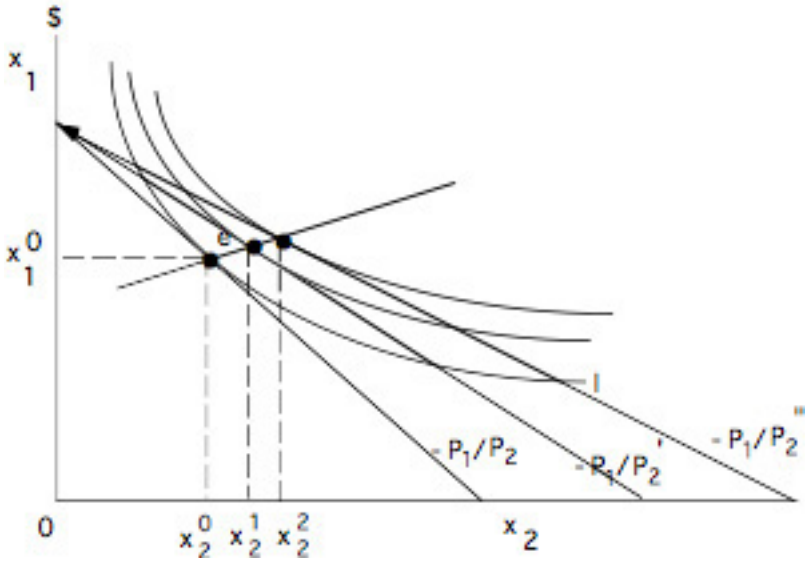
VOLUME 7, ISSUE 20 | JUNE 21, 2011

Orthopedics This Week

week in review



picture of success

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: The end of the Fed's money pump (otherwise known as QE2) has most everyone, including us, a bit concerned. The issue is liquidity or access to capital. No capital, no growth. No capital, no R&D. No capital, no clinical studies. QE2 ends this month and starts affecting the economy sometime around Q4.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	14.72%	6.08%	Bob Vaters is OFIX's new CEO. No drama succession—another example of Milinazzo's exemplary style and substance.
2	2	NuVasive	6.84	6.52	NUVA's short interest as percent of the stock's float is 16.66%. Conditions are good for an old fashioned short squeeze.
3	4	Johnson & Johnson	26.33	0.55	3.40%. That's the dividend yield. Name one bank that pays as much. And JNJ is buying Synthes. Up one spot.
4	3	Zimmer	27.75	(9.90)	BUY recommendation from Wall Street firm Collins Stewart. Third best overall ortho value.
5	8	Kensey Nash	34.24	0.41	New, $35 million unsecured line of credit. Why? Working capital and M&A.
6	7	Smith & Nephew	22.80	(5.96)	No summer doldrums at SNN. Q2 Sales growth rates close to 7%—Wall Street estimates. Higher than full year rates.
7	6	Stryker	25.23	(9.83)	SYK starting to use its cash to strategic advantage. Appears to be gravitating to a materials technology focus.
8	5	Alphatec	(2.01)	(5.82)	Consensus sales growth estimate this quarter is 9.70%. Spine is tough right now.
9	NR	Exactech	8.08	1.79	The first quarter was better than expected. Buyers are starting to find EXAC attractive at these prices. Q2's report continue Q1's momentum?
10	10	Wright Medical	8.76	(8.55)	After the shock of the resignations and firings, maybe the dust is settling. Maybe not. But there's probably more upside than down.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	NuVasive	NUVA	$33.49	$1,329	6.52%
2	Orthofix	OFIX	$40.49	$731	6.08%
3	Tornier N.V.	TRNX	$27.37	$1,069	3.24%
4	Synthes	SYST.VX	$173.22	$20,574	2.44%
5	Exactech	EXAC	$18.15	$237	1.79%
6	ArthroCare	ARTC	$33.37	$911	0.72%
7	Johnson & Johnson	JNJ	$66.29	$181,710	0.55%
8	Kensey Nash	KNSY	$24.29	$207	0.41%
9	Orthovita	VITA	$3.84	$296	0.26%
10	MAKO Surgical	MAKO	$27.14	$1,112	-5.07%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Bacterin Intl Holdings	BONE	$2.76	$105	-20.00%
2	TiGenix	TIG.BR	$1.42	$44	-16.61%
3	Symmetry Medical	SMA	$8.44	$307	-12.36%
4	Medtronic	MDT	$38.19	$40,840	-11.60%
5	Zimmer Holdings	ZMH	$62.05	$11,911	-9.90%
6	Stryker	SYK	$57.71	$22,392	-9.83%
7	RTI Biologics Inc	RTIX	$2.67	$147	-8.87%
8	Wright Medical	WMGI	$14.23	$555	-8.55%
9	Integra LifeSciences	IART	$46.55	$1,330	-8.47%
10	ConMed	CNMD	$26.63	$754	-6.33%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Medtronic	MDT	$38.19	$40,840	11.64
2	Zimmer Holdings	ZMH	$62.05	$11,911	13.70
3	Johnson & Johnson	JNJ	$66.29	181,710	13.75
4	Kensey Nash	KNSY	$24.29	$207	13.80
5	CryoLife	CRY	$5.18	$145	14.00

