis of inside information. Which is why, in case you may be wondering, their buy and sell decisions consistently result in returns that outperform the returns generated by those of us who rely on press releases. And the group relying on public information, by the way, includes roughly 90% of all institutional investors.

As it turns out, the fact that insiders routinely outperform the rest of us when buying or selling their own company's stock has been a well-established fact for several decades.

In a landmark study on this subject, researchers at the University of Pennsylvania (Fischer Black and Eugene Fama) found that insiders routinely outperformed the market. One small study conducted by University of Pennsylvania researcher Jeffrey F. Jaffe reported *(The Journal of Finance, Vol, XXXI, No. 4, September 1976)* that when three or more insiders bought their company's stock AND there were NO insiders selling, the stock returns to those insiders in the following six months were, on average, 9.5% greater than the return to the stock market as a whole.

In a much larger study by Hasan Nejat Seyhun of the University of Michigan Graduate School of Business Administration, Division of Research, the results were not as strong but still showed that insiders have the upper hand when it comes to stock market information. *(Why Does Aggregate Insider Trading Predict Future Stock Returns? By HN Seyhun – The Quarterly Journal of Economics, 1992 – www.jstor.org)*

Dr. Seyhun looked at more than 1.5 million insider transactions in publicly held firms over a six-year period. The transactions were conducted by insiders at 790 firms. Dr. Seyhun selected the firms by using a stratified random sampling technique on the size of the firms' equity.

Dr. Seyhun also divided his analysis into four basic holding periods: the first from one day after the insider trading day to 120 days thereafter. The second period was from insider trading day one to 33 days thereafter. The third period was 34 days after the insider trading day to 72 days after the insider trading day. The last period was from 73 days after insider trading to 120 days after the insider trading day.

What did he find out?

The average gross profit ABOVE market returns was 2.5% for the overall period, and it was 1.4%, 0.6%, and 0.5% for holding periods two, three and four, respectively.

All three values for the subperiods are statistically significant given the large sample size.

While the magnitude of the average abnormal profit following insiders' transactions was small, it was statistically significant and also probably illustrated that many of these transactions were due to non-information reasons.

So, it seems, ALL insider transactions still deliver above-average market returns. But when those transactions (as in Jaffe's study) are strongly weighted in one direction or another, then the potential returns are higher (9.5% in the Jaffe study versus 2.5% in the Seyhun study).

The bottom line is that stock prices rise abnormally following insiders' purchases and decline abnormally following insiders' sales.

Since January, then, which orthopedic company managers or directors have been buying shares of their own company and which have been selling?

Buyers first.

Insiders at four orthopedic manufacturers are clearly signaling BUY with their own transactions. They are:

1. **Symmetry Medical.** **14 buys – 0 sells.** Since January fully 14 insider buys have been registered with the SEC versus zero sells. What's really interesting is that up until January, virtually all insider transactions were sells. The surge in buying occurred actually quite suddenly in January and has been sustained ever since.
2. **TranS1.** **10 buys – 0 sells.** Since January records at the SEC show 10 insider buys and zero sells. Someone clearly knows something and likes this stock at these levels.
3. **Alphatec Spine.** **7 buys – 0 sells.** The records at the SEC match with the buzz right now around ATEC. At surgeon meetings, surgeons are now talking about the resurging Alphatec.
4. **Wright Medical.** **4 buys – 0 sells.** As our extremities analyst Dev Joshi noted in a companion article, Wright Medical is increasing its extremities business significantly and is poised, we think, to overtake DePuy to become the largest supplier (measured in sales) of extremity implants and instruments. Buyers, incidentally, included CEO Gary Henley.

Sellers next.

1. **Kensey Nash.** **2 buys – 80 sells.** This list was really something to behold. After poring over 26 company records, when we saw KNSY's record we were impressed. Since January, insiders have filed 80 times to sell stock.
2. **NuVasive.** **0 buys – 16 sells.** One thing to remember, there are many reasons to sell a stock when you are an insider. New house to buy, etc. But there is really only one reason to buy a stock—you think it will go higher. We are reminded that NUVA posted the strongest market share gain of any spinal implant company in 2008. And the trend toward lateral access appears to be accelerating.
3. **MAKO Surgical.** **0 buys – 13 sells.** This Florida-based company is innovating a new computer and robot-guided knee surgery platform. Although there were 13 sells, it was only one seller—the co-inventor of MAKO's technology, Rony Abovitz.
4. **Integra LifeSciences.** **0 buys – 3 sells.** Again, only one seller – the CFO and EVP of Administration, John Henneman III.

Insiders of the following companies either weren't buying or selling or they did both—so no clear direction could be determined.

1. **J&J.** 1 buy – 3 sells
2. **CONMED.** 3 buys – 3 sells
3. **Zimmer.** 0 buys – 0 sells
4. **Smith & Nephew.** 0 buys – 0 sells
5. **Stryker.** 0 buys – 0 sells
6. **Orthofix.** 0 buys – 0 sells. Although it was notable that in the final quarter of 2008, insiders (along with dissident shareholder Ramius) were buying the stock!
7. **Medtronic.** 0 buys – 0 sells
8. **Exactech.** 0 buys – 0 sells
9. **Orthovita.** 0 buys – 0 sells
10. **RTI Biologics.** 0 buys – 0 sells

Anyone can look this up. A website that has organized this handy information is http://www.insidercow.com/.

Who says you can't use inside information to buy stocks? Good hunting all.

Bone Stimulators "Whistleblown"

By Walter Eisner

Are bone stimulating devices reusable and should patients rent or buy them?

Those questions are at the heart of a 2005 whistleblower suit that was unsealed on April 15 in Boston.

The suit was filed by Jeff Bierman, co-owner of a Missouri medical billing service that has been recognized by the government as a "Gold Star Preferred Billing Service."

In amended complaint, Bierman claims that Orthofix, DJO Incorporated, Biomet, and Smith & Nephew sold over $300 million worth of osteogenesis stimulators to Medicare beneficiaries since 1998 in violation of the Federal False Claims Act. He's suing, on behalf of the government, for triple damages and $11,000 for each false claim made to Medicare.

The same day the suit was unsealed, some of the companies named in the suit announced that they had received subpoenas from the Justice Department in connection with the suit. This indicates that the government is still considering whether or not it will join the suit. The issuance of subpoenas means that the Justice Department is serious.

This whistleblower case doesn't have the juicy details of alleged bribery, payoffs and sales reps behaving badly at strip clubs, but it does have the mundane details of how sales reps from the companies advised their physician and hospital customers how to fill out Medicare claims forms. The reps, claims Bierman, advised providers to fill out CMS forms so that the bone stimulating devices would be claimed as a purchased instead of a rented device.

In 2003 Bierman had a physician client looking to diversify and expand his practice. The physician wanted to look into becoming a supplier of osteogenesis stimulators and other medical equipment prescribed to his patients, and he asked Bierman to look into it.

After talking to EBI (Biomet subsidiary) and Orthofix and being told that their devices were not generally available for sale to suppliers, he got curious because that seemed very unusual to him. He checked with his hospital clients and looked over their CMS claims documents. He determined that the devices should have been billed as rentals instead of purchases.

Bierman then filed suit on behalf of the federal government, 18 states with Medicaid programs, and the cities of New York and Chicago.

Orthofix, DJO, Biomet, S&N Targeted

The defendants in the case are:

Orthofix International N.V.

Orthofix Stimulators

Orthofix markets the Spinal-Stim, Physio-Stem and Cervical-Stim osteogenesis stimulators. The company received FDA clearance to begin marketing the Cervical-Stim for use in the cervical spine in 2005.

This isn't the first time that Orthofix has been involved with the government over allegations of false claims regarding its stimulation devices.

In September 2003, the government announced that Orthofix agreed to pay a $1.5 million settlement in a whistleblower suit brought by former Orthofix employee Karen Neel. That suit was brought because Orthofix filed claims with the Department of Defense's health care

program for use of its device to treat the cervical spine, an off-label use at the time. That use is now approved.

OrthoLogic Corp.

Prior to 2003, OrthoLogic sold the SpinaLogic and OL1000 Bone Growth Stimulators. After 2003, OrthoLogic sold its stimulator business to dj Orthopedics (now DJO Incorporated) for $93 million.

DJO Incorporated

SpinalLogic Stimulator

DJO sells the OL1000 and SpinaLogic stimulator through its CMF Bone Growth Stimulators Division. DJO was acquired by Reable Therapeutics in 2007. The Blackstone Group bought Reable in 2006.

Biomet

EBI (and Bioelectron, which EBI bought in 2000) is a wholly owned subsidiary of Biomet and makes the SpinalPak and OrthoPak stimulators.


SpinalPak® II Spine Fusion Stimulator

Smith & Nephew

EXOGEN System

Smith & Nephew makes the EXOGEN Bone Healing System, an ultrasound stimulator that transmits a low intensity ultrasound signal to the fracture site through coupling gel.

Purchase vs. Rental

Bierman claims that the evidence he presents shows that the devices were rarely used more than a few months and that those devices could be reused. According to Bierman, the companies pursued this "purchase" business model to bolster their profits and offered kickbacks to beneficiaries and physicians in the form of waiving co-pays and offering free devices to physicians to give to their indigent patients.

This case reminds us of the whistleblower suit regarding billing procedures for a Kyphon device, which was settled by Kyphon before it was acquired by Medtronic.

Medicare Coverage

Osteogenesis stimulator devices are lightweight, battery operated devices worn externally by patients for a few hours each day. They promote bone growth and healing by inducing weak electromagnetic fields or ultrasonic waves in the bone. The FDA approved them in 1979 and they are covered by Medicare under codes for long bones and the spine.

The length of time needed to achieve bone healing varies from patient to patient. Bierman cites clinical studies which show that most patients use the devices for periods of between three and six months. After a physician has determined whether or not the device has worked, the use of the device is discontinued. Orthofix and S&N offer money-back guarantees if their devices don't work within six months.

Medicare coverage for stimulators has been going on since 1980 and was originally limited to nonunion of long bone fractures. Coverage was expanded in 1996 to include spine fusion. In 2001 ultrasound treatments were added. In 2005 the cervical area of the spine was added.

Excessive Charges

In the suit, Bierman says the defendants represented that the devices should be paid as purchase items, "when in fact, and to the defendants' knowledge, they should have been billed as rental items." He further alleges that the devices were sold for periods of time "that were far in excess of the medical needs of the patients, and in the vast majority of cases, the useful lifetime of the devices themselves."

Medicare pays for stimulators on a monthly rental or purchase basis. When Medicare pays on a rental basis, the payments eventually stop. According to Bierman, based on a fee schedule, the purchase price consistently is approximately 10 times more than the rental price. Therefore, a device "would have to be used for a period of 10 months or more for the accrued rental payments to reach the purchase price."

But since the devices are typically used for only three to six months, the rental charges would never reach the purchase price.

The significance of submitting documents to Medicare under a purchase claim is the difference between a $360 per month rental charge and a $3,600 purchase price.

DJO's and Biomet's devices contain a computer chip that is programmed to cause the device to automatically deactivate after nine months of regular use. Yet, Bierman says that in the company's 1979 Premarket Approval Application (PMA), Biomet stated that "routine clinical observations over five years indicate this device causes no known risks."

Bierman claims that 70,000 new stimulators, which federal state and local governments bought on behalf of patients are now "sitting idle in the homes of those patients or have been thrown out or otherwise disposed of." The suit states that some devices sell on eBay for as little as $50.

Misleading Providers

Orthofix, Biomet and DJO misled physicians and their clerical staff into filling out documents with a code that indicates the devices "are medically necessary for the patient's lifetime or for periods of time that exceed the devices' nine months of useful life..," alleges the suit. Physicians' clerical assistants typically rely on the equipment suppliers' representatives for advice on how the reimbursement forms should be completed.

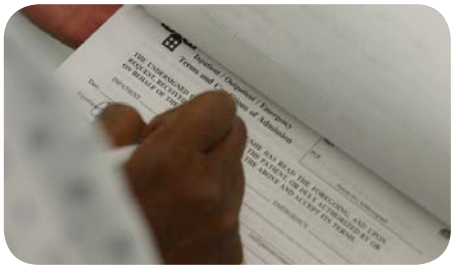
These reps, says Bierman, misled the staffs by instructing them to specify a number of months on the forms that would support payment for the item as a purchase.

The suit says that the defendants "routinely claim that the devices have been designated by the FDA as devices that are disposable and can only be used by one patient." Bierman says that the defendants cite the fact that the devices deactivate after a period of time and cannot be reused. Apparently, says the suit, on that basis the concept of a single-use device is incompatible with rental.

Bierman claims that an Orthofix rep told him, after Bierman pointed out that Medicare had assigned a rental code to the device, that "nobody honors it."

Single-Use Devices

The FDA parlance for a device that can be used by only one patient is "single-use device" (SUD).



Bierman says the SUD designation is NOT an FDA requirement, but it is applied at the discretion of the device manufacturer and many SUDs are reprocessed for patient use in compliance with FDA rules.

SUDs are frequently misdesignated by manufacturers to boost profits, says the suit. Bierman cites in the suit a June 2000 GAO report that stated:

"Many health care professionals believe that some SUDs can be reused. They told us they distrust the single-use label for some devices because (1) FDA cannot require manufacturers to support the designation of a device as single-use; (2) they perceive that manufacturers have an economic incentive to market devices as single-use that could just as well be sold as reusable; and (3) FDA's approval requirements for SUDs are less extensive than those for reusable devices...."

Bierman alleges that the single-use designation for osteogenesis stimulators is economically, not clinically, motivated. The suit says that the devices are non-sterile, they are worn externally, often over clothing, and any electrodes intended to be attached to the skin are disposable.

The suit cites a 1993 *St. Petersburg Times* article that stated:

"Ron McNeill, sales and marketing director for Bioelectron, said the company doesn't plan to ask the FDA to allow multiple-patient use for two reasons: It is concerned about inappropriate use, and it would lose its profit margin.... 'We think we're already saving an individual money.'"

Company Impact

At this point, the financial impact of the suit on the public companies involved is unknown.

Senior Analyst Mike Matson of Wachovia estimates that Orthofix generated around $170 million (33% of total revenues) in sales from its stimulators in 2008. He estimates that Smith & Nephew generated around $120 million (3% of total revenues) in sales from its osteogenesis stimulation devices in 2008.

But, says Matson, since gross margins on these devices are very high (around 90%), the products likely make up a much larger portion of these firms' earnings. Matson thinks that deferred prosecution agreements are one potential outcome of this suit, although it may take years for this to play out.

He downgraded Orthofix on April 17, citing the subpoena overhang as one reason. The company's stock price dropped by 10% that day.

On a related note, the U.S. Attorney in Boston, Michael Sullivan, submitted his resignation the same day the subpoenas were announced. President Obama will appoint a successor. Given the history of health care investigations out of Boston, we think the next U.S. Attorney may be even more aggressive in prosecuting health care fraud.

In the meantime, if you know anyone in need of a bone stimulator, suggest a rental or eBay.

company news

DePuy's Spine Bolsters J&J's Quarter

Johnson & Johnson announced sales of $15 billion for the first quarter of 2009, a decline of 1.2% on an operational basis to last year's first quarter.

Among its three divisions, only the Medical Devices & Diagnostics division posted positive operational growth of 3.1%. Total division sales of $5.5 billion decreased 2.9% versus the prior year. The division can thank DePuy Spine 13% operation growth for that.

Their confidence in orthopedics was evident when they told analysts that orthopedics and surgery performed "very well" in the face of economic challenges and helping to offset declines in more economically sensitive parts of their business.

The company told analysts during an April 14 conference call that the primary contributors to the operational growth included Ortho-Clinical Diagnostics' professional products; Ethicon's surgical care products; Ethicon Endo-Surgery's minimally invasive products; and DePuy's orthopedic joint reconstruction, spine, sports medicine, and trauma businesses.

DePuy had operational growth of 7.3% when compared to the same period in 2008 with the U.S. growing 8% and outside the U.S. growing by 6.4% operationally.

DePuy Spine Inc.
a Johnson & Johnson company

DePuy's first quarter's orthopedic sales growth on an operational basis showed the following:

Hips	9%
Knees	3%
Spine	13%

During a question and answer period, Dominic Caruso, the company's top financial officer acknowledged some slow down in their knee business, but was happy with their spine results.

He pointed out that the company had projected that the joint reconstruction business overall would just be a point or so slower then the prior year and it's what they're seeing as they look at the marketplace.

Johnson & Johnson devotes very little time or detail about its orthopedics business during quarterly conference calls with analysts. The health care company is such a giant enterprise that most of the discussions with analysts are about foreign currency exchanges, taxes, and other issues more related to stock price than the company's business.

But from what we heard the company say, orthopedics is beefing up the parent company. Perhaps one day, their orthopedics business will leave home.

—WE (April 15, 2009)

Intrinsic and Sidow Go European

Woburn-based spinal medical technology company Intrinsic Therapeutics, Inc. reported on April 14 that it had received its CE mark to market its Barricaid anular prostheses in the European Union.

Barricaid Anular Reconstructive Device

The Barricaid is used in the reconstruction of soft tissue in the spine as part of a standard discectomy procedure.

According to Barry Sands, Vice President Regulatory, Clinical and Quality Affairs at Intrinsic, the device is a partial disc prosthesis that enables surgeons to reconstruct the anulus—the fibrous ring surrounding the outside edge of the intervertebral disc—in patients with lumbar disc herniations and sciatica.

company news

The company writes on its Web site that "Ruptures of the anulus, the outer wall of the intervertebral disc in the spine, can result in disc herniations and related pain including sciatica. While patients frequently experience significant pain relief immediately following surgical discectomy, these ruptures are commonly left open. This contributes to recurrent sciatica from reherniation which has been reported in up to 27% of patients; and is particularly common in patients with larger anular defects. Further, disc height loss following discectomy has been reported in 98% of patients and has been linked to accelerated degeneration and increasing low back pain."

The company Board includes a well know name in spine, Kevin Sidow.

Sidow joined their Board last September after many years with DePuy and St. Francis Medical. He led St. Francis' successful acquisition of Kyphon. He is currently heading Moximed, a start-up orthopedic company on the West Coast.

—*WE (April 15, 2009)*

legal & regulatory

Sullivan Nabs Third Stryker Rep

U.S. Attorney Michael Sullivan's office in Boston announced another guilty plea to "felony misbranding" by a third former Stryker Biotech sales reps on April 14.

Stryker Biotech is where, among other things, OP-1 is manufactured and sold under a Humanitarian Device Exemption for certain uses approved by the FDA.

At the plea hearing for former sales rep, Shane Doyle, the government told the judge that Doyle promoted a combination of the HDE devices with a bone void filler that was not approved by the FDA.

Prosecutors said that Doyle, "in his capacity as a territory manager for his employer, promoted the use of the devices in a manner that was different from its FDA approved use; namely he promoted a combination of the HDE devices with a bone void filler, and in furtherance of that promotion provided mixing instructions to surgeons, medical technicians and others."

On March 6, Sullivan sent Stryker a letter telling them that they are the target of a federal grand jury investigation for the alleged illegal promotion of OP-1 and Calstrux.

Apparently the prosecutor believes he has enough evidence to return an indictment against the company itself.

The questions now are how high does this go and where does it stop?

Stryker's efforts to get OP-1 to market are slowly becoming legendary. The criminal investigation and guilty pleas comes on top of a "No" recommendation for approval from the FDA Ortho Panel and FDA warning letters for their plant in Massachusetts. Warning letters and criminal investigations are a high price to pay for a product that has yet to be approved by the FDA.

The agencies involved in this case are the FDA - Office of Criminal Investigations and the Department of Health and Human Services, Office of Inspector General of the FBI and the U.S. Attorney's Office in Boston.


U.S. Attorney Michael Sullivan

With the retirement of

company

Christopher Christie in New Jersey, Sullivan is becoming the most active U.S. Attorney investigating and prosecuting cases in orthopedics.

Stryker's quarterly conference call with analysts on April 20 will give company CEO Stephen MacMillan a chance to tell the market what comes next for OP-1.

—*WE (April 15, 2009)*

Zimmer Sued Over Durom Hip

The Madison/St. Clair Record reported on April 13 that 42 people from around the country filed a $2.1 million suit on April 8 against Zimmer in St. Clair County Court in Illinois.

They're suing Zimmer over injuries they claim occurred after having the Durom Hip implanted.

Lawrence Dorr, M.D. first brought up problems with the hip last April. Zimmer responded by retraining surgeons in the surgical techniques for implanting the device.

The suit alleges that early in 2008, Dorr reported his concerns to executives at Zimmer. However, the executives blamed Dorr's surgical techniques on the problems his patients were experiencing.
The plaintiffs say that Dorr is "a veteran of more than 5,000 hip replacement surgeries, [and] is one of the most renowned surgeons in the world."

St. Clair County Courthouse, Illinois

Furthermore, they say after Dorr took his concerns to the American Association of Hip and Knee Surgeons, Zimmer finally announced it was investigating Dorr's complaints. Still, the company did not suspend sales as doctors recommended.

The suit continues that Zimmer's own investigations revealed Durom System failure rates as high as 5.7% at some clinics.

Because of their ongoing problems with the Durom System, plaintiffs claim they take pain medication for their constant pain. They contend that they also incurred medical, monitoring, rehabilitative, and pharmaceutical expenses and may have lost income, lost opportunity, lost family and social relationships, and may have been prevented from pursuing their normal activities.

Finally, say the plaintiffs, Zimmer represented its product as safe to customers but "failed to conduct sufficient testing, failed to include adequate warnings about potential risks and serious side effects and failed to advise the FDA, the health care industry and the public about adverse reports it had received."

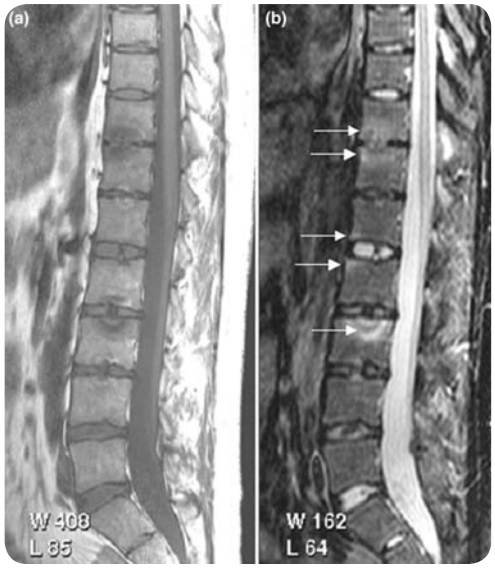
—*WE (April 16, 2009)*

large joints

Psoriatic Arthritis Drug Tops Placebo

In a recent study published in *Arthritis & Rheumatism* (2009; 60: 976-86), researchers who set out to assess the effectiveness and safety of golimumab for psoriatic arthritis (PsA), found that the drug outshone placebo. The study was structured such that PsA patients with at least three swollen and three tender joints and active psoriasis either received placebo injections (n=113) or golimumab 50 mg (n=146), or golimumab 100 mg (n=146) every 4 weeks.

The researchers, led by Arthur Kavanaugh, M.D., of the University of San Diego, used the following as measures of efficacy: the American College of Rheumatology 20%



MRI of Psoriatic Arthritis

large joints

improvement criteria (ACR20), the Psoriasis Area and Severity Index (PASI) in patients in whom at least 3% of the body surface area was affected by psoriasis at baseline, the Short Form 36 Health Survey (SF-36), the disability index of the Health Assessment Questionnaire (HAQ), the Nail Psoriasis Severity Index (NAPSI), the physician's global assessment of psoriatic nail disease, and enthesitis (using the PsA-modified Maastricht Ankylosing Spondylitis Enthesitis Score [MASES] index).

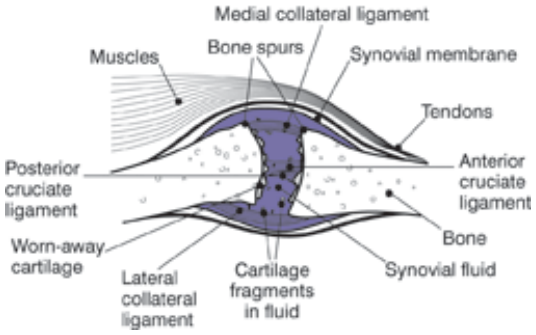
Taking measurements at week 14, the researchers found that 48% of all patients receiving golimumab, 51% of patients receiving golimumab 50 mg, and 45% of patients receiving golimumab 100 mg achieved an ACR20 response (the primary end point), compared with 9% of patients receiving placebo. Among the 74% of patients in whom at least 3% of the body surface area was affected by psoriasis at baseline, 40% of those in the golimumab 50 mg group and 58% of those in the golimumab 100 mg group had at least 75% improvement in the PASI at week 14 (major secondary end point), compared with 3% of placebo-treated patients. Investigators found significant improvement for other major secondary end points (the HAQ and the SF-36), the NAPSI, the physician's global assessment of psoriatric nail disease, and the PsA-modified MASES index in each golimumab group compared with placebo. This efficacy was maintained through week 24.

Commenting to *OTW,* Dr. Kavanaugh stated, "Psoriatic arthritis is being increasingly recognized as a severe type of arthritis that, untreated, can result in significant deformity and hence the potential for orthopedic intervention. Fortunately, the introduction of novel therapies has allowed improvement for a number of affected patients."

—EH (April 15, 2009)

New Guides on Knee OA

Cartilage may wear out, but those advocating for osteoarthritis patients do not. According to an article on Medical News Today ("New Plain Language Guide On Treatments For Osteoarthritis Of The Knee," April 15, 2009), the Agency for Healthcare Research and Quality (AHRQ) has rolled out two new guides that discuss the effectiveness, safety, and adverse effects of various treatments for osteoarthritis (OA) of the knee. These documents—one targeted at patients and another meant for clinicians—cover topics such as glucosamine and chondroitin, fluid injections, arthroscopic surgery, pain medications, and other approaches.



Joint with Severe Osteoarthritis

The guides, produced by the Agency's Effective Health Care program, summarize the results of a new report that addresses several issues, including the effectiveness of glucosamine and chondroitin for knee OA, whether losing weight and staying active makes a difference, and whether there are side effects and risks associated with shots or arthroscopic surgery.

The patient guide defines OA and provides answers to basic questions that will hopefully guide patients through discussions with their clinicians. The provider guide includes the same information but is designed for people with a clinical background; it contains a confidence scale that rates the available evidence.

large joints

Speaking of evidence, as indicated in the article, there is evidence pointing to the possibility that some common treatments for knee OA are not helpful and may have side effects. Glucosamine and chondroitin, for example, were not shown to offer improvement and can cause upset stomach, diarrhea, and headache. The report also noted that fluid injections don't reduce pain or improve movement and can cause swelling, minor infection, and pain. Another finding was that arthroscopic surgery does little to reduce the pain of knee osteoarthritis and can result in more pain, swelling, infection, and blood clots in the legs.

The guides also note that physical activity can help reduce pain and allow for easier joint movement, and that weight loss takes stress off of knees. Also, says the article, some prescription and over-the-counter medications, including NSAIDs, have been found to help relieve the pain of knee osteoarthritis.

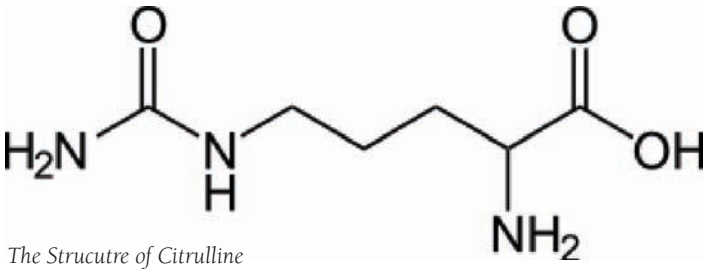
—EH (April 15, 2009)

Twin Study on Genes, RA

Below sea level, but on top of their game. Researchers from The Netherlands—with a little help from twins—are shedding light on risk factors for autoantibody-negative rheumatoid arthritis (RA) risk factors. As indicated in the news release, most of the genetic risk factors identified to date have been associated with autoantibody-positive RA, which affects about two-thirds of RA patients. Separating this out from its less destructive "cousin," autoantibody-negative RA, is becoming increasingly important.

The researchers, led by Diane van der Woude of Leiden University Medical Center in The Netherlands, were assisted in their work by 148 twin pairs in which one twin had RA. Participants were tested for anti-citrullinated protein antibodies (ACPAs), which are used because of their specificity and predictive value and for HLA SE (human leukocyte antigen shared epitope) alleles, the most important genetic risk factor for RA.

The study, published in the April issue of *Arthritis & Rheumatism,* found that ACPA-positive and ACPA-negative RA



The Strucutre of Citrulline

are associated with different genetic and environmental risk factors, and may in fact constitute distinct entities with different disease mechanisms. The results also showed that the variation in disease susceptibility that can be explained by genetic factors was about 66% for both ACPA-positive and ACPA-negative RA.

The HLA SE alleles contributed 11% to the total genetic variance of RA, 18% to the genetic variance of ACPA-positive RA, and only about 2% to the genetic variance of ACPA-negative RA. In the past, HLA genes were estimated to contribute 37% to the overall inherited risk of RA.

While new genetic risk factors for RA have recently been identified, like the HLA SE alleles, they are predominantly associated with ACPA-positive RA. This may be because studies typically include mainly ACPA-positive patients. The authors suggest that new studies incorporating more ACPA-negative patients will show that these risk factors also predispose individuals to this variant of the disease.

According to the news release, the known risk factors for ACPA-negative disease do not confer as high a risk of developing RA as the HLA SE alleles. Given the finding of the similar heritability of ACPA-positive and ACPA-negative RA, the authors note, "This means that genetic predisposition also plays an important role in the pathogenesis of ACPA-negative RA, for which most individual genetic risk factors remain to be identified."

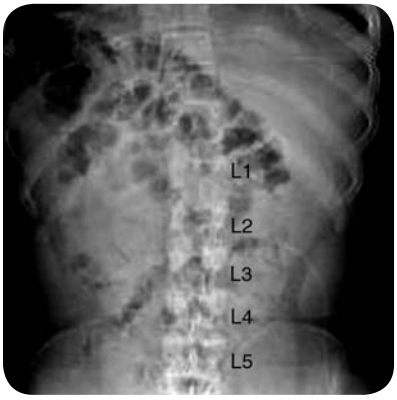
—EH (April 17, 2009)

spine

The Complexities of Treating Dwarfism

A recent literature review published in the April 2009 issue of the *Journal of the American Academy of Orthopaedic Surgeons* brings to light the complexity of managing dwarfism, and in particular, achondroplasia, the most common form of dwarfism.

Regarding limb lengthening as a treatment for achondroplasia patients, for example, mixed results are the reality.



© Journal of the American Academy of Orthopaedic Surgeons, 2009

"Not only is limb lengthening a huge time commitment for the families involved, but children with achondroplasia are taken out of the environment where they play, interact and have fun to be placed in treatment for several years," said study co-author Michael C. Ain, Surgery and Neurosurgery, Johns Hopkins Hospital, Baltimore, Maryland, added, "At the end of the day, these kids may be able to reach a higher shelf, but their level of physical activity in both athletic and sporting events may be very limited or not existent at all."

On another note, although the researchers found a number of studies indicating that height increases are possible with growth hormone injections, they question whether the average height increase of six to eight centimeters is worth undergoing five years of daily injections. After an initial increase in height, such growth stops once the treatments end. Also less than promising is that these hormone injections may cause or accelerate symptoms of spinal stenosis. Surgical treatments can produce greater increases in height, but also carry a much higher risk of complications.

The authors also found that the earlier one can diagnose and treat the manifestations of achondroplasia—sometimes even prior to the point of becoming symptomatic—the better things could be later in life for these patients. For example, accompanying achondroplasia is sometimes a condition known as stenosis of the foramen magnum, a situation where the hole in the base of the skull that allows the spinal cord to be connected to the brain is too small. This compresses the brain and cord, resulting in developmental delays and possibly even death.

© Journal of the American Academy of Orthopaedic Surgeons, 2009

As indicated in the news release, symptoms of stenosis of the foramen magnum usually present themselves in the first two years of life, but may not appear until later, when developmental delays become apparent. Therefore, the American Academy of Pediatrics recommends that all infants with achondroplasia be screened via computed tomography scan or magnetic resonance imaging, so that surgery can be performed.

"With so many medical specialties involved, each needs to be aware of all of the symptoms of achondroplasia," stated study co-author Eric D. Shirley, M.D., in the news release. Dr. Shirley, Lieutenant Commander, Medical Corps, United States Navy, and attending pediatric orthopaedic surgeon, Naval Medical Center Portsmouth, Portsmouth, Virginia, added, "Many of these conditions are interrelated."

Many children with achondroplasia may also develop thoracolumbar kyphosis, evident when the child appears to slump forward instead of sitting upright. While this oftentimes

spine

improves as the child learns to walk, in the event that it doesn't, it can result in a severe curvature of the spine and other medical and skeletal conditions. Early interventions such as bracing, increasing trunk strength, or even spinal fusion surgery, may be required to ensure that the child can sit and walk properly.

Commenting to *OTW,* Dr. Ain stated, "Parents should be looking to see that infants and children are meeting or achieving motor milestones for various ages. For example, an unaffected child should be able to sit upright at age four months. Achondroplasts also have age appropriate milestones. Also, parents should be sure that children are sleeping well at night and not having any breathing episodes during their sleep."

As for the emotional issues related to this condition, Dr. Ain told *OTW,* "Orthopaedic surgeons do in fact look for psychological trouble, and stress that achondroplasia is in fact a condition, not a disability. A child can grow up to do whatever they want to do. The condition should not be a limiting factor in one's life."

—EH (April 14, 2009)

Orthofix Pens Spine Agreement

Nothing like working with a trusted old friend. Orthofix International N.V. has announced that it has signed a new agreement with the MBA Group (MBA), with whom it has worked for more than 20 years. The new five-year arrangement is meant to expand the distribution of Orthofix's spine implant and biologic devices in the UK.

MBA, the largest private independent distributor of orthopedic devices in Europe, generated more than $100 million in total sales in 2008. Orthofix's exclusive distributor of orthopedic devices in Spain and Portugal for more than 20 years, MBA expanded their relationship with Orthofix in 2008 and became the company's exclusive distributor of spine implant products in those countries.

"MBA has been a key partner during Orthofix's growth over the last 20

years and, after successfully expanding our relationship last year to include the distribution of our spine implant products in Spain and Portugal, we are excited to further expand our spine distribution agreement with them into the important U.K. market," said Alan Milinazzo, President and CEO of Orthofix International, in the news release.

Paul Griffin, MBA's Chief Operating Officer and a member of their Board of Directors added, "MBA's excellent and long-standing relationship with Orthofix, together with our very successful 2008 spine launch led to this latest agreement after the management teams from both organisations met to explore opportunities to further expand our mutually beneficial strategic partnership."

Mr. Griffin also said in the news release, "The U.K. is one of Europe's top five spine markets, and by combining Orthofix's extensive spine product portfolio with MBA's highly experienced UK management team and marketing know-how, we feel confident in our plans to develop a very successful business together in this key market. MBA has an excellent and long-established international reputation for marketing

spine

and distributing medical devices, an unparalleled reputation for customer service in Spain, Italy and Portugal and is now ready to expand these services into other key areas in Europe."

—*EH (April 15, 2009)*

Minimally Invasive Spine Surgeons Meeting

You will walk away from the International Intradiscal Therapy Society meeting (in Phoenix May 19-23) with at least three important new pieces of information that are practical and can be incorporated into your spine practice to benefit your patients.


Anthony T. Yeung, M.D.

Anthony T. Yeung, M.D., the society's Executive Director guarantees it.

Reimbursement declines but patient demand for relief of back pain increases, says Yeung. "What [attendees will] learn will be reproducible and cost effective, especially if they attend the cadaver demonstration and live surgery pre-meeting workshop, taught by leaders in the field of MIS techniques focusing on minimally invasive foraminal decompression and fusion."

Attendees will learn what can be done to surgically address the pain generator in the spine, including treating failed back surgery syndrome from lateral stenosis, foraminal osteophytosis, and recurrent HNP.

The end result of that, says Yeung, is that you have a "loyal patient rather than just a satisfied patient."

Yeung says that we are undergoing a very rapid evolution of minimally invasive spinal diagnostic, therapeutic, and minimally invasive surgical techniques. "There is a special need for a forum for scientific discourse with debates...where ideas are welcomed without medical 'censorship' simply because their ideas are not considered "mainstream."

We've written about this meeting before. It's is one of those smaller meetings we like where you can take time to talk to colleagues and leaders in their field.

The society was founded in 1987 and has evolved into a MIS surgery society. Its members are primarily orthopedic surgeons, neurosurgeons, anesthesiologists, radiologists, and rheumatologists dedicated to treatment, research, and education involving intradiscal spinal therapies.

"The society will continue to focus on what is best and most beneficial and cost effective for the patient, both from the risk/benefit ratio aspect or cost/benefit ratio. I will continue to focus on true MIS surgery, connecting pain management with MIS surgery focused on the pain generator," concluded Yeung.
Hansen Yuan, M.D., will lead the nucleus replacement and annular repair session, while Wolfgang Rauschning, M.D., and Alex Hadjipavlou, M.D., will be talking about the degenerative process in the spine and focus on pain generators.

Dr. Yeung will talk about the efficacy of foraminal endoscopic decompression and nerve ablation in treating painful degenerative conditions of the lumbar spine.

The rest of the faculty for the meeting includes:

- Thomas Apostle, D.O.
- Gun Choi, M.D., Ph.D.
- Akira Dezawa, M.D., Ph.D.
- Daniel Farkas, Ph.D.
- Justin Field, M.D.
- Avrom Gart, M.D.
- Daniel Gastambide, M.D.
- Satishchandra Gore, M.D.
- Eric Gozlan, M.D.
- Thomas Hoogland, M.D.
- J. Patrick Johnson, M.D.
- Martin Knight, M.D., FRCS
- Sang Ho Lee, M.D., Ph.D.
- Christopher Meredith, M.D.
- Chan-Shik Shim, M.D., Ph.D.
- William Tobler, M.D.
- Anthony T. Yeung, M.D.
- Christopher A. Yeung, M.D.
- Hansen Yuan, M.D.
- Phil Yuan, M.D.
- Chris Zarembinski, M.D.

You can link here to read more about the meeting: http://www.iits2009.org/index.php

—*WE (April 16, 2009)*

4th ANNUAL SPINE TECHNOLOGY SUMMIT — LONDON

SPINE TECHNOLOGY SUMMIT

APRIL 27, 2009

East Wintergarden, Canary Wharf London

Presented by:

P&M CORPORATE FINANCE, LLC

INVESTMENT BANKING FOR THE MIDDLE MARKET

Robin Young

Ry Publications

RESERVE YOUR SPOT AT STS 2009

Meet us at the East Wintergarden at Canary Wharf Convention Center in London for a comprehensive lineup of spine experts representing more innovations, technologies, industry sectors, and networking opportunities than ever before.

Don't miss 2009's premier spine technology meeting for investors, surgeons, and spinal implant and instrumentation companies.

- 35 corporate presenters and approximately 300 attendees
- Tracks focusing on new materials (biomaterials, metal coatings, and bone void fill materials) and products for the aging spine
- Valuable market data from P&M Corporate Finance, the new organizer and host of the Summit, and Robin Young, its founder and co-host
- In-depth surgeon panels
- Closing networking reception with additional presentations from sponsors

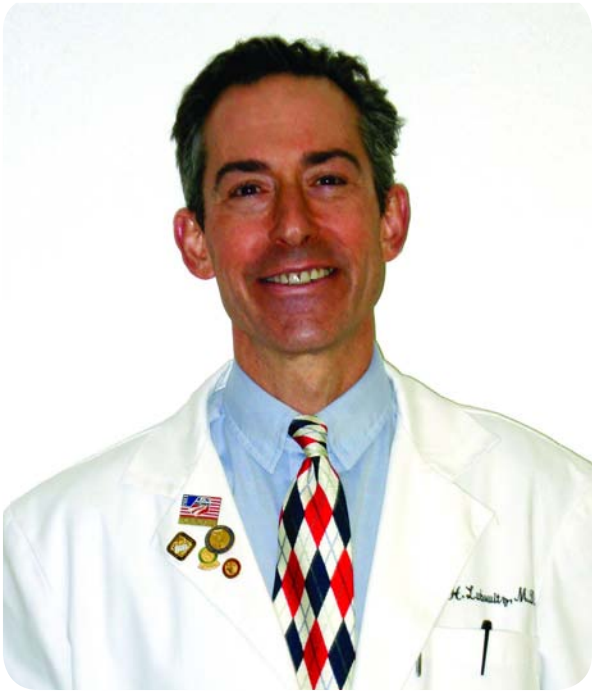
Pre-register now and save!

SAS Members: $650
Advance Registration: $950

To learn more and register, visit spinetechsummit.com.

The Picture of Success: Dr. James H. Lubowitz

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



If a patient wants to discuss Oscar Wilde or deliberate about Roman sculpture, Dr. James H. Lubowitz, founder of the Taos Orthopaedic Institute in New Mexico, is up to the challenge. But this native of suburban Philadelphia could never have run from a medical career…his family history wouldn't let him. Dr. Lubowitz laughs, "You know the old joke—the Jewish parents say to the son, 'So, what do you want to be? A doctor or a lawyer?' My medical path was also influenced by the fact that my grandfather was the first orthodontist in Philadelphia and my father was an ophthalmologist. Their first goal for me was that I attend a top college; fortunately I had a high aptitude for academics and a disciplined personality."

A twist of fate (and of a lower extremity) would help lead James Lubowitz to orthopedics. "As a result of my time on the soccer field in high school, I had a minor ankle fracture, and went to see an orthopedist who worked with the Philadelphia 76ers. This led to a fascination with sports medicine that I carried into my undergraduate days at Harvard. I continued playing sports, including squash, knowing that medical school was in my future. Because of this, I chose to take a minimum of premed courses so that I could round out my studies with things such as English literature and art history. Throughout the years I have found that such knowledge helps me communicate with my patients in a more thorough manner. It has also made me a better writer and editor in that I can think critically in a different way from a pure scientist."

But time spent meditating on Mycenaens meant less time for polymers. "When I arrived at the University of Pennsylvania for medical school, I was surprised how much catching up I had to do. Having been an art history major, unlike my new classmates, I didn't have the benefit of having taken anatomy, biochemistry, histology, etc. And it was shocking to find that after class we'd have to do clinic time, followed by an evening of reading and studying. Despite the rigors of the program, I enjoyed it, in part because 'Penn' was one of the first schools to diversify in terms of gender and race."

To a large extent, weather would make the decision as to which residency program Dr. Lubowitz would attend. "I did my interviews in January, visiting the Mayo Clinic and Hospital for Special Surgery, both of which were blanketed in snow. When I stepped off the plane for my interview at U.C.L.A., however, it was 72 degrees and sunny. Then, after running into a friend from college, something just clicked. My transition was smooth and I felt well prepared."

Although the weather was easy on Dr. Lubowitz, his coursework was rigorously: "The training at U.C.L.A. was tough, with long hours and high expectations. I worked with an orthopedic oncologist named Dr. Jeff Eckhardt, an incredibly thorough physician who never missed anything. He always dictated progress notes in front of the patients, thus allowing him to review things one more time with them. I saw how impressed the patients were and have, when possible, done this myself. In the joint replacement arena I learned from Dr. Burt Thomas, an extraordinarily nice guy who achieved excellent outcomes, never rushed his teaching, and checked everything in the OR twice. Spine guru Dr. Rick Delamarter was just starting out when I was in my residency, and taught me the value of being incredibly organized and efficient. While spine was not my primary area of interest, I was still able to learn the fundamentals from him."

To refine and pull together all that he had learned, Dr. Lubowitz returned to his home turf of Philadelphia. "My choice for a fellowship was The Rothman Institute, which was at that point affiliated with the Pennsylvania Institute. I spent time with the renowned Dr. Arthur Bartolozzi, who has this magical allure that makes patients fall in love with him. They are willing to patiently wait to see him, even if it means having to spend extra time in the waiting room. Dr. Mike Ciccotti, a physician who had just started his practice, was a great role model for how to make the transition from fellowship to practice. The most important thing he conveyed about this was achieving a balance between teaching, research, patient care, and family. Dr. Larry Miller, now Chief at Cooper University Hospital across the river in New Jersey, was a sublime technician who measured his surgeries in millimeters, while Dr. David Rubenstein, who remains at Lankenau Hospital, was the height of efficiency."

"It was a very hands on, high volume experience with great training in knee and shoulder arthroscopy and open sports surgeries," adds Dr. Lubowitz. "Perhaps the most important thing I walked away with was the concept of subspecialization. Their focus on knee and shoulder, accompanied by a meticulous approach to surgical techniques, led me to see that subspecialization was indeed the wave of the future."

Leaving fellowship, the last official step in the metamorphosis of becoming a fully trained orthopedist, can be jarring to say the least. Dr. Lubowitz: "In the months leading to practicing on my own, I focused on developing autonomy and confidence in diagnosis and surgical treatments. You are also expected to display a higher level of professionalism, in part regarding how you communicate with patients. Being involved in medical training is such a long process that you essentially have a prolonged latency or childhood compared to other professions. You're not ultimately responsible for patients for quite awhile, but this ultimate lack of accountability evaporates after fellowship."

Getting used to this level of responsibility, says Dr. Lubowitz, is not something one accomplishes by reading a textbook. "The higher level of stress that comes with your new role is not something that is easy to prepare for. You must experience it yourself; no one can really explain it. There are tools, however, that can alleviate some of the anxiety, including positivity, something that can be helpful, for example, when you get frustrated with other personnel. Conflict is not in the best interest of the patient so we must learn to keep our emotions in check and find a way through the issues. Years ago surgeons would scream and even throw things when they were upset, behaviors that are no longer tolerated."

If there was going to be any screaming, Dr. Lubowitz thought, the only appropriate place would be on a double-black diamond trail. "When I began looking for jobs I focused on places that had a mountain ski resort, and where I could be clinically productive and academically involved with fellows. I was interested in a ski resort for professional, athletic, and social reasons, and because I was tired of pollution and traffic. I also had the impression that a lot of orthopedic surgeons worked hard for 50 weeks a year so they could ski one week a year and go to the beach one week a year, so I figured, 'Why not live in a ski area?' Besides, I knew that because Western mountain resort areas have such active populations, they were a proven model for orthopedic sports medicine as far as staying clinically busy. Being academically productive was not difficult either because there tends to be a lot of sports medicine training programs in these areas."

So in 1994 Dr. James Lubowitz found his way to Taos, New Mexico where he would display a bit of moxy in unveiling his future plans. "It was a small town with a hospital that was old and even crumbling in some parts. They were just opening a new hospital with the idea that their marquis

service would be orthopedic sports medicine. I answered their ad in the *Journal of Bone and Joint Surgery* and the hospital helped me get started in private practice. Boldly proclaiming my 1500 square feet entity, 'The Taos Orthopaedic Institute,' I in fact was running a three person show…me, someone who answered the phone, and an X-ray technician. Fifteen years later we are living up to the name, with three attending surgeons, two fellows (three beginning in August), four satellite clinics (in Santa Fe, Los Alamos, Raton, and Las Vegas, New Mexico), and a total of 25 employees."

"We're beyond rural," someone once said to Dr. Lubowitz of his outlying clinics. "We're remote!" Dr. Lubowitz: "Our goal is to have only one standard of care, no matter where the patient is being treated. I want to provide the same quality of outcome, clinical attention, ambiance, and service that someone receives on Park Avenue. We manage to do this despite being at a smaller hospital where we are sometimes required to transport level one trauma patients to centers in Albuquerque or Denver by air. Working with people in rural areas is a unique experience—especially in the West where people drive long distances to see a doctor (sometimes four hours), but don't seem to mind. And this is not only for surgery, but for things such as getting stitches removed, as well as follow up appointments."

"Also unique about practicing in rural areas is being exposed to some unusual ways of making a living. We treat ski instructors, fishing guides, golf pros, ranchers, and bullriders, among others. Instead of the prototypical older person who does gardening in the city or suburbs, we have someone who might tend to an apple orchard containing hundreds of acres."

Dr. Lubowitz may look at averages, but his research is anything but. "In 2008 my colleagues and I were honored with an award by the *American Journal of Sports Medicine* for our research involving a meta analysis on outcomes of single bundle versus double bundle ACL reconstructions. Historically, the general recommendation has been a one bundle procedure, but anatomically there are two bundles. Many thought leaders, including the visionary Dr. Freddie Fu, advised that double bundle procedures be investigated further. In our research we found that the clinical outcomes of each procedure are equal; however, it may be that we need improved ways of measuring outcomes. We have this impression because although both procedures seem to stabilize the knee anteriorly and posteriorly, there is also a rotational component involved. At the present time, though, we have no tools to quantify rotation. There is a pivot-shift examination, but it is subjective and particularly hard to do on someone while he or she is awake."

"In 2008," continues Dr. Lubowitz, "we also received the award for the best innovation in arthroscopy from the European Society of Sports Medicine, Knee Surgery and Arthroscopy. Using methods previously found in economics, namely decision analysis, we asked the question, 'Should patients over 40 have surgical or nonsurgical treatment for an ACL tear?' Interviewing hypothetical patients, the norm for decision analysis, we found that those individuals over the age of 40 would prefer the surgical option. This, the research revealed, was because they were willing to assume the risks associated with surgery, but unwilling to accept that their knee might buckle on them when engaging in pivoting activities. This work was also awarded the Richard O'Connor Prize by the Arthroscopy Association of North America."

As always in research, there are limitations and modifications that could be made to improve future investigations. Dr. Lubowitz acknowledges, "One of the issues with the research was that the people in the Taos area would likely have different activity levels than those living in downtown Manhattan. Then there is the issue of the hypothetical patients.

This approach was undertaken because we were looking for patients who had not torn their ACLs, been to a doctor and been biased. But what using hypothetical patients means is that these individuals may find it easier to say, 'I choose surgery' because they know it's not reality."

Dr. Lubowitz continues, "In the future, I would like to do a study involving patients who may have torn their ACLs and get them to complete a survey *before* they talk to a healthcare provider. I did attempt something like this already, having fellows go to a ski resort clinic on the slope and ask the nurses to distribute the surveys. Patients were asked to complete them during the few minutes while they were waiting to see a physician. It was a failure, however, because patients got upset at the thought that they might need surgery…and had not even seen a doctor yet. We also listed all of the possible risks involved in surgery, including loss of life. That was also alarming to the patients. I will try again next year and plan to take a more hands on approach and spend a lot of time explaining the benefits of the research to the clinic staff."

Of his current research, Dr. Lubowitz notes, "The project I am most excited about now is my work comparing standard single bundle ACL reconstruction to a modified technique that is slightly less invasive. Known as the all-inside technique, this method was pioneered in the '90s by Dr. Craig Morgan. The way he was doing it, however, was technically challenging and so his fellows didn't use it. In 2006 I described the transtibial all-inside technique in *Arthroscopy: The Journal of Arthroscopic & Related Surgery,* in which we use allograft and only need three 'portals.' Our hypothesis is that this technique will result in less pain and faster recovery times with equal long term outcomes."

Having spent years involved in journal work, Dr. Lubowitz has had ample late nights to think about the process and implications of good—and bad—research. "I started out as a reviewer, keeping in mind the words of Dr. Thomas Byrd, a pioneer in hip arthoscopy, who wrote that the best way to become a good scientific researcher and writer is to be a reviewer. I then moved on to Associate Editor and am now Assistant Editor of *Arthroscopy.* What we are learning as a field is that most medical literature is of a low level of evidence, with most surgical literature being a level 4. This particular level, a case series study, is flawed because there is no control group. How, then, do we know that the treatment we're studying is superior to any other treatment, or for that matter, to no treatment at all? This topic is timely because one of the first federal laws that was proposed by our new President and approved by Congress was to spend over a billion dollars for comparative effectiveness research."

He continues, "Some in the medical community fear that this may result in evidence-based treatment algorithms that will advise doctors as to the best way to treat patients. We need to keep in mind that research trials conducted on large numbers of patients create broad averages and result in treatment algorithms that don't take into account the individual patient. Each person brings to the table a different race and gender, as well as activity level, medical comorbidities, social, economic, and cultural differences. We as physicians need to lead and not be led or misled. Even randomized trials that are well conducted may draw the wrong conclusions. Today, the government says that such results would not be used to determine how to treat patients; a concern is that, over time, this could change."

With such a strenuous schedule, and weighty issues to manage, it's good to have a little comfort…and a little comfort food. Dr. Lubowitz: "I am spoiled in that my significant other of 10 years, Gina, is a chef. This works out well because I exercise a lot—meaning that I can eat a lot. There was a period in which I took call every night and she worked every night. I would call her restaurant from the hospital at 10pm and order up a salad, steak and chocolate cake to go. When my call schedule lessened and I began lecturing and traveling she was still working all the time. I begged her to sell her half of the restaurant, which she eventually did. Now she just cooks for one private client—me."

Orthopedics This Week

VOLUME 5, ISSUE 13 | APRIL 21, 2009

Orthopedics This Week | RRY Publications LLC

Robin R. Young, CFA
Editor and Publisher
robin@ryortho.com

Elizabeth Hofheinz, M.P.H., M.Ed.
Senior Writer
elizabeth@ryortho.com

Walter Eisner
Senior Writer
walter@ryortho.com

Tom Bishow
Vice President of Sales
tom@ryortho.com

Julia Cecil
Marketing & Promotions
julia@ryortho.com

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Production Coordinator
jayme@ryortho.com

Eileen Mesi
Art Director / Designer
eileen@ryortho.com

Main Contact Information:
RRY Publications LLC
116 Ivywood Lane • Wayne, PA 19087
TOLL FREE: 1-877-817-6450
Fax: 610-260-6451