VOLUME 6, ISSUE 35 | NOVEMBER 9, 2010

Orthopedics This Week

week in review

picture of success

31 **Dr. Joel Press** ◆ Dr. Joel Press, a former NASS President and physical medicine specialist, knows the value of nonoperative spine care. An advocate of staying in touch with patients, Dr. Press often says, "Nothing ruins a good outcome like follow-up."

breaking news

For all news that is Ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Wall Street's investors thought the third quarter's results would divine the direction of U.S. healthcare. So much was riding on these numbers that emotions, ultimately, overcame judgment. OFIX beats analyst's forecasts—but declines. NUVA lowers guidance by 10% then stock drops 35%. We've seen this movie before. Buying low, NuVasive is our #1 company this week and OFIX jumps four spots.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	NR	NuVasive	6.51%	(30.41%)	27% sales growth. A management team that's building a billion dollar, 30% ROE company. At 20 P/E, NUVA is #1 this week.
2	2	Stryker	24.71	10.49	Not only exceeded sales and earnings expectations in Q3, but used some of its cash to bag BSX's Neuromodulation biz.
3	7	Orthofix	13.51	(14.69)	Spinal implant and biologics sales up 20%. Rising operating profit margins. Solid, solid numbers… again.
4	5	Integra LifeSciences	15.37	10.47	Beats estimates and increases guidance for the year. Sales grew 8%, but earnings grew 12%.
5	1	Alphatec	1.59	4.07	NuVasive's stumble cast a pall over all spine companies this week. Consensus is that ATEC will report 40% sales growth.
6	9	Medtronic	32.59	5.02	It may not be visible in the quarterly reports yet, but my gut is telling me that the worst is over. Pays 2.5% dividend while we wait.
7	3	Zimmer	27.69	(1.16)	Big Blue just can't shake the blues. Revenues for the Q3 were under forecast.
8	6	Johnson & Johnson	27.1	2.95	JNJ has been an institutional investor favorite for several weeks and valuation is no longer in the cheap seats.
9	10	Smith & Nephew	22.83	4.43	Very modest orthopedic sales in the quarter. Global recon up 3% and trauma up 5%. But sports med and profit margins up solidly.
10	4	CONMED	8.76	(1.88)	Powered surgical instruments hit air pocket—down 7%. Profit margins up sharply due to restructuring. Is business growing?

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TiGenix	TIG.BR	$2.91	$90	49.3%
2	Mako Surgical	MAKO	$11.36	$384	16.8%
3	Integra LifeSciences	IART	$43.36	$1,230	10.5%
4	Medtronic	MDT	$35.35	$38,170	5.0%
5	Smith & Nephew	SNN	$47.60	$8,460	4.4%
6	Alphatec Holdings	ATEC	$2.30	$201	4.1%
7	Synthes	SYST.VX	$123.54	$14,662	4.0%
8	Stryker	SYK	$52.43	$20,810	3.7%
9	Exactech	EXAC	$16.38	$211	3.6%
10	Orthovita	VITA	$2.19	$168	3.3%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	NuVasive	NUVA	$24.00	$945	-30.4%
2	Orthofix	OFIX	$26.83	$476	-14.7%
3	Kensey Nash	KNSY	$27.26	$235	-9.5%
4	Symmetry Medical	SMA	$8.63	$310	-7.9%
5	Bacterin Intl Holdings	BIHI.OB	$7.00	$249	-6.4%
6	Wright Medical	WMGI	$13.72	$538	-4.9%
7	TranS1	TSON	$2.37	$49	-2.9%
8	CryoLife	CRY	$6.00	$169	-2.8%
9	CONMED	CNMD	$22.39	$636	-1.9%
10	Zimmer Holdings	ZMH	$51.81	$10,290	-1.2%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Medtronic	MDT	$35.35	$38,170	10.56
2	Wright Medical	WMGI	$13.72	$538	12.07
3	Kensey Nash	KNSY	$27.26	$235	12.13
4	Zimmer Holdings	ZMH	$51.81	$10,290	12.33
5	Exactech	EXAC	$16.38	$211	13.24

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$47.60	$8,460	65.55
2	Synthes	SYST.VX	$123.54	$14,662	34.53
3	RTI Biologics Inc	RTIX	$2.57	$141	33.61
4	Symmetry Medical	SMA	$8.63	$310	22.54
5	NuVasive	NUVA	$24.00	$945	19.72

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$24.00	$945	0.65
2	Orthofix	OFIX	$26.83	$476	0.76
3	Exactech	EXAC	$16.38	$211	0.98
4	Smith & Nephew	SNN	$47.60	$8,460	1.12
5	Medtronic	MDT	$35.35	$38,170	1.13

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CONMED	CNMD	$22.39	$636	17.08
2	Kensey Nash	KNSY	$27.26	$235	3.48
3	Alphatec Holdings	ATEC	$2.30	$201	3.45
4	Johnson & Johnson	JNJ	$64.65	178,070	2.24
5	*Average*			*$12,055*	*1.95*

Lowest Price to Sales Ratio (TTM)

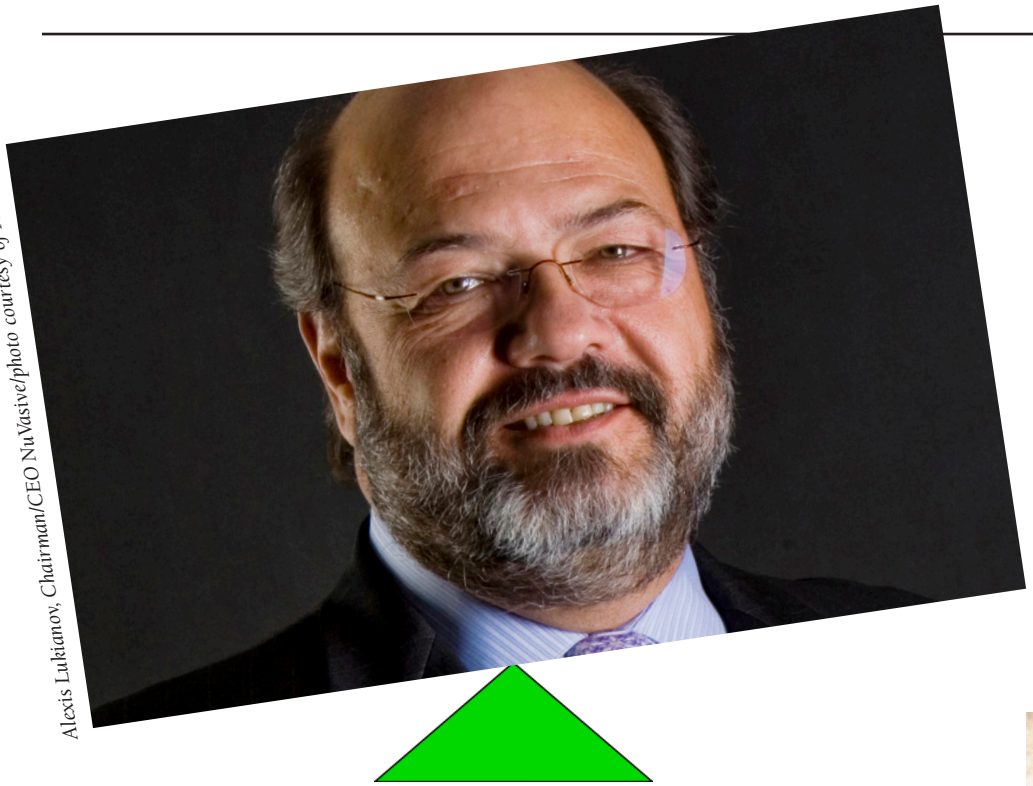
	Company	Symbol	Price	Mkt Cap	PSR
1	RTI Biologics Inc	RTIX	$2.57	$141	0.80
2	CONMED	CNMD	$22.39	$636	0.88
3	Symmetry Medical	SMA	$8.63	$310	0.94
4	Wright Medical	WMGI	$13.72	$538	1.00
5	Exactech	EXAC	$16.38	$211	1.12

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$2.91	$90	321.16
2	Bacterin Intl Holdings	BIHI.OB	$7.00	$249	26.17
3	Mako Surgical	MAKO	$11.36	$384	11.61
4	Synthes	SYST.VX	$123.54	$14,662	8.13
5	Kensey Nash	KNSY	$27.26	$235	3.02

Lukianov's Tipping Point

By Walter Eisner



Alexis Lukianov, Chairman/CEO NuVasive/photo courtesy of NuVasive

NuVasive reported a 27% increase in sales for the third quarter on October 28 after the markets closed.

The next morning the company's stock dropped off the cliff, falling from $38 to $26 per share. Wall Street punished NuVasive for admitting to being surprised by how the last week of the quarter unfolded with cancelled surgeries. Analysts hate surprises.

Did something fundamentally change in NuVasive's business model? Did payers decide to stop paying for the company's XLIF procedure? Did the company's irresistible march toward taking market share from its larger competitors stop?

Nope, none of that happened.

Insurer Pushback

Company CEO Alexis Lukianov told analysts that simply put, insurers were pushing back on spine surgeries and scheduled surgeries were being cancelled during the quarter.

Specifically, Lukianov said the insurers were doing two things.

"First, they have increased the criteria necessary to preauthorize lumbar spine fusion surgery, and second, they have increased the level of scrutiny for the surgeries.

"The increased criteria leads insurers to deny coverage for fusion surgery if patients present without meeting each condition in the list of stringent indications such as, instability, neural compression or stenosis, and radicular leg pain. Each of these conditions must now be well documented."

As an example, Lukianov noted many doctors' offices are not in the habit of sending X-rays to document instability since it has never been previously mandated.

The result of the payers' behavior, noted Lukianov, has been confusion and uncertainty in the marketplace, creating a significant overcorrection. An overcorrection he suggested amounted to roughly 10% to 20% of

"Sadly, there is a lack of industry leadership in the spine market right now but we will gladly fill that void going forward. We are addressing insurer pushback head-on, much like we successfully did when XLIF was deemed by some payers as experimental."

RRY Publications

when degenerative disc disease is an indication. More on that in a minute.

Jefferies Research analyst Raj Denhoy put it simply: "A deteriorating spine market has caught up to NuVasive and the company lowered guidance."

Advocacy Effort

"Fusion simply cannot be postponed indefinitely, so we are hopeful that the impact of this increase back and forth between surgeons and insurers will be transitory."

NuVasive is not leaving this to chance. Lukianov bemoaned the lack of an industry response to this new insurer dynamic.

The company plans to lead the charge to improve coverage of spinal fusion through data from a pipeline of clinical trials as well as by marshaling the their patients and fight for coverage of spinal fusion.

"Sadly, there is a lack of industry leadership in the spine market right now but we will gladly fill that void going forward. We are addressing insurer pushback head-on, much like we successfully did when XLIF was deemed by some payers as experimental.

"We are at the beginning stages of driving an advocacy effort that will better educate the payer and surgeon communities to the essential nature and improved outcomes made possible with fusion procedures as well as to the proper preparation of documentation to obtain preauthorization," promised Lukianov.

The company will try to "drive through some solutions" with payers as it did with XLIF as the company was able to unite all of the different players, "from surgeons to associations to payers. We're looking to do the exact same thing right now again, and that's a very big strategic undertaking and it's one that we've already started," promised Lukianov.

Pushback Impact on NuVasive Guidance

Lukianov told analysts the pushback from insurers to surgeons is having a temporary impact on the company's volume growth and visibility. "These dynamics led to lower-than-expected revenue in the third quarter and contin-

"The best way to look at NuVasive's business right now, noted Lukianov, is that the lumbar business can be flat, but the other parts of their business will continue to grow at a much faster pace."

ues to challenge growth in the current quarter." As a result, the company now expects full year 2010 revenue in the $470 million to $475 million range, down from the $485 million to $495 million range expected previously. Strategic investments into the growth drivers of the business will also result in lower than previously expected profitability.

"The market is exceptionally unpredictable right now and our 2011 expectations are 10%to 20% growth, which assumes that U.S. volume growth is in the process of bottoming. We have good visibility to growing our business at a baseline of 10%, largely attributable to the more predictable growth of our biologics, cervical, and international revenue. Upside to 10% growth will come from our U.S. lumbar product platforms as the market restabilizes."

He added:

"We are truly at the tipping point of the ship, from open to minimally disruptive spine surgery, and we are optimistic that expanded offerings in the category will only help to validate the market."

Analysts asked Lukianov if the 10% to 20% contraction of approved fusion surgeries might be permanent.

Lukianov said the company heard inklings of this contraction coming out of the summer. "We're hearing a lot more of it throughout October. And, again, what I'm talking about is back pain alone without radicular symptoms. Our **concern is that part of the spine market may be gone right now.** We're not sure exactly when that's going to come back. We don't know what happens to those patients that have just isolated back pain. Do they go on to a discectomy? Do they go on to a laminectomy? Do they end up having a fusion in six months or a year?"

Analysts asked Lukianov if the cancellations are for all back surgeries or just the 20% of those with back pain, (no leg pain, DDD) patients?

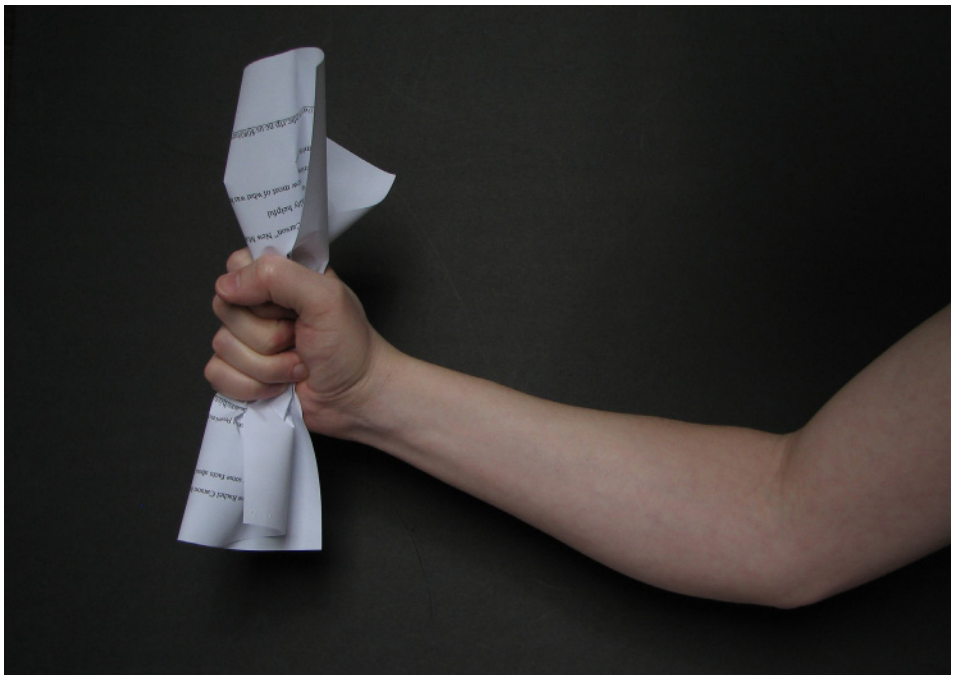
"Our best guess," said Lukianov, "is if you ask us what do we think is the percentage right now of patients that have isolated back pain and are receiving fusions, our guess is that number is somewhere in the 10% to 20% range."

"Those patients are being outright denied. That [10%-20%] is absolutely out of the equation." He believes those patients are not likely to get a fusion and that's causing a spillover effect into other fusions and more stringent indications are being sought.

Permanent Market Contraction Possible

One analyst noted that the main reason insurance companies are pushing back on that 20% of cases is that the data for low back pain without radicular symptoms is "just not very good." Could this 20% reduction be permanent?

"I think it's a very real possibility," said Lukianov. "And just to be clear, though, we're not trying to go out there and



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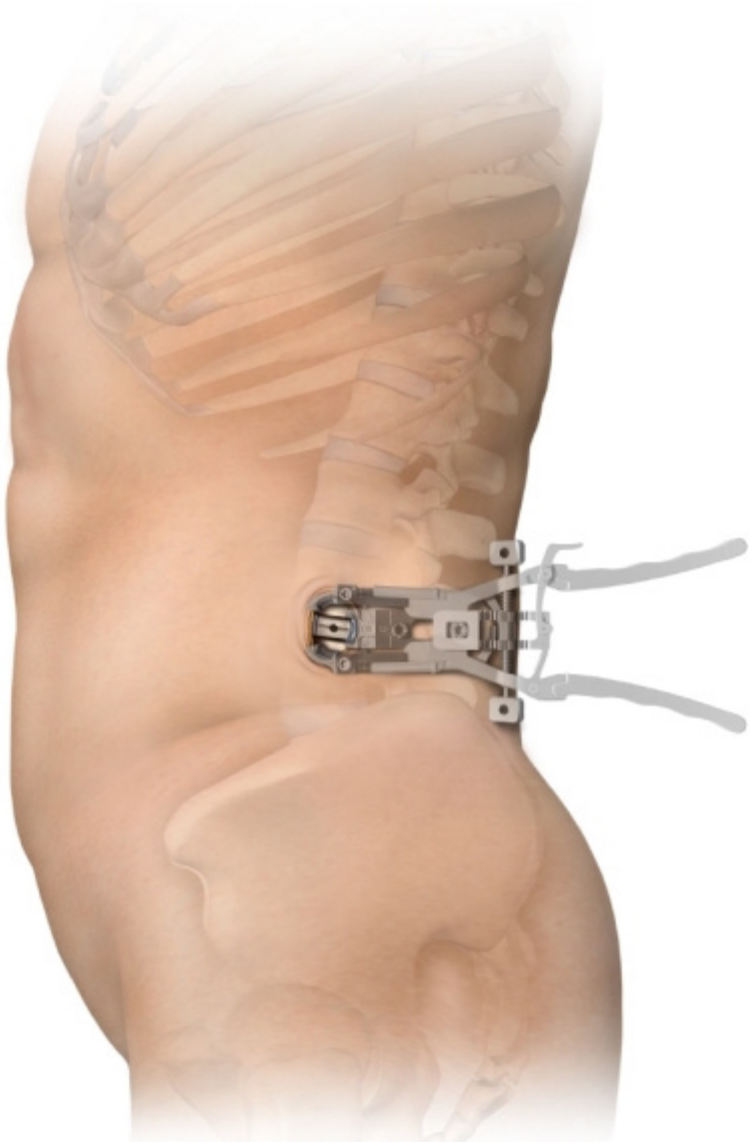


NuVasives XLIF/RRY Publications

defend back pain in and of itself. If as much as 20% goes away, it goes away. That does not fundamentally change our outlook, our thesis, because we don't think we're getting—we're getting next to none of that business today."

Lukianov said while it's certainly possible that a big part of the market could "absolutely" disappear, if somebody has legitimate back pain, the chances of them entering "the downward cascade that leads to fusion" may just be postponed. "It's very unlikely that they would absolutely be able to avoid it. It just may mean that now they're two years away or five years away. Or they have a discectomy or a laminectomy instead or they have nothing and just deal with the pain."

The best way to look at NuVasive's business right now, noted Lukianov, is that the lumbar business can be flat, but the other parts of their business will continue to grow at a much faster pace.

One analyst pointed out that NuVasive's biologics and international businesses would have to grow by 30% and 70%, respectively, next year to allow the company to reach 10% growth even if the base business doesn't grow.

Lukianov replied that he thinks NuVasive's international sales will actually grow 100% next year and sees an upside in biologics with the Progentix product. "Even if, for some reason, that was delayed due to the FDA, we have tons of momentum going through right now with the Osteocel Plus going very, very well."

He said Central and Latin America are opening up very well and sees a lot of upside in Europe. "Germany has been growing well, U.K. has been growing well…We see that really taking off. Next year, we start to get our first footstep into China. We start to see some early revenue coming out of Japan next year.

The company is on track to execute to a long-term goal of generating at least 10% of total revenue outside of the U.S.

Patent Protection Efforts

Other strategic initiatives noted by Lukianov were the company's legal efforts to protect its intellectual property. "A few weeks ago, we initiated a patent infringement lawsuit against Globus Medical, which contends that Globus Medical's LLIF lateral fusion offering infringes NuVasive's XLIF intellectual property. We also initiated a dispute against Orthofix earlier in the year in defense of patents acquired in the Osteocel transaction."

Lukianov's Tipping Point

Lukianov concluded by acknowledging that, "This is a difficult time for

NuVasive and the entire spine industry but we view the current conditions as an opportunity to advance our position in the market, expand our technological leadership, and garner more surgeon respect."

He cited a peer-reviewed, published XLIF study that showed a nearly 10% hospital cost reduction using minimally disruptive spine surgery compared to open surgery in the perioperative period.

NuVasive's leader did not back away from the goal of reaching $1 billion in sales with "500 photo-carrying representatives producing $2 million in average annualized sales."

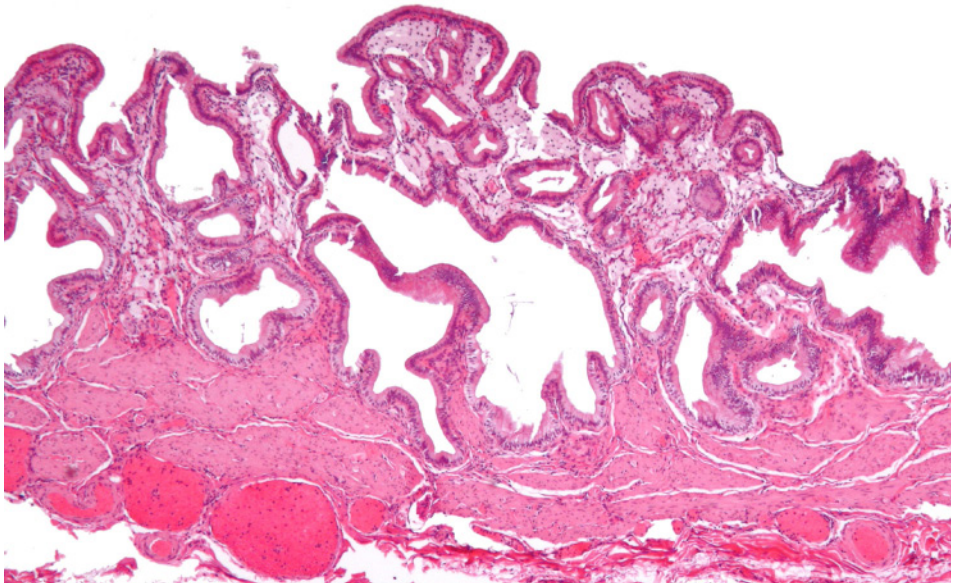
As Lukianov noted, the industry and science has reached a tipping point. And we might add, given the CEO's offer to lead an industry advocacy effort, so has Alexis Lukianov. ◆

Yet *Another* Stem Cell for Bone Growth

By Robin Young

How many types of stem cells can grow bone? Apparently more than we knew.

Last week the California Institute for Regenerative Medicine (CIRM) announced a series of grants to four UCLA researchers—Drs. Bruno Peault and Chia Soo, professors of orthopedic surgery ($5,391,560), Dr. Noriyuki Kasahara, professor of digestive diseases ($3,370,607) and Dr. Sophie Deng, assistant professor of ophthalmology ($1,654,058).



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PSC, MSC, ELA….But wait, There's Still More!

What caught our attention was Peault and Soo's plan to study a form of stem cell called the Perivascular Stem Cell (PSC) which can be collected from fat tissue via liposuction.

All currently available allograft or FDA approved stem cell products are based on the mesenchymal stem cell (MSC). Soon, Alphatec Spine is expected to bring to market their allograft cell product based on yet another stem cell—the unique adult stem cell called the ELA stem cell.

PSC, MSC and ELA. How many more bone growth stem cell lineages, or partial lineages are there?

Cliff Notes Version of Stem Cells

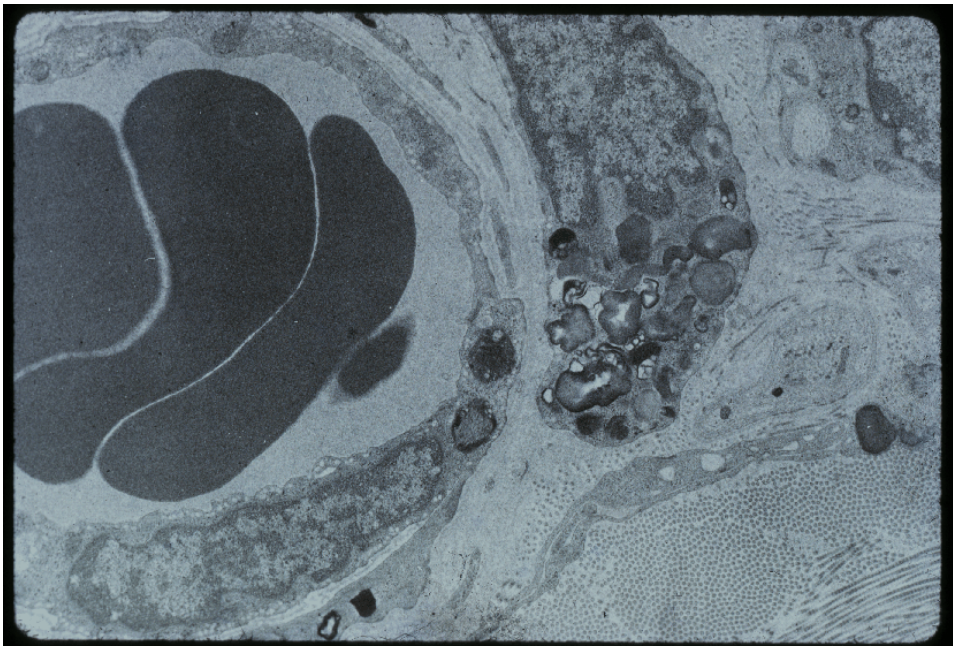
Just to recap, stem cells are the original cell. Or, at least, the cell that can metamorphose into a vast array of functional tissues. In the beginning, meaning the point of embryonic inception, there are four pathways available for those first stem cells to follow—primordial germ cells, ectoderm cells, mesoderm cells and endoderm cells. Each pathway leads to a wider range of specific tissue types. The mesoderm pathway, for example, results in heart, muscle, blood or mesenchymal tissues. The endoderm pathway takes cells to the intestine, pancreas, liver or lung cells.

Along any of those pathways—also called lineages—cells are at various stages of commitment. Early along the lineage, they are largely uncommitted and could, through a variety of signals and other factors, become any one of a wide variety of tissues from that lineage. Later in the lineage, they're committed and are what they are. Kind of like a typical 58-year-old publisher like me.

The first and still most popular and common form of stem cell for therapy is the mesenchymal stem cell which is part of the lineage that creates muscles, nerves and bone. MSCs are adult stem cells. They also, as they change, emit various signals which are themselves

Dr. Bruno Peault

Dr. Chia Soo



National Eye Institute/Wikimedia Commons

therapeutically valuable. Some of these signals down regulate inflammation. Other signals recruit more cells and growth factors. Yet other signals are themselves growth factors for, depending on the environment, new bone or new nerve tissue growth.

Cousins of MSCs in Vascular Tissues!

So it is very interesting to read accounts of other cells which are also along the mesenchyme lineage and are probably new versions of MSCs—cousins perhaps.

Like MSCs, these newly identified precursor cells also have self-renewal and bone regenerative capabilities. Like MSC's these newly identified cells are also isolated from adult donors. The ELA stem cell which Alphatec is working on is a highly concentrated form of these cells. They are derived using a proprietary isolation method that has the potential to yield up to six hundred times more cells than a similar volume of mesenchymal stem cells harvested from bone marrow.

Since Alphatec is a spinal implant company, these early lineage cells are being targeted at patients with back problems requiring spine fusion, bone fractures, herniated disks and, potentially, osteoporosis. If successful, their study could provide an alternative to traditional bone grafting.

Pericytes

Last year at the New York Stem Cell Summit, Dr. Arnold Caplan, who wrote many of the seminal papers regarding MSCs and is the "father" of modern stem cell therapies, spoke about some obscure little critters called pericytes.

Sounds like something that was in the pool water last summer.

In Caplan's view pericytes may well be the source of most MSCs. And pericytes are everywhere in the human body including skeletal muscle, pancreas, adipose tissues, placental tissues, in vascular tissues and teeth. Pericytes are not your father's MSCs—which seemed to exist only in bone marrow or adipose tissues. Pericytes are found in more areas of the body and they include perivascular cells.

UCLA researcher Bruno Peault has been writing for several years about perivascular cells (PSC). He has shown in various articles that perivascular cells are myogenic in culture and in vivo. Furthermore, regardless of their origin (Peault has used cells from cord blood, adipose tissue and other sources) they are osteogenic. Other researchers have shown that PSCs are also chondrogenic and that they express MSC markers. **To take this even further, both Caplan and other researchers have been saying for a while now that blood vessel walls harbor a large amount of pericytes/progenitor cells that are very probably key to the origin of MSCs and other adult stem cells.**

Stem Cells From Vascular Tissues in Fat

The PSC cells which UCLA researchers Peault and Soo are studying will be the subject of a three-year study which will put to the test a new combination of antibodies and cell sorting. The researchers hope the study will prospectively isolate these stem cells populations from fat. The PSCs, like ELA or MSC, are also traveling along the lineage leading to bone, muscle or nerve tissues.

PSC, however, have one important differentiating aspect. Unlike traditional fat-derived MSCs, PSCs are not cultured for weeks before identification. This may be especially important from a therapeutic standpoint. Using this approach, patients could in theory be treated more quickly and self-produce a higher yielding, purer form of stem cell population while also lowering the risk of contamination. In the UCLA protocol, the PSCs would be combined with a potent growth factor, NELL-1, to amplify the particular signal to "tell" PSC to form bone.

If successful, Peault and Soo hope to come up with a candidate drug or cell therapy or, at a minimum, make significant strides toward a drug candidate. Of course, if Peault and Soo's studies are successful then their new drug candidate would be eligible for the FDA regulatory gauntlet to be followed by the, umm, CMS (Centers for Medicare and Medicaid Services) keelhauling.

It is in Peault and Soo's plan to obtain PSC source material by way of fat liposuction from patients who are candidates for bone regeneration. If successful, Peault and Soo would demonstrate a new method for rapidly isolating a new form of MSC and thereby increase the speed of new bone formation or at least prove to be faster than current methods of culture deriving MSCs from fat.

UCLA Broad Stem Cell Center

Peault and Soo join a long list of scientists from the UCLA Broad Stem Cell Center who have, in the aggregate, received CIRM grants totaling more than $133 million.

UCLA's stem cell center was conceived in 2005 with a five-year $20 million seed commitment from UCLA. Funds from the Eli and Edythe Broad Foundation in 2007 resulted in the renaming of the center to the Eli and Edythe Broad Center of Regenerative Medicine and Stem Cell Research. The center and its 200 members are committed to a multidisciplinary, integrated collaboration of scientific, academic and medical disciplines for the purpose of understanding adult and human embryonic stem cells.

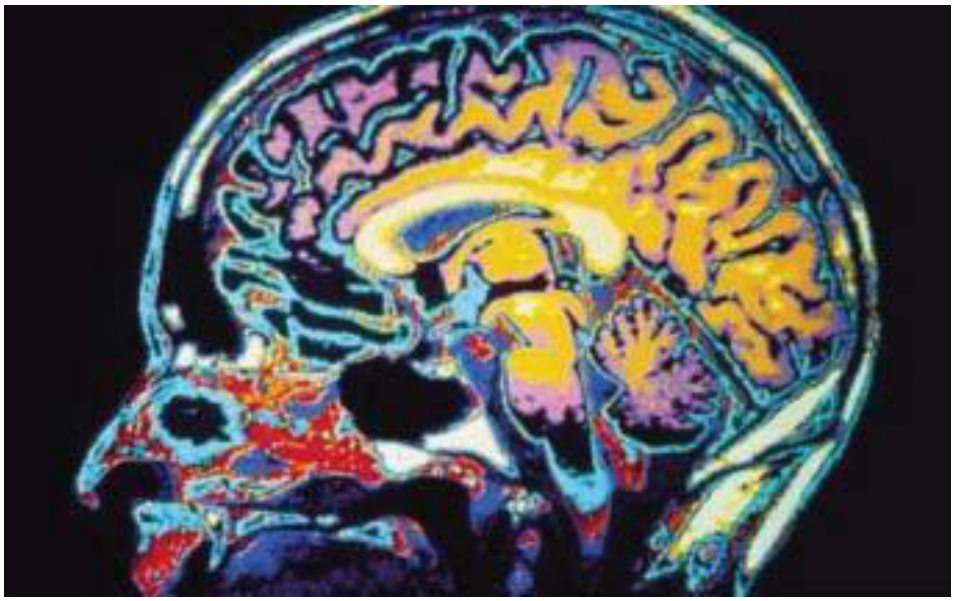
Who'd have thought there were so many therapeutic stem cell candidates? Or so many sources in the human body? ◆

The Rise of the Concussion

By Jacqueline Rupp

Type the word *sports concussion* in any search engine and literally two million hits come up for everything from new studies and programs to prevention methods and treatment concepts. The flood of information on this traumatic brain injury is a sign of the times and, yes, changes in sports medicine.

Sports-related concussion (SRC) is the new hot button issue in sports medicine. But it's not just talk. Serious funding is flowing into the treatment of SRCs, with the most recent examples being the opening of the Chicago Sports Concussion Clinic at Rush University Medical Center.



Brain Image of Concussion/Creative Commons

But Why Now?

What has thrust concussions into the sports medicine spotlight? Many studies have looked at the incidence and characteristics of concussion in professional, college and high school athletes, however, as authors Powell and Barber-Foss wrote in their article "Traumatic brain injury in high school athletes (*JAMA* 1999:282(10):958-963), "solid concussion data do not yet exist for pre-high school populations and there is growing speculation that concussion in young athletes may produce more severe long-term development and cognitive problems than are seen in the adult athlete".

Authors Lisa Bakhos, M.D., Gregory Lockhart, M.D., Richard Myers, BS and James Linakis, Ph.D, M.D., tackled this issue in their study in *Pediatrics*, the official journal of the American Academy of Pediatrics. In this study, the authors showed that children ages 8 to 19 years had an estimated 502,000 ER visits for concussion between 2001 and 2005. The incidence rate of sport-related concussions rose over this same five-year period of time.

The authors pointed out that 8- to 13-year-olds accounted for 35% of ER visits and approximately half of those visits were for SRC. Approximately 25% of all SRC visits in the 8- to 13-year-old group occurred as a result of organized team sport (OTS). During the study period, 4 in 1,000 children aged 8 to 13 years and 6 in 1,000 children aged 14 to 19 years had an ER visit for SRC.

These are seriously high incidence rates. And they appear to be rising. From 1997 to 2007, although participation by children in organized sports declined; emergency department visits for concussions doubled. Even more concerning was that the rate of ER visits for SRC among the 14-to 19-year-old group had increased by more than 200%—according to the study authors.

The study by Bakhos et al. points out that the rise of concussion related sports injuries among children is NOT related to more players participating in sports. In fact, as noted above, the numbers of children participating in organized sports declined over the study period. As the authors stated at the end of their article, additional research is clearly required if for no other reason than to understand why concussion rates are rising. Are players paying more aggressively? Are players larger?

Clearly the level of awareness of the risks of head injuries is on the rise. In addition to children, female athletes also appear to be experiencing higher inci-

dence rates for concussions, although the causes again are somewhat vague. Weaker neck muscles could play a part or some have even mentioned the more aggressive play by girls is a contributing factor.

The increased availability of incidence statistics combined with the rising number of ER visits aren't the only reason sports-related head injuries are receiving so much attention. Recent studies have demonstrated that, for example, Lou Gehrig's Amyotrophic Lateral Sclerosis was, in his specific case, due to repeated head injuries during this playing career. The Center for the Study of Traumatic Encephalopathy (CSTE), at Boston University School of Medicine is issuing a steady stream of studies which show that SRCs, far from being innocuous, invisible injuries, actually confer tremendous brain damage.

An entire sports mindset is being changed. Not that long ago a hard hit or a bang to the head wasn't something that required a trip to the ER. It was in fact, an opportunity for a kid to prove his toughness by getting back on the field after a few minutes rest.

Younger Athletes, More at Stake

The CDC has developed the *Heads Up: Concussion in Youth Sports* initiative to help ensure the health and safety of young athletes by providing information about concussions to coaches, parents and athletes in youth sports. With the slogan, "It's better to miss one game than the season," *Heads Up* supplies information in three key areas: preventing, recognizing, and responding to a concussion.

Concussions are doubly dangerous for younger athletes. Not only are they more apt to sustain an injury, but the results can be far more damaging, especially if left untreated. Serious risks of concussion include fatal Second Impact Syndrome, prolonged symptoms that last weeks or months (Post-Concussive Syndrome) and long-term diseases or disorders after the injury is sustained, such as depression, cognitive delay and Parkinson's-like symptoms.

Dr. Jeffrey Mjaanes evaluating a patient at the Chicago Sports Concussion Clinic at Rush/ Rush Photo Group

A Multi-Disciplinary Approach

The new Chicago Sports Concussion Clinic at Rush University Medical Center is employing a lot of the knowledge and best practices that doctors have accumulated over several years in the hope of offering a more comprehensive concussion care service. The Clinic is housed in the Rush orthopedics building and, according to a university press release features one of the largest multi-disciplinary teams in the Midwest to assess and manage concussions in athletes.

"Our clinic is based on the idea that having a multidisciplinary, comprehensive approach to concussions is paramount in importance," says Dr. Jeffrey Mjaanes, director of the Chicago Sports Concussion Clinic and assistant professor of pediatrics and orthopedic

surgery. Mjaanes is a primary care sports medicine physician, fellowship-trained and board certified in pediatrics and is one of the team physicians for DePaul University and the U.S. Soccer national teams.

"We have assembled a team of primary care sports medicine specialists, neurologists, neurosurgeons, rehabilitation physicians, neuropsychologists and therapists all of whom have special training in concussion diagnosis and management."

One of the main goals of the center is to offer assessments within 24 to 48 hours after injury. The Clinic will treat child, teen and adult athletes and provide evaluation and treatment as well as medical clearance for those athletes who wish to return to organized sport activity. Patients are evaluated using multi-disciplinary methods which combine traditional patient feedback with a series of more high-tech techniques.

"The diagnosis of concussion is fairly standard since it relies on the athlete's reporting of symptoms," explains Mjaanes . "Our symptom list is based on guidelines outlined by international concussion specialists at the Zurich Conference in 2008, now followed by most collegiate and professional sports organizations. At the Chicago Sports Concussion Clinic at Rush, however, we use tools such as computer-based neurocognitive testing, balance testing, [and] formal neuropsychologic testing to analyze symptom severity."

Rush Orthopedics Building/Rush Photo Group

A New Day for Concussion Care

Today's "surge" in concussion awareness and diagnosis has been quietly building for close to a decade. A 2002 international conference brought concussion experts from around the world together in Vienna. Mjaanes says the experts in Vienna recommended the old grading system be thrown out because it was out-dated and too complex.

Two revisions later, with the latest guidelines coming from a 2008 conference in Zurich, doctors now have concrete, black and white guidelines. "The newest guidelines are based on several important tenets: athletes should be evaluated by a trained health professional, no symptomatic athlete should return to play and, once all symptoms

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have resolved, athletes should progress through a graduated program of increasing activity before returning to full, contact sports," explains Mjaanes.

He says most colleges, universities and professional sports organizations now subscribe to these newest guidelines. With the NFL coming out with its own set of concussion guidelines in 2009, it appears even the toughest (most concussion-heavy) sports are seeing the importance of concussion care.

A Movement Who's Time Has Come

Rush Medical is part of a trend to increase the level of healthcare services for SRCs. "At Rush, we have been seeing athletes with concussions for years. However, although international guidelines for concussion management changed in 2002, we still found that many young athletes with head injuries were being misdiagnosed and mismanaged," says Mjaanes. "We decided we needed to have a more comprehensive approach to diagnosis and management of concussions to ensure that these young athletes were returning to sport safely. Last year we began laying the groundwork for this clinic and now are excited that we are getting it off the ground."

Mjaanes says there is still a long way to go, with prevention being the ultimate goal. He says that so far, the technology in sports equipment like helmets and head gear hasn't translated into decreasing the number of concussions, which means prevention of complication is the next best thing.

"At this time the most effective way to decrease the incidence of concussions is education. We need to inform players, parents and coaches about the significance of concussions and the importance of reporting symptoms. The best way, though, to prevent complications from concussions—such as fatal Second Impact Syndrome or Post-Concussive Syndrome—is by not allowing symptomatic athletes back in the game. Concussed athletes need to rest and not participate until all symptoms have resolved." ◆

Does UNC Offer the Best Musculoskeletal Curriculum?

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

For decades, musculoskeletal conditions have been elbowed out of medical school curricula by other areas of study, despite the well-documented prevalence of visits to doctors' offices for musculoskeletal complaints. Years ago, Frank Wilson, M.D., Kenan Professor of Orthopedics at the University of North Carolina (UNC) School of Medicine and a former president of the American Board of Orthopaedic Surgery, decided to think and act locally, with an eye toward expanding the emphasis on musculoskeletal disorders in medical schools across the country. His work, "Development and Use of a Second-Year Musculoskeletal Organ-System Curriculum: A Forty-Year Experience," was co-authored with Robert Esther, M.D., and was recently published in *The Journal of Bone and Joint Surgery.*

Seattle Municipal Archives/Wikimedia Commons

Dr. Wilson provides a bit of history, "Even back in the late 1960s there were studies showing that we weren't doing a good job of preparing medical students to handle the musculoskeletal issues they might encounter. In 1970, the University of North Carolina School of Medicine redesigned the preclinical curriculum to implement an organ-system approach that included the musculoskeletal system. Taught primarily by the orthopedic faculty, the two-week course is given in the second year. It focuses on the basic science of the musculoskeletal system, which includes development, structure and function, normal physiology and biochemistry of bone, cartilage, synovium, and muscle, and pathologic changes produced in these tissues by injury or disease. It then proceeds to correlations between the pathologic, X-ray, laboratory, and clinical aspects in patients with musculoskeletal disorders."

Often voted "best second-year course" by medical students, the program boasts six faculty members who have participated in the course for more than 20 years. So what nuggets of basic science wisdom are being imparted? Dr. Wilson: "We initially cover the normal development of the musculoskeletal system, and then detail the ways in which this development can go awry to produce congenital malformations. Then we review the gross anatomy of the limbs and back and discuss its connection to common clinical disorders. Following this, we cover the individual tissues of the musculoskeletal system with respect to microscopic structure, physiology, biochemistry, and pathology. Cartilage and the arthritides are also discussed, as is trauma. The course

"We're not trying to teach the latest in hip replacement…we're teaching the anatomy, pathology, physiology, and biochemistry that underlie the problems that doctors encounter clinically."

has changed very little each year, since the basics of musculoskeletal disorders don't change a great deal. We're not trying to teach the latest in hip replacement…we're teaching the anatomy, pathology, physiology, and biochemistry that underlie the problems that doctors encounter clinically."

The UNC course consists of 40 contact hours equally divided between lectures and small-group sessions. "We make use of X-rays, photomicrographs, physical examination, and patient presentations in the daily small group sessions, which are the most valuable aspect of the program. The points made in the lectures are illustrated and amplified in interactive small group sessions. From the faculty perspective, small groups are very useful because we can more easily determine which students did not understand points made earlier in the day."

Clara Natoli/morgueFile

"And," says Dr. Wilson, "the UNC medical students do very well on this section of the USMLE-1. Not only do our students consistently rate the musculoskeletal course highly, but their test scores compare favorably with those of students from other schools."

Opening a window into his program, Dr. Wilson states, "For example, we might put up a normal X-ray, then put up an abnormal one and ask, 'What do you see here?' We call on a student, who comes up, examines the X-ray, and discusses it. We are not trying to put them on the spot, but this teaching method has worked exceptionally well. If someone stumbles, then we help him or her along, saying, 'Remember xyz this morning and apply that to this situation.' If the student is still having trouble, we encourage them to use their peers for consultation. At this point we are more concerned with process and the correct approach than we are with the final answer. We try to minimize discomfort while maximizing learning. Indeed, the students regularly comment that they appreciate the nonthreatening environment that we try to create."

There is nothing that drives home an academic point like the patient standing in front of you. "One of the areas that students are most interested in is arthritis. When studying this disease, we bring patients into the small group discussions and let the students hear from them

about what it is like to have this condition. The students also see the patients' X-rays to round out the learning."

If the students weren't learning, the teachers wouldn't be putting so much effort into this unique program. "Three orthopedic faculty members meet four to six times a year to prepare the course schedule, review examination questions, and modify course content as needed. We first assess how students scored on the 100 question, end of course exam in the previous year. If we detect an area where it is obvious that our message didn't come through as clearly as we'd have liked, we try to strengthen that portion in next year's program. For the development of the exam, each lecturer—who may come from orthopedics, anatomy, biochemistry, and rheumatology—submits questions that are based on educational objectives. For example, the objective might be to learn the functions of the muscles in the forearm, and the question might be to predict the disability that would occur if one of those muscles were not functioning."

Dr. Wilson: "About 25 of the questions are new each year, but we don't use any questions from the last three years, so students can't study from last year's test. A subset of the questions are practical, i.e., based on the student's ability to put various aspects of anatomy, pathology and physiology together with clinical information and X-rays to reach a conclusion about what is going on. The students' learning experience is greatly enhanced by the fact that throughout the course basic science lecturers are asked to demonstrate clinical relevance, and clinicians are asked to point out the basic science underlying the clinical disorders. Throughout the program we keep going back and forth between basic science and clinical medicine."

While the basics of musculoskeletal medicine haven't changed much, technology has. "The fact that all lectures are now presented with PowerPoint slides, which are posted on the UNC School of Medicine's web site, really facilitates learning for the students. They also have access to the audio files from lectures. The audio and PowerPoint files are available to students for approximately one year from the date of the lecture, making it easier for them to review for the course exam as well as the U.S. Medical Licensing Exam-I (USMLE-1)."

"And," says Dr. Wilson, "the UNC medical students do very well on this section of the USMLE-1. Not only do our students consistently rate the musculoskeletal course highly, but their test scores compare favorably with those of students from other schools."

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For this and other reasons, you would think that the UNC program would be frequently replicated. "Not necessarily," states Dr. Wilson. "Nationwide, increasing clinical pressures have compromised the teaching and research activities of faculty. While many orthopedic chairs have requested copies of our syllabus—which we have gladly provided—the problem with replicating the program is manpower. When they hear that we put 150 man-hours per year into the program, the chairs are hesitant. Generally speaking, there is so much more clinical pressure these days…so many people appearing in emergency rooms with musculoskeletal problems that it is hard to find enough time to teach."

And despite financial support from the UNC School of Medicine, says Dr. Wilson, "The remuneration provided by the school is not commensurate with the clinical revenues lost due to faculty time spent in preparing and administering the course. We are fortunate that the musculoskeletal course has become an integral part of the UNC orthopedic department's activities—even the more clinically oriented faculty members contribute to the course each year."

Dr. Wilson concludes, "Less than half of the 127 medical schools in the continental U.S. and Hawaii have a preclinical musculoskeletal course. Our hope is that over time such programs will grow in numbers and elevate the quality of musculoskeletal medicine available to all patients." ◆

company

The Orthopedic Social Network?

Call it the Facebook of bones and joints, OrthoMind is hoping to capture a following with surgeons who want to network online.

If you've seen *The Social Network* you know that the online socializing phenomenon has swept the nation. Facebook alone boasts a whopping 500 million users and which one of us hasn't posted a status update or tweeted recently. Now however there is a social networking web site designed specifically for orthopedic surgeons.

OrthoMind (OM) promises to connect orthopedic surgeons and we aren't talking about for playing Mafia Wars or tagging photos either. Although medical social networks aren't rare, this is the first we've seen geared specifically to the orthopedic market.

Jon Hyman, M.D., orthopedic surgeon in Atlanta, Georgia, and board member at OM says the site can help a surgeon's practice in a number of ways. "Surgeons have access to powerful and automated tools which make it easy for them to stay current with research publications in their area of interest, poll their peers on any topic and get real time feedback, collaborate on difficult cases, share surgical technique tips, images and videos, filter peer reviewed literature and news relevant to their interests, share job opportunities and discuss the political, legal and regulatory matters that impact their field." Surgeons can also share clinical outcomes experiences in a HIPAA compliant manner assures Hyman.

Currently the site has over 5,000 members globally. OM began two years ago when a group of Harvard-affiliated orthopedic surgeons collaborated on designing a site dedicated to orthopedic surgeons, where they could share insight using online tools inspired by popular sites like Facebook, Twitter and LinkedIN. "The site was built on the foundation of privacy, security and exclusivity in that it was free from industry sponsorship and was only for surgeons," adds Hyman.

Adds site administrator, Christina Kirkland, " We offer a place for surgeons to gather and speak freely with each other regarding technological advancements, difficult cases, and status updates on society conventions, without fear of repercussion or sales pitches from product manufacturers."

When asked for the top three reasons why a surgeon should join the site, Hyman said the following:

1. "It saves the surgeon time in keeping up with the orthopaedic literature. The site lets the surgeon customize and automate the process of reading journals and publications.

2. It saves the surgeon time by aggregating knowledge and shortening feedback cycles. If a surgeon posts a question, CME activity or poll, answers can be generated by several peers very quickly.

3. OM improves patient care and the practice of orthopaedic surgery. Collaborative wisdom about outcomes, complications, regulatory matters and best practice strategies gives OrthoMind surgeons an added value."

But in order to join you have to be an orthopedic surgeon and that means either a licensed U.S. orthopedic surgeon, American Academy of Orthopaedic Surgeons physician member or invited international orthopedic surgeon.

—JR November 4, 2010) ◆

OrthoMind Homepage/OrthoMind

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Integra's Ortho Rocks 3Q

Integra LifeSciences beat its own revenue expectations for the third quarter and increased sales by 8.3% to $186.6 million. Even better, the company's orthopedics division increased sales by 13.8%.

Record Revenue

"Integra delivered record revenue this quarter, surpassing both our expectations and the Street's," said Stuart Essig, Integra's Chief Executive Officer. "Looking ahead, we expect the development and acquisition of new product lines and the continued performance of our selling organizations to drive top-line growth."

The company generated $29.6 million in cash flows from operations and used $7.2 million of cash on capital expenditures in the third quarter of 2010. During the quarter, Integra repurchased 859,000 shares in the open market, using $31.3 million of cash.

During the quarter, the company also established a $450 million, five-year, senior secured revolving credit facility and a $150 million, five-year, senior secured term loan A, replacing its old credit facility.

Forbes: "One of 100 Best"

Recognizing the company's performance, Integra was named to Forbes magazine's 2010 list of "America's 100 Best Small Companies." This is the third consecutive year and the sixth time in the last seven years that Integra has been named to Forbes list of "Best Small Companies."

—WE (November 3, 2010) ◆

Integra LifeSciences 3Q10	Sales $ in million	% Change
Total Sales	$186.6	up 8.3%
Orthopedics	$72.9	up 13.8%
Neurosurgery	$69.8	up 3.8%
Instruments	$43.8	up 7.2%

Source: Integra LifeSciences

Ranier Lumbar Disc Receives CE Mark

English-based Ranier Technology recently received CE Mark approval for the company's Cadisc-L; an elastomimetic spinal disc replacement device for the lumbar spine. The device is intended to treat DDD (degenerative disc disease) of the lumbar spine.

Ranier CEO Dr. Geoffrey Andrews said the approval will allow the company to implement plans for full commercialization of the device in Europe.

Initial Outcomes

"The initial outcomes in the clinical study are very pleasing. By using the Cadisc-L spinal disc replacement, we found patients had significant reductions in average leg and back pain, and overall disability, and coupled with an

Cadisc-L/Cadisc-C/Ranier Technology

increase in quality of life there are very strong indications of early phase performance," added Ian Quirck, the company's director of clinical and regulatory affairs.

The company believes the utilization of the elastomeric and load bearing properties of the company's PPM (precision polyurethane manufacturing) technology to develop a polymeric disc is a significant development. This past July, the company announced a European patent grant (#01953244.9 based on PCT/GB2001/03441) for the PPM technology.

PPM Technology

According to a company statement, the PPM technology "employs process intensification and control to manufacture consistent and reproducible polyurethanes, characteristics that are fundamental to the success of any medical polymer. The dynamic control of the reaction conditions and stoichiometry provided by the PPM process, also facilitate the provision of a reactive material feed that enables the design and production components with regions of graduated hardness, conferring both programmable mechanical properties and high durability under load."

In addition to the Cadisc-L, Ranier also manufactures a compliant lumbar total disc implant, Cadisc-C, a total replacement disc for the cervical spine. The company's current focus is on total disc implants, but believes its PPM technology platform is suited to a wide range of orthopedic applications. Ranier also produces a range of surgical instruments in support of the company's discs.

—WE (November 3, 2010) ◆

Zimmer 3Q: Tough Sledding

Zimmer's sales declined 1.1% in the third quarter to $965 million.

While company CEO Dave Dvorak told analysts that the company needed to improve its execution, he also expressed the same confidence in the "compelling" long-term benefits of orthopedic procedures that his industry peers have noted in their calls with analysts. He also focused on a "solid" bottom line and cash flow.

Sales for knees declined 3%, hips were flat and spine dropped by 9%

Zimmer 3Q10	Sales $ in million	% Change
Net Sales	$965.0	down 1.1%
Reconstructive	$724.0	down 2%
Hips	$287.0	flat
Knees	$403.0	down 3%
Spine	$56.0	down 9%
Extremities	$34.0	up 3%
Trauma	$58.0	up 1%

Source: Zimmer Holdings

Pricing, Austerity and Volume Slow Downs

Joanne K. Wuensch, BMO Capital Markets analyst, wrote that pricing pressure appears to have accelerated for Zimmer in hips and knees in the quarter, down 2.2% to 2.3% from 1.5% to 1.6%, respectively, in the second quarter. She also noted that sluggish reconstructive sales reflect European austerity measures, volume slow downs in the Americas, price, and some share losses (particularly knees).

Knees, Hips and Spine

For knees, Dvorak said important advances for the quarter included a broader rollout of the company's Patient Specific Instruments and a limited rollout of posterior referencing instruments. He said he was encouraged by the "increasing momentum" the company is experiencing in the commercialization of new hip products, particularly the Continuum Acetabular Cup System."

"In our spine business, we continue to drive operational changes and pursuing an aggressive new product development pipeline," said Dvorak.

Market Share

With the majority of the orthopedic manufacturers having reported, Wuensch says it looks like Zimmer continued to lose share, but at a meaningfully slower rate, declining to 23.0% from 23.4% year-over-yearand 24.4% quarter-over-quarter.

U.S. Army Photo/Wikimedia Commons

The core element of executing the company's strategic plan, according to Dvorak, "involves new product introductions across our businesses. These introductions will position us for an improved performance in the fourth quarter and accelerate growth beyond 2010 as the economy strengthens."

Dvorak concluded:

> **"Even with the economic pressures that we've seen over the last 18 to 24 months, healthcare providers and third-party payers recognize that these replacement procedures are cost effective. They take costs out of the system as opposed to continuing to manage the chronic conditions to which patients would otherwise be exposed. We remain committed to executing our strategic plan with the focus on disciplined financial performance."**

—WE (November 2, 2010) ◆

Wright's 3Q Extremity Surge

Wright Medical's sales rose 3% in the third quarter to $121.7 million.

Hip and knee sales were down 0.2% and 1.9%, respectively. However extremity products surged 17.9%, and biologics sales were up 1.2%.

Kenn W. Kiser/morgueFile

Gary D. Henley, President and Chief Executive Officer, commented, "Global economic factors continued to negatively impact procedural volumes across all areas of our business. Despite these headwinds, the growth rates of our combined biologics and extremities business accelerated for the second straight quarter. Additionally, we are pleased to have resolved our Department of Justice investigation this quarter and look forward to working with our independent monitor over the next 12 months."

Wright Medical 3Q10	Sales $ in million	% Change
Total Sales	$121.7	up 3%
Knees	$30.0	down 1.9%
Hips	$40.0	down 0.2%
Extremities	$30.0	up 17.9%
Biologics	$20.0	up 1.2%

Source: BMO Capital Markets

Extremities Impressive

Joanne Wuensch of BMO Capital Markets said that the company's extremity franchise "continues to impress, but the orthopedics and biologics businesses continue to struggle from a tough orthopedic environment compounded by a lack of new products (the exception being the Evolution Pivot system, which should help in knees)."

Wuensch added, "The extremity franchise held up extremely well during the recession and thus far during the recovery as a result of relatively low procedure costs, faster recovery times, and to the company's efforts; an extensive product portfolio, strong sales force, and marketing execution. The extremities segment, which includes INBONE Technologies, the Valor Hindfoot Fusion Nail System, and now EZ Frame external fixator, should help keep Wright Medical in the positive growth realm while new products in the reconstructive franchise are developed and launched."

Outlook Lowered

The company revised its 2010 net sales outlook to a range of $507 million to $512 million as compared to its previously-communicated range of $515 million to $530 million. This revised target represents growth of 4% to 5%.

—WE (November 2, 2010) ◆

Orthofix's Spine Rises

Alan Milinazzo is a happy camper in Texas in the third quarter of 2010.

Refinancing Orthofix's debt to a lower interest rate, consolidating corporate facilities in Texas and putting up strong spine and biologics sales for the quarter, allowed the company's president and CEO to report earnings growth while larger competitors were trying to manage procedure slowdowns, expired COBRA benefits and payer push-backs.

Orthofix Headquarters/Orthofix

Orthofix 3Q10	Sales $ in million	% Change
Total Sales	$139.9	up 3%
Spine Stim	43.2	up 9%
Implants/Biologics	34.2	up 20%
Total Spine	77.4	up 14%
Orthopedic	34.0	up 2%
Sports Medicine	23.7	down 4%
Other	3.8	down 58%

Source: Orthofix

Total revenue for the quarter rose 3% to $138.9 million. However sales in the spine division rose 14% to $77.4 million.

Said Milinazzo:

> **"We were very pleased with our third quarter results, which included strong revenue growth in both our spinal implants and biologics and spine stimulation divisions. Additionally, with the improved operating leverage we have achieved as a result of our recent reorganization, we were able to generate solid earnings growth despite the need to absorb higher costs associated with certain ongoing legal matters."**

Revenue

The growth in spinal implants and biologics was primarily due, said Milinazzo, to an increase in U.S. sales of the Firebird pedicle screw system, Pillar SA interbody device, and the Trinity Evolution allograft.

Orthopedics revenue growth was driven primarily by international sales of the company's internal and external fixation devices and U.S. sales of Trinity Evolution.

Milinazzo said other revenue decreased in the third quarter as a result of the company's elimination of non-core revenue. The decrease was due to the previously announced sale of the company's vascular business, as well as the expiration of two laryngeal mask distribution agreements in Italy and the United Kingdom.

The company expects total revenue for the year to reach between $564.5 million and $568.5 million. Cash balance rose to $37.2 million from $25.0 million at the end of 2009.

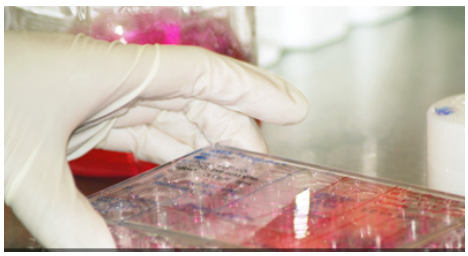
—WE (November 1, 2010) ◆

biologics

Fat Gets Funding

UCLA researchers use liposucked fat as a source for perivascular stem cells and bone regeneration.

The California Institute for Regenerative Medicine (CIRM), the Golden State's stem cell agency recently awarded researchers at the Eli and Edythe Broad Center of Regenerative Medicine and Stem Cell Research at UCLA Early Translational II in the sum of $10.4 million.


CIRMCalifornia Institute For Regenerative Medicine

Three research teams will share the grants, with Dr. Bruno Peault and Dr. Chia Soo, professors of orthopedic surgery leading the stem cell/fat tissue work, along with two other groups in the fields of digestive diseases and ophthalmology.

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Innovating for life.

CIRM awarded a total of $67 million for 19 grants during this awards cycle and is planning to award grants of this size every year to 18 months with the hopes that each project will result in either a candidate drug or cell therapy or make a significant step in such a direction, ultimately working towards FDA submission and clinical trials.

The bone regeneration plan could aid in the treatment of back pain and assist with spine fusion, bone fractures, herniated disks and, even osteoporosis. And with approximately 10 million Americans currently suffering from osteoporosis and the National Osteoporosis Foundation predicting this number to increase 34 million additionally at risk.

Peault and Soo plan to use liposucked fat to obtain stem cells which will then be used to regeneration bone, ultimately offering an alternative to bone grafting. But here's what makes this project different than other stem cells from fat tissue projects. The researchers plan to collect data for a three-year study that attempts to isolate purified stem cell populations from the fat tissue using a combination of antibodies and cell sorting.

And the stem cells the team is using aren't like the traditional ones typically used from fat tissue. The UCLA group is using perivascular stem cells (PSCs). Because they aren't cultured for weeks, PSCs can offer quicker treatments of purer population of stem cells.

After being mixed with growth factors, the combination would be implanted to regenerate bone. And because the fat would come from a patient's own body, the risk of rejection would be minimized. Peault and Soo would like to demonstrate that PSCs offer a better method than previous fat tissue stem cell harvesting.

In other UCLA biologics news, the new Terasaki Life Sciences Building opened its doors on October 25. The Terasaki building which will house numerous labs spanning the spectrum of study will include an emphasis on biomedical innovations. In fact the Broad Stem Cell Research Center–California Institute for Regenerative Medicine Laboratory will be located on the third floor and conduct human stem cell research, led by Dr. Owen Witte, director of the UCLA's Broad Stem Cell Research Center and a Howard Hughes Medical Institute investigator.

—JR (November 5, 2010) ◆

large joints

Dual Openings at Surface Dynamics

It's twins for implant coating company Surface Dynamics. The company announced this week the opening of two coating manufacturing facilities, one in Memphis and another in Cincinnati.

Both plants will provide the same services, applying biomedical coatings and thermal spray coating solutions for orthopedic, dental and spinal implants. The company uses porous plasma sprayed CP-Titanium coatings (Ti), Hydroxyapatite (HA) coatings, and plasma sprayed coatings of Ti or HA on PEEK.

According to the American Academy of Orthopaedic Surgeons, there are currently 193,000 total hip replacements and approximately 581,000 total knee replacements performed in the U.S. each year.

The Cincinnati facility is 9,000 square feet, with the Memphis site eclipsing that with 14,000 square feet. Both locations have the same quality systems and manufacturing capabilities, including laser and e-beam sintering for rapid manufacturing and metallurgical laboratory.

"We strategically placed our plants in Memphis and Cincinnati to accommodate our customers, who design, engineer and manufacture medical implants", says Memphis Managing Director, Roy Smith in a press release.

But the company also has plans to open a plant overseas to better service global clients. Surface Dynamics already partners with the Italian biomedical coating company, Eurocoatings. This is a key component to the company's offerings according to CEO and founder of Surface Dynamics Leo Glass.

"Our goal in joining with Eurocoatings is to improve or 'raise the bar' on coat-

Hip Replacement/Surface Dynamics

ing value while continually improving quality. With Eurocoatings' superior HA coating and our titanium coating technology, we will improve the overall outcome for the device manufacturer as well as the ultimate customer, the patient."

Surface Dynamics is also excited about their research and development work, which involves plasma sprayed titanium coatings on PEEK, Meeting FDA Guidance requirments is currently the goal here.

—JR (November 4, 2010) ◆

iDuo G2 Available for Knees

Just for you, Mrs. Jones…and just in time…ConforMIS just announced the commercial availability of the iDuo G2, the next generation of its bicompartmental knee resurfacing system. According to the company, the iDuo G2 shines because it incorporates proven principles for patella treatment from traditional total knee replacement with the unique advantages of the ConforMIS partial knee system.

The iDuo G2 is designed to be a less invasive alternative to total knee replacement for patients suffering from disease in the medial or lateral compartment of the knee, along with the patellofemoral joint. Only the diseased parts of the joint are addressed, meaning that the iDuo G2 results in the preservation of ligaments and far more bone than a traditional total knee replacement. According to the company, the iDuo G2 provides an engineered patellofemoral joint to correct deformity, a wear optimized implant design, and improved surgical instrumentation and iView planning images for an efficient surgical technique.

"Considering that nearly one third of joint replacement patients have pain limited to two compartments of their knee, the iDuo G2 is an important expansion to the treatment options surgeons can offer," said Raj Sinha, M.D., Ph.D., in the news release. Dr. Sinha, one of the early users for the iDuo G2 and a member of ConforMIS' Scientific Advisory Board, added, "ConforMIS' ability to apply surgeon feedback to introduce a second generation of its implant so quickly is a testament to the advantages of their just-in-time model and their dedication to the patient-specific approach."

Detailing how the iViews work was Dr. Philipp Lang, CEO of ConforMIS, who told *OTW*, "The iViews demonstrate the clinical value that we can add with our patient specific approach. Our iViews represent 3D images of a patient's individual knee both before and after the implants are in place. By providing these images before each procedure, we allow the surgeon to visualize the location of interfering osteophytes, plan their bone resections, and confirm the placement of the iJigs and implant components during surgery."

He also commented to *OTW* regarding the "just-in-time" concept: "Every ConforMIS implant is made for a single patient and shipped to the hospital, with all the instruments in one disposable kit. Hospitals no longer need to maintain multiple rooms of implant or instrument inventory that need to be cleaned, reprocessed and transported. For patients, this model allows each individual patient to get customized cutting guides that can both speed the surgery and enhance its safety. Our system avoids the very real complications that can come from improper instrument reprocessing, use of the intramedullary canal for alignment, or navigation pin fractures."

—EH (November 4, 2010) ◆

ConforMIS/morgueFile

Orthopedics Mission Nearly Thwarted

Operation Walk Canada's orthopedic volunteer work in Guatemala was nearly roadblocked by red tape.

The organization Operation Walk Canada had overcome all the hurdles of preparing for a humanitarian orthopedic mission. They had the team of qualified volunteer surgeons and support staff along with the right combination of instruments and implants to pull off their charity operation in Guatemala. But there was one variable they hadn't counted on that threatened to sideline the entire mission: the Guatemalan customs department.

Airport Security/Creative Commons

On Saturday, October 30, surgeons, anesthetists, nurses, and physiotherapists waited, their hands figuratively tied, with nothing to do. An ambitious agenda of hip and knee replacement operations loomed for the upcoming week. But for the 50-person team, whose members had traveled from all around North America and Spain, the mission was in question.

Patients were waiting as well. More than 70 patients in fact. The surgical team and patients waited, while the implants and surgical instruments sat in a Guatemala customs office, with no sign of them landing in an operating room anytime soon.

The London-based charity hadn't experienced a roadblock like this since dedicating their focus to helping correct serious orthopedic conditions in the native Mayan population who lack this type of advanced medical care. With half of the nation's population below the poverty line, this Central American population relies on this type of humanitarian care.

With some swift maneuvering and the help of Guatemala's ambassador to Canada, Licenciado Georges de La Roche, late Saturday the implants were freed for use.

And so on to the business at hand: hip and knee replacements.

On a side note, it appears doctors have found a striking difference between their Mayan patients and the patients they generally treat in the U.S. and Canada. According to Free Press medical reporter John Miner, who's travelling with the doctors during this mission, the Guatemalan patients are requiring a significantly less amount of painkillers. Additionally the team found out that these Mayan patients can't tolerate opioid painkillers.

Five years ago when the team began making missions they were treating the patients the same way they would their everyday patients. But it didn't work well and many of the Mayan patients suffered side effects. So this year the team is using only the most basic of painkillers in small amounts and seeing far better results.

So far Ofelia, a young mother with a new baby has received surgery to repair a broken hip from a recent fall and Orlando has been treated with a revision surgery after having lived for a decade with a prototype implant. But these are the rare cases of orthopedic repair in the country as one statistic demonstrates. A third of all hip and knee surgeries that are performed in Guatemala each year on its population that tops 13 million can be credited to the Walk Canada team. Surely thousands more go without.

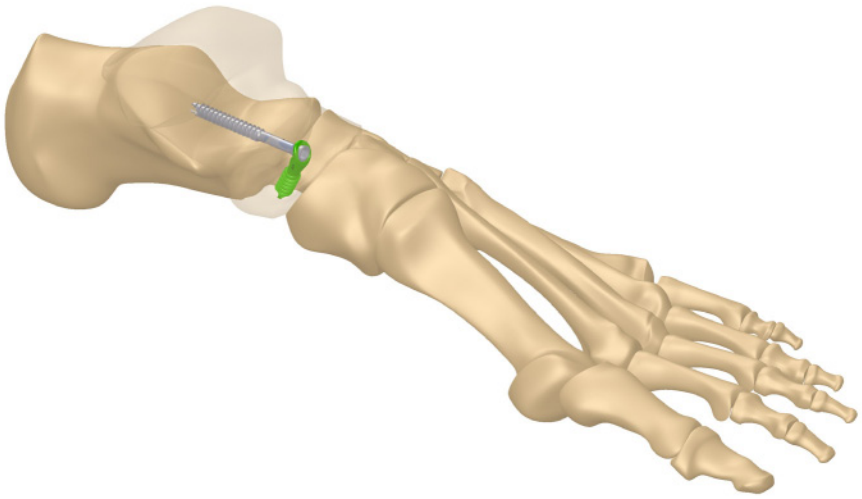
—JR (November 2, 2010) ◆

extremities

FDA Clearance for Extremity Medical

Surgery through a pinhole? Not exactly, but in the case of Extremity Medical, the incisions are getting smaller. The company has recently announced the receipt of 510(k) clearance from the FDA on the IOFiX Intraosseous Fixation System for foot and ankle procedures. The company also announced that the CE Mark has been received for this product.

"This system has been designed to fill a large void in foot and ankle surgery by applying the well-accepted principles of intramedullary fixation," stated Christopher DiGiovanni, M.D., in the news release. Dr. DiGiovanni, Professor and Chief of the Division of Foot and Ankle Surgery in the Department of Orthopaedic Surgery at Brown University/Rhode Island Hospital, added, "While these concepts have enjoyed amazing success in other parts of the musculoskeletal system, they have never really been adapted to, nor taken advantage of, by foot and ankle specialists.



Extremity Medical

Our intention is for these foot-specific devices to offer the surgeon a significantly improved modularity, ease of use, and construct rigidity capable of facilitating many surgical techniques involving trauma and reconstructive surgery of the forefoot, midfoot, and/or hindfoot —all in one set. We anticipate that the introduction of intramedullary fixation to the foot will continue to evolve into less complicated, more stable, and lower profile fixation than can otherwise now be obtained.

We are also very excited about the potential this technology offers in performing these procedures through smaller and smaller incisions with increasingly less soft tissue dissection and hardware prominence, as well as hopefully enabling faster progression to weight bearing in the post-op setting, much akin to what has already been realized with the traditional IM devices currently in use in other areas."

Jamy Gannoe, President and Co-Founder of Extremity Medical, stated in the news release, "Introduction of this product further demonstrates our commitment to delivering useful and different products with new, clinically beneficial functions. The IOFiX Foot and Ankle System complements the HalluX, TarsX, and IOFiX MCP Intramedullary Fixation Systems and adds to a growing portfolio of specialized devices specific to the needs of distal extremities surgeons."

Gannoe told *OTW*, "In reviewing available technologies for foot and ankle reconstruction, we found many underserved indications. We found potential to improve outcomes through specialized design. The Extremity Medical approach is to observe cases, listen to surgeons and study the specific needs for an indication. This is different from adaptation of a product designed for something else. When engineers examine the specific needs at the outset of the design process, the result is a new and useful solution like the IOFiX Platform, and the TarsX, HalluX and IOFiX MCP Systems. These are products with clear advantages."

—EH (November 4, 2010) ◆

people

Terry Schlotterback Joins Affinergy Board

Affinergy has announced that veteran orthopedic expert Terry Schlotterback has joined its Board of Directors. For 20 years, Schlotterback lent his guidance to Zimmer, most recently in two key leadership roles as President of Zimmer Trauma Division and President of Zimmer Spine Division. He was also VP at Zimmer in Sales, Product Development, and Global Marketing Services roles as well as leadership roles at DePuy and Mitek Surgical Products, divisions of Johnson and Johnson.

"Affinergy's robust product pipeline and compelling vision for growth gives me great enthusiasm to actively support this drive to commercial success," said Schlotterback in the news release.

Terry Schlotterback

"These products can improve patient outcomes while simultaneously containing healthcare costs. I am confident that surgeons will be eager to incorporate these proprietary products into their practices and distributors will find them to be valuable additions to their offerings."

"Terry has a unique combination of experiences across orthopedic markets as well as across functional areas such as product development, sales, and executive leadership," added Peyton Anderson, CEO of Affinergy. "He has already proven to be a tremendous advisor in terms of our product development and hiring plans for the Affinergy commercialization team. Terry's expertise and deep industry connections will be critical to our long-term growth plans. On a personal level, Terry is a thoughtful mentor with impeccable integrity who is deeply committed to improving patient outcomes."

Terry Schlotterback told *OTW*, "I am very excited about joining the Board of Directors of Affinergy. My experience in large and small companies allows a broad perspective on the challenges we face when commercializing a new product into the orthopedic market place. My years of developing new products and working closely with the distribution channels will be a benefit to Affinergy as we prepare to launch products into this space. I will draw upon my experience with Mitek Surgical Products; as a startup company we introduced new products while building a distribution channel. At Zimmer I led the Spinal Division while introducing an innovative approach to spinal fusions and building a strong distribution channel. I believe these experiences will be a benefit to Affinergy as the company prepares for commercialization of their new product."

—EH (November 2, 2010) ◆

THE PICTURE OF SUCCESS

Dr. Joel Press

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

Dr. Joel Press

As he stood at the lectern for his first speech as president of the North American Spine Society (NASS), Dr. Joel Press, Founder and Director of the Sports Rehabilitation Program at the Rehabilitation Institute of Chicago, thought he might be "booed" offstage. His words that day had little to do with reimbursement or the latest, greatest spine surgery…they had more to do with the sociology of treating patients. But the audience welcomed his message, because, as Dr. Press has discovered over the years, simplicity often strikes a strong chord.

Dr. Press, a physical medicine specialist, widened the eyes of NASS members to the importance of nonoperative spine care. And he is known for always finding a way to encourage patients—even if he cannot help them. Years ago Dr. Press developed an appreciation for working with severely disabled people, looking at the positive, and working with what they have. But he doesn't leave it at that. Dr. Press has been involved in the development of an innovative elliptical trainer that could revolutionize how those with many disabling conditions, from knee pain and arthritis to cerebral palsy live their lives.

Blessed to have an infectious passion for patient care, Dr. Press could have instead spent his days on an assembly line. "I was raised in a blue collar town in Illinois where my dad was an executive at a meat packing plant. There was a substantial amount of discussion about how I would *not* go into the meatpacking business. I was sold on that idea… from the age of 12 until I was 21 I spent most of my summers there, making boxes and grinding hamburgers. I didn't know what I was going to do, but I studied extra hard to ensure that meatpacking was not in my future."

Accused by his family of being "too optimistic," Dr. Press admits that sometimes he "sells a little hope." "There is no point in saying to someone, 'Your back is in terrible shape.' Why not say, 'There are some things that might be able to improve your back' and, 'I will help you learn how to deal with this problem.' This is one of the lessons I learned in childhood when I came into contact with several physician role models. There was a physician in our neighborhood who was especially calm and encouraging. I was moved by his compassionate manner and therein began to develop an interest in medicine."

And while he gave the surgical disciplines a chance, Dr. Press found that his calm in the center of the storm of options was nonoperative. "I spent a lot of time working with orthopedists and neurosurgeons, but came to feel that becoming a surgeon would move me away from interacting with patients. I followed my strengths and decided to learn what awaited me in the nonoperative realm."

To those who doubt the role of nonoperative care, Dr. Press says, "A full 90% of patients with back pain do not need surgery. My NASS presidential speech discussed the fact that it's not about the spine—it's about the patient with the spine problem. I had numerous positive comments along the lines of, 'Thanks for reminding us what is

"Physical medicine is often a mystery to those in other specialties. But surgeons have a responsibility to understand the different aspects of nonoperative care; and physical medicine specialists must educate themselves as to what exactly surgery can offer patients."

important.' It is really telling that when you ask patients what is important (the doctor listens to me) and then ask the surgeon what is important (surgical techniques), that you get two different answers. In fact, the best surgical outcomes occur in patients who have had the best nonsurgical care. The key to patient care—and to doctors 'playing nice in the sandbox'—is to be knowledgeable about, and respect, one another's talents."

But this can't happen, says Dr. Press, if one medical hand doesn't know what the other is doing. "Physical medicine is often a mystery to those in other specialties. But surgeons have a responsibility to understand the different aspects of nonoperative care; and physical medicine specialists must educate themselves as to what exactly surgery can offer patients. The bottom line is to know what you know and what you don't."

Dr. Press had ample time to consider this and other medical issues—his own pain as well—while pedaling nearly 4,000 miles across the U.S. "In 2007 I undertook a 'Ride for Rehab' to raise awareness and funds for the Rehabilitation Institute of Chicago. Funding of nonoperative care is truly lacking. It certainly doesn't come from industry… who is going to pay you to develop a better exercise?"

While funding is an uphill battle, truth in treatment should not be. "We physicians need to be willing to look at our failures. There are certainly times when I 'miss' something that is going on with a patient. In both the surgical and nonsurgical worlds we treat patients and then when we don't hear from them, assume that they improved. In fact, many times, they just went elsewhere for more treatment. The true test of treatment is how people do down the road. Following up with patients cuts down on the BS…as I like to say, 'Nothing ruins a good outcome like follow-up.'"

So when patients climb off Dr. Press' new elliptical trainer for the last time, he will be checking in with them months and years later. "We have done research on the role of the muscles around the hip and pelvis as they relate to the knee. We have traditionally done strength training for the lower extremities on Nordic Tracks, which operate front to back in the sagittal plane. Because it is also important to train side to side and rotationally, I have been part of a team that has developed an off axis elliptical trainer with inversion/eversion motion at the hip. This will help train different muscles to develop more functionality. We are doing the prototype now and are applying for funding to work with kids who have cerebral palsy."

Dr. Press, who has obtained several R01 grants from NIH (National Institutes of Health), states, "The key to research is to have strong collaborations between those with clinical backgrounds and those whose talents lie in the basic sciences. Scientists think they can prove everything, but don't always know what is important to prove. In contrast, clinicians think that they know what is clinically important and what is the best way to prove it, when actually their research methods are not as good as they think. In the end, the great science is being done on that which is clinically relevant."

When asked about his secrets of success, Dr. Press' answer is simple. "I love what I do; my goal is to work until I'm old…until one day I walk out of my office and drop dead. Feeling such a connection to my work means that I am more engaged with and available to patients. Not only that, but if you are not passionate about your work, you will take short cuts (such as not staying up on the literature) and the quality of your work will suffer. If you regard every patient as a learning experience then you will be willing to do your best work. I tell young doctors coming up that they should remember that it is a privilege to do what we are doing."

"My other 'secret' to success comes from the service industry. I once went on a backlot tour of Disney with a group of executives, many of them from hospitals. The thing that impressed me most was the Disney drive to consistently exceed their customers' expectations. Since that time I have used the same model, doing simple things that can help patients have a better than expected treatment experience. For example, every patient that calls me during the day gets a return call that night. I usually say, 'Sorry that it took me so long

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to get back to you.' I think patients are expecting more than ever. We physicians as a whole are not very good at meeting, let alone exceeding those expectations."

While Dr. Press does his utmost to exceed patient expectations, he himself doesn't have outrageous expectations of life. "I am tremendously pleased with my life. I married the person I wanted to, I have a roof over my head, and I live in a terrific country. While it is easy to get wrapped up in complaining about things such as Medicare reimbursement, etc., I really think this is akin to background noise. We have to keep our perspective. In this country we still have opportunities to do what we think is best for patients. Yes, things are more restricted than they used to be, but we still have the best thing going. If you look around the world you will find that medicine is still like the 'Wild Wild West' in a lot of places. My advice to young doctors is to refrain from complaining and to be part of the solution."

Alas, there are some things that while he might not like it, just evolve. "My wife and I are empty nesters and I just hate it. Fortunately, we still talk to our daughter and son every day. I'm left with more time to do my bike riding, however, and to explore the country."

Dr. Joel Press…a quiet hero who cares deeply, has elevated non-operative care, and gives 110% to his patients. ◆

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