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	NuVasive	NUVA	$33.49	$1,329	39.87
2	ArthroCare	ARTC	$33.37	$911	28.04
3	Synthes	SYST.VX	$173.22	$20,574	22.64
4	Wright Medical	WMGI	$14.23	$555	21.89
5	Exactech	EXAC	$18.15	$237	21.10

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Orthofix	OFIX	$40.49	$731	0.92
2	Kensey Nash	KNSY	$24.29	$207	1.05
3	Exactech	EXAC	$18.15	$237	1.18
4	NuVasive	NUVA	$33.49	$1,329	1.24
5	Symmetry Medical	SMA	$8.44	$307	1.26

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Alphatec Holdings	ATEC	$3.40	$303	2.95
2	CryoLife	CRY	$5.18	$145	2.71
3	ConMed	CNMD	$26.63	$754	2.26
4	Johnson & Johnson	JNJ	$66.29	181,710	2.06
5	ArthroCare	ARTC	$33.37	$911	1.76

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Symmetry Medical	SMA	$8.44	$307	0.85
2	RTI Biologics Inc	RTIX	$2.67	$147	0.89
3	ConMed	CNMD	$26.63	$754	1.06
4	Wright Medical	WMGI	$14.23	$555	1.07
5	CryoLife	CRY	$5.18	$145	1.24

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	MAKO Surgical	MAKO	$27.14	$1,112	25.10
2	TiGenix	TIG.BR	$1.42	$44	18.35
3	Bacterin Intl Holdings	BONE	$2.76	$105	5.63
4	Synthes	SYST.VX	$173.22	$20,574	5.58
5	Tornier N.V.	TRNX	$27.37	$1,069	4.70

PSR: Aggregate current market capitalization divided by aggregate sales and the calculation excluded the companies for which sales figures are not available.

Demand for Hip Replacements, Knee Replacements and Spine Fusiont

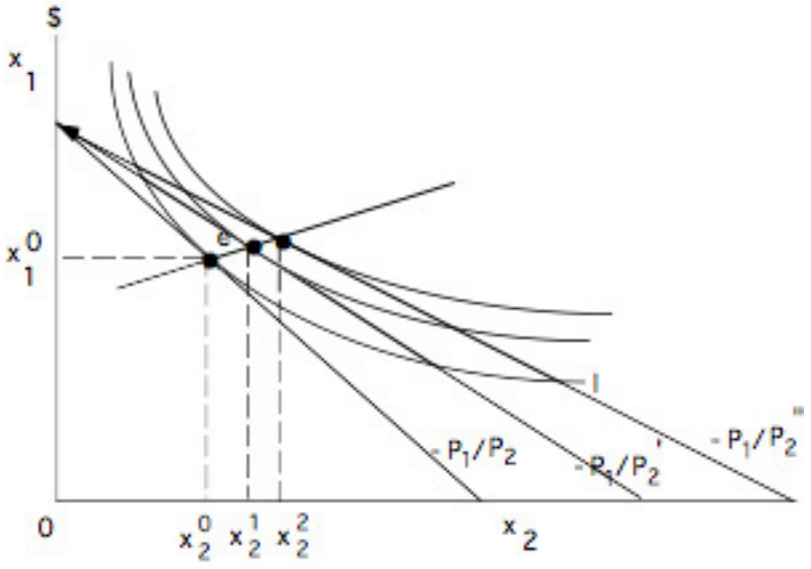
By Robin Young

After the pain comes the test of will. From onset to wheelchair, the task is the same: contain the pain…maintain mobility… stay working. Problem is, arthritis doesn't read the newspapers, isn't clued into budget deficits and never adjusts to economic news. Arthritis exacts its toll regardless of job status. More than anything, that fact may well define whether the price of arthritis will be paid with surgical intervention, with pharmacopeia or in misery. It may also define whether suppliers of orthopedic implants can return to the robust growth of five years ago.

Pathology of Degenerative Musculoskeletal Diseases

The human body reaches its physical apex sometime between the 22nd and 29th year of life. After that, because of DNA, wear and tear or other factors, the body's systems begin to degenerate. When those degenerative processes affect the musculoskeletal system, they are called "osteoarthritis," "osteoarthrosis," "degenerative disc disease" or one of several other descriptive terms for the same basic physiologic process.

The correlation between age and the onset of the degenerative processes is positive and absolute. As the musculoskeletal system matures, osteophytes and subchondral cysts can form, spines can become more compact and unstable and millions of patients show up at their doctor's office asking for relief from chronic and severe pain.



Source: Wikimedia Commons and David Levinson

These are natural processes. They are universal. They are not going away.

Cost of Hip/Knee/Spine Procedures in the United States

When the pain of a degenerated joint or disc becomes debilitating, surgery is often the best long-term treatment. The cost of surgery, however, is high.

The following three tables provide the most recent data available on the cost and reimbursement of hip arthroplasty, knee arthroplasty and spine fusion procedures in the United States. This data, provided by PearlDiver Technologies Inc., is aggregated from Ingenix and the Centers for Medicare and Medicaid Services (CMS).

U.S. Hospital Charges to Private Payers

PearlDiver

The data below is drawn from the PearlDiver Private Payer Database, which contains inpatient and outpatient procedures covered by private insurers. Presented below are the charge results by year based upon the ICD-9 procedure coding billed by facilities.

PearlDiver

Procedure	Region	2006	2007	2008	2009
Hip Arthroplasty	Midwest	$39,338	$42,016	$42,567	$45,065
Hip Arthroplasty	Northeast	$44,072	$47,045	$47,620	$51,118
Hip Arthroplasty	South	$49,641	$53,129	$54,236	$54,950
Hip Arthroplasty	West	$57,608	$61,144	$61,545	$65,938
Knee Arthroplasty	Midwest	$36,037	$38,970	$39,849	$42,031
Knee Arthroplasty	Northeast	$43,690	$47,987	$46,486	$45,847
Knee Arthroplasty	South	$45,041	$49,101	$50,919	$52,291
Knee Arthroplasty	West	$51,164	$56,150	$59,461	$59,804
Spinal Fusion	Midwest	$63,694	$70,908	$78,275	$81,173
Spinal Fusion	Northeast	$67,673	$72,403	$80,063	$82,084
Spinal Fusion	South	$73,285	$82,994	$89,192	$90,451
Spinal Fusion	West	$103,575	$115,385	$126,054	$124,189

PearlDiver Technologies, Inc.

U.S. Hospital Charges to CMS

PearlDiver

The data below is drawn from Center for Medicare and Medicaid Services Inpatient Standard Analytical File, which contains inpatient procedures covered Medicare. Presented below are the charge results by year based upon the ICD-9 procedure coding billed by facilities.

PearlDiver

Procedure	Region	2006	2007	2008	2009
Hip Arthroplasty	Midwest	$35,531	$38,108	$40,658	$42,524
Hip Arthroplasty	Northeast	$40,598	$43,230	$45,455	$47,627
Hip Arthroplasty	South	$41,978	$44,725	$47,614	$50,096
Hip Arthroplasty	West	$53,736	$57,312	$61,528	$65,077
Knee Arthroplasty	Midwest	$32,908	$35,150	$37,364	$39,365
Knee Arthroplasty	Northeast	$37,792	$40,090	$42,492	$44,995
Knee Arthroplasty	South	$38,549	$41,157	$43,833	$46,329
Knee Arthroplasty	West	$49,540	$53,776	$57,351	$61,001
Spinal Fusion	Midwest	$62,057	$67,868	$74,174	$79,737
Spinal Fusion	Northeast	$71,547	$75,821	$83,505	$88,556
Spinal Fusion	South	$65,888	$71,381	$77,810	$84,332
Spinal Fusion	West	$96,930	$108,286	$117,906	$127,912

PearlDiver Technologies, Inc.

U.S. Medicare Reimbursement For Specific Hip, Knee and Spine Surgeries

PearlDiver

The data below is drawn from Center for Medicare and Medicaid Services Inpatient Standard Analytical File, which contains inpatient procedures covered Medicare. Presented below are the reimbursement results by year based upon the ICD-9 procedure coding billed by facilities.

PearlDiver

Procedure	Region	2006	2007	2008	2009
Hip Arthroplasty	Midwest	$9,923	$10,252	$10,515	$11,168
Hip Arthroplasty	Northeast	$11,746	$12,050	$12,318	$13,147
Hip Arthroplasty	South	$10,189	$10,419	$10,735	$11,385
Hip Arthroplasty	West	$11,527	$11,335	$11,610	$12,887
Knee Arthroplasty	Midwest	$9,907	$10,137	$10,295	$10,896
Knee Arthroplasty	Northeast	$11,725	$11,957	$12,196	$13,027
Knee Arthroplasty	South	$10,004	$10,267	$10,420	$10,991
Knee Arthroplasty	West	$11,544	$11,329	$11,547	$12,752
Spinal Fusion	Midwest	$18,238	$19,696	$21,039	$22,857
Spinal Fusion	Northeast	$21,357	$22,773	$24,267	$26,094
Spinal Fusion	South	$17,167	$18,317	$19,406	$21,117
Spinal Fusion	West	$21,668	$23,009	$25,158	$27,819

PearlDiver Technologies, Inc.

Between 2006 and 2009, hospital charges to private payers for hip arthroplasty increased from $39,338 in the Midwest region of the U.S. to $45,056, a 14.5% increase. Charges for knee arthroplasties similarly rose as did charges for spinal fusions. All told, charges for these three procedures ranged from a high of $127,000 to a low of about $39,000.

Medicare reimbursement for these procedures also increased between 2006 and 2009, but the amount being reimbursed, which ranged from about $28,000 to about $11,000 was substantially less than the amounts being charged by hospitals.

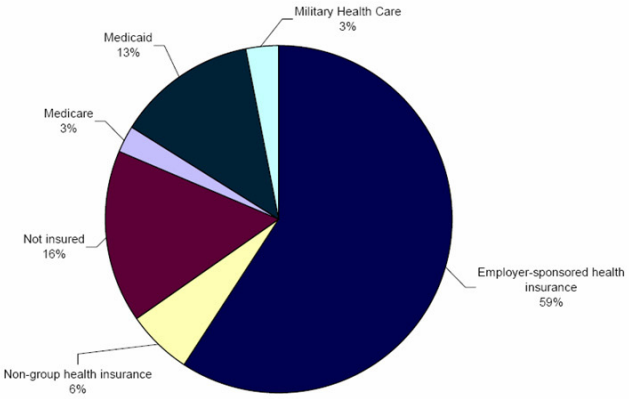
Even with insurance, reimbursements for these basic procedures do not appear to fully cover the charges.

The Recent Drop in Health Insurance Coverage

Earlier this year, the U.S. Census Bureau reported that the number of people covered by some form of health insurance had declined and that this was the first overall decline since records began to be compiled.

As the table below shows, the number of people in the United States who are covered by insurance declined by about 6 million to 253,606,000 in 2009 (the most recent data available). Most of those people (194 million) are covered by private health insurance. Most of those people (169.7 million)

Health Insurance Status (Under 65 Years of Age)



Source Wikimedia Commons and White House Counsel of Economic Advisors

are covered by employment-based insurance plans. It was, in fact, the drop in employment-based insurance that accounted for virtually the entire overall drop. Every other category of insurance coverage increased in 2009. Only employment-based health insurance coverage fell.

Year	Number of People Covered by Private or Government Health Insurance (000s)								
	Total	Private Health Insurance			Government Health Insurance				Not Covered
		Total	Employment Based	Direct Purchase	**Total**	Medicaid	Medicare	Military Health Care	
2009	253,606	**194,545**	169,689	27,219	**93,167**	47,758	43,440	12,412	50,674
2008	255,143	**200,992**	176,332	26,777	**87,411**	42,641	43,029	11,560	46,340

U.S. Census Bureau and RRY Publications

The Recent Drop in Employment

Not coincidentally, the number of people employed in the civilian labor force in the United States also dropped in 2009. The number of people employed in the U.S. in 2009 fell to 139.9 million from 145.4 million. The unemployment rate increased from 5.8% to 9.3%. Those trends have continued into 2010 and 2011. In 2010, the number of people employed in the civilian labor force in the United States declined slightly to 139.0 million. The unemployment rate edged even higher to 9.6%. So far this year, the unemployment rate is hovering around 9.1%

Year	Civilian Labor Force								Not in labor force
	Total	% of population	Employed				Unemployed		
			Total	% of population	Agri-culture	Nonagri-culture	Number	% of labor force	
2009	154,142	65.4%	**139,877**	59.3%	2,103	137,775	14,265	9.3%	81,659
2008	154,287	66.0%	**145,362**	62.2%	2,168	143,194	8,924	5.8%	79,501

U.S. Census Bureau and RRY Publications

When the health insurance coverage data for 2010 and 2011 is finally released by the U.S. Census Bureau, there is no doubt, we think, that the number of people with employment-based health insurance will likely to have declined again.

Also between 2008 and 2010, unit growth rates for hip, knee and spinal implants declined significantly. Could the drop in employment and therefore private insurance coverage be the main culprit?

We think so.

Employment Forecasts for 2012 and Beyond

Two recent economic forecasts point to a slight improvement in the overall employment rate this year but, for the next two to three years, stubbornly and historically high overall rates of unemployment.

The report from the University of Michigan's Research Seminar in Quantitative Economics (RSQE), George A. Fulton, Director, wrote in their most recent report: "This year, with a new Congress in place, the focus is on deficit reduction through spending cuts. Some deficit reductions will occur automatically as the 2009 stimulus provisions expire, and lower troop commitments abroad should lead to slower growth in defense spending. An urgency has also developed regarding budget imbalances at the state and local levels. Federal dollars have been a stopgap over the past few years, but that funding is unlikely to continue. The fiscal restraint at all levels of government will likely be an impediment to economic growth over our forecast horizon."

The RSQE report goes on: "The unemployment rate inches down over the next two years, reaching 8.4% by the closing quarter of 2012. The improvement in jobless rate is slowed by workers re-entering the labor force as job prospects improve. The unemployment rate averages 8.8% this year and 8.5% in 2012, down from a 9.6% reading for calendar 2010."

In a speech delivered to the International Monetary Conference last week in Atlanta, Fed Chairman Ben Bernanke said, "Although hours of work have increased during the expansion, this measure still remains about 6.5% below its pre-recessionary level. Other indicators, such as total payroll employment, the ratio of employment to population, and the unemployment rate, paint a similar picture. Particularly concerning is the very high level of long-term unemployment—nearly half of the unemployed have been jobless for more than six months."

Bernanke went on to say; "Although the jobs market remains quite weak and progress has been uneven, overall, we have seen signs of gradual improvement. For example, private-sector payrolls increased at an average rate of about 180,000 per month over the first five months of this year, compared to less than 140,000 during the last four months of 2010 and less than 80,000 per month in the four months prior to that. As I noted, recent indicators suggest some loss of momentum, with last Friday's jobs market showing an increase in private payrolls of just 83,000 in May. I expect hiring to pick up from last month's pace as growth strengthens in the second half of the year."

Bottom Line

The link between employment and health insurance coverage and then the further connection to demand for hip arthroplasties, knee arthroplasties and spine surgeries is, we think, clear.

While underlying demand in the form of incidence rates of osteoarthritis or degenerative discs will increase in the U.S. over the next few years. (We know exactly what an aging populations means in terms of degenerative processes in the joints and the spine). Getting from diagnosis to procedure is proving to be ever more difficult.

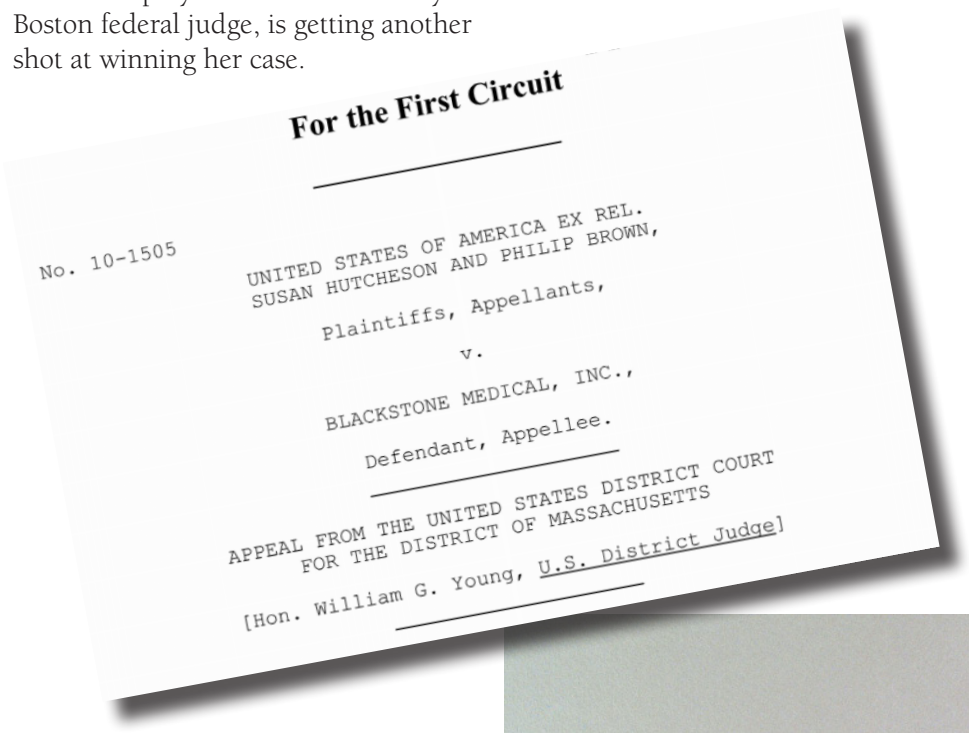
Surgical intervention may represent the best solution for millions of these new patients but historically low rates of employment and insurance coverage are putting millions of prospective patients in a painful and debilitating holding pattern. For the patient in pain, there are no easy answers. Drug prescriptions go only so far. The single most common prescription for legal marijuana is to treat musculoskeletal pain.

So, despite the best of intentions and the most hopeful predictions, without higher rates of employment and, therefore, health insurance coverage, the outlook for orthopedic implant unit shipments in the United States will likely continue to be flat. ◆

Blackstone Whistleblower Wins Appeal

By Walter Eisner

Susan Hutcheson, the former Regional Manager for Blackstone Medical, Inc., whose 2006 qui tam (whistleblower lawsuit) against her former employer was dismissed by a Boston federal judge, is getting another shot at winning her case.



For the First Circuit

No. 10-1505

UNITED STATES OF AMERICA EX REL.
SUSAN HUTCHESON AND PHILIP BROWN,

Plaintiffs, Appellants,

v.

BLACKSTONE MEDICAL, INC.,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. William G. Young, U.S. District Judge]

A federal appeals court in Boston ruled on June 1 that the district federal judge who dismissed her case made a mistake by accepting Blackstone's arguments that allegations of kickbacks to surgeons could not, according to the law, result in hospitals filing false claims for Medicare reimbursements because the hospitals didn't know of the kickback allegations. The decision not only gives Hutcheson another bite of the apple, but creates a new legal landscape which expands the responsibilities of everyone involved in the food chain of Medicare reimbursements.

Hutcheson's Kickback and False Claims Allegations

First, a little background.

After being terminated by Blackstone, now a division of Orthofix International, N.V, in January 2006, Hutcheson filed the whistleblower lawsuit alleging the company engaged in a nationwide kickback scheme to induce physicians to use its devices in spinal surgeries and knew this scheme would cause physicians and hospitals (unwittingly) to present federal healthcare programs with payment claims that contained material misrepresentations.

These kickbacks, Hutcheson alleges, included: "monthly payments under sham consulting agreements; paid development projects; research grants; royalties; exorbitant and sometimes illicit entertainment expenses; high-end travel and accommodations; speaking engagements and seminars[;] and other illegal incentives."

Wikimedia Commons

Hutcheson alleged that Blackstone's previous management (prior to the company's purchase by Orthofix) supervised the kickback scheme and knew that Medicare beneficiaries represent a significant percentage of spine surgery patients. As a result of the kickbacks, doctors across the country performed spinal surgeries on Medicare and Medicaid patients using Blackstone's devices.

She claimed that Blackstone paid surgeons between $1,666 and $8,000 a month to make sure they used the company's implants. Although the alleged payments were officially to recruit surgeons for Blackstone's "medical advisory board," the company expressly linked the payments to sales of its products for the physicians' surgeries. She further claimed that surgeons who stopped using the devices were admonished by company reps and then dropped from the payment list.

This, argued Hutcheson, was a violation of the federal Anti-Kickback Statute (AKS) and that Blackstone "knowingly" caused hospitals and physicians to submit materially "false and fraudulent" claims to Medicare.

In November 2008, her whistleblower case was unsealed after the U.S. Department of Justice filed a notice saying the government would not intervene at that time because it was still investigating her claims. The government however, filed an amicus (friend of the court) brief in support of Hutcheson's appeal.

Suit Dismissed

The federal district court dismissed her suit after agreeing with Blackstone's arguments that there were no false claims because the hospitals submitting claims for payment to Medicare weren't accused of violating the kickback laws, didn't know about the alleged kickbacks and therefore couldn't be held responsible for false claims.

In short, the district court held that the hospital claims were not false, and that while the doctor claims may have been false, those claims were not materially false.

The $50 Million Reserve

When the previous owners of Blackstone Medical, including founders William, Matt and Michael Lyons, sold their company to Orthofix for $333 million, they agreed to set aside in an escrow account a $50 million reserve to pay for future potential penalties or whistleblower settlements arising from any disputes regarding Blackstone's surgeon consulting arrangements.

What is interesting is that the appeals court ruling comes after a string of at least seven federal court decisions which have required that conspirators expressly acknowledge they are breaking the law when fraudulently applying for reimbursement from the federal government for medical expenses. For all practical purposes, this meant that Medicare would practically have to find a written confession in order to demonstrate false claims. As such, wrote Jim Edwards on *bnet.com* on June 3, those decisions virtually legalized drug price inflation through fraud and kickbacks.

In this case, says Hutcheson, Blackstone did indeed make the surgeon payments in full knowledge that it was against the law.

Defining "False"

Hutcheson and the government argue that a claim is "false or fraudulent" under the FCA (False Claims Act) if it does not meet a material precondition of payment.

They argue that compliance with the AKS, 42 U.S.C. § 1320a-7b, is a precondition for Medicare reimbursement and thus that Blackstone, in providing the alleged kickbacks, caused the hospitals and physicians to submit false claims.

They argue, moreover, that the hospital and physician claims were materially false because the alleged kickbacks would have been capable of influencing Medicare's decision whether to pay the claims had it been aware of them.

Blackstone's attorneys argued "no" saying that a claim can only be false under the FCA if it (1) misstates facts, (2) incorrectly certifies compliance with a statute or regulation, or (3) does not

meet an express condition of payment stated in a statute or regulation—and Hutchison's claim did not meet any of these criteria.

Blackstone also argues that even if the claims were false, they were not materially false because the claims made by hospitals and the services provided by physicians were not influenced by kickbacks.

Factually False/Legally False

The appeals court didn't buy it.

There is an old saying in law school that says, if the law is against you, argue the facts. If the facts are against you, argue the law. In this case the appeals court admonished the lower court for playing semantics and creating an unsupportable legal construction that a claim is "false or fraudulent" if it is either "factually false" (the facts) or "legally false," (the law).

A factually false claim, said the lower court, is a claim "in which the goods or services provided are either incorrectly described, or make [a] claim for a good or service never provided." A legally false claim, it held, is a claim in which "a party certifies compliance with a statute or regulation as a condition to government payment, but did not actually comply with the statute or regulation."

"I Didn't Know" Defense

The appeals court said the lower court found that the hospital claims were not on-their-face false but did not address the possibility that the claims could be based on a false set of facts. The lower court said that the Hospital Cost Reports which were used to claim reimbursement were not specific enough to "create an express certification of compliance with the AKS." In other words, the Cost Reports did not specifically include a representation that the physicians were compliant with the AKS.

The lower court also ruled that the physician reimbursement claims were not materially false. The reasoning was that the doctors, despite allegedly receiving kickbacks and potentially submitting false certifications of compliance with the AKS, had requested reimbursement for their services, not for Blackstone's products. As a result, any AKS misrepresentation had not influenced the government's payment decision.

The appeals court disagreed.

http://www.ca1.uscourts.gov/

Blackstone's argument, said the appeals court, that only express statements in statutes and regulations can establish preconditions of payment is not in the text of the FCA. Additionally, the notion that a claim can be false only if the submitting entity knew or should have known it was false also doesn't cut it.

Goodbye "I Didn't Know" defense.

Supreme Court: Everybody's Liable

According to the appeals court, the Supreme Court decided long ago that a non-submitting entity (like Blackstone) may be liable for knowingly causing a

submitting entity (like a hospital) to submit a false Medicare claim.

In 1976, the Supremes held that a subcontractor was liable for causing a contractor to seek payment for materials that, apparently unbeknownst to the contractor, were labeled incorrectly.

The False Claims

So, did Hutcheson's complaint actually identify a materially false claim?

Her complaint says that Blackstone's customers' Medicare claims stated that they were compliant with all material preconditions of payment—including that there had been no kickbacks. Blackstone's attorneys countered saying because the hospital claims related to a diagnosis-related group which does not address a particular service, the claim cannot be false.

Here, again, the appeals court sided with Hutcheson. Specifically it said, Medicare's rules say that CMS (Centers for Medicare and Medicaid Services) will not pay claims if the hospital asking for reimbursement has—knowingly or not—violated the AKS. "Blackstone seeks to divert attention from this clear language by focusing on whether the hospitals knew of the underlying kickbacks, a fact that has no bearing on Blackstone's potential liability under the FCA."

"If kickbacks affected the transaction underlying a claim, as Hutcheson alleges, the claim failed to meet a condition of payment."

Back to Court

The whistleblower case now heads back to district court under new, less stringent requirements. With the appeals court ruling in her favor, Hutcheson's attorney's can now focus on arguing the facts. With the government also stepping in, the stakes have risen beyond the $50 million reserve to an expanded definition of liability. Does this open a new Pandora's Box of liability for all implant suppliers or hospitals and physicians submitting Medicare claims? Stay tuned. ◆

IGOT: Musculoskeletal Health for All

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

Orthopedics offers many ways to impact patients' lives…you can reach across the OR table and you can reach across the world. Dr. Richard Coughlin, an orthopedic surgeon with the University of California, San Francisco (UCSF), has found that the most impact lies in the latter.

The co-founder and director of IGOT, the Institute for Global Orthopaedics and Traumatology, Dr. Coughlin states, "If a child has an open fracture in sub-Saharan Africa, there is a good chance that he will develop chronic osteomyelitis and will require an amputation. This eventually impairs his ability to make a living, and he becomes a burden on his family. There are more instances like this than you can imagine…there are more of these cases than there are of HIV."

Indeed, says Dr. Coughlin…according to studies, musculoskeletal problems are more of a global health burden than HIV, malaria, and tuberculosis combined. To address this, in 2006, Dr. Coughlin, along with Drs. Richard Gosselin and Harry Jergesen set out to give a man a fishing pole. "We could see that the most powerful and lasting way to impact global musculoskeletal health was through empowering orthopedists in less resourced areas. To that end, IGOT focuses on building research capacity and infrastructure via academic to academic partnering. That way, countries can foster their own clinical and research capabilities, and find answers to their own questions."

"Flap" course/Dr. Richard Couglin

"Housed at the Orthopaedic Trauma Institute at the San Francisco General Hospital (SFGH), IGOT resides in the Department of Orthopaedic Surgery at UCSF." Dr. Coughlin: "SFGH has a strong tradition of caring for the vulnerable, so it was only natural that we selected that facility as a 'home' for IGOT. And because of our academic affiliation with UCSF, we can readily partner with academic institutions around the world. For example, IGOT has provided financial and leadership support for orthopedic residents in Uganda who are conducting research projects. We have also funded visiting professorships for African academic leaders to UCSF and the AAOS Educators Course."

You might think of Richard Coughlin as Mother Teresa with a database. An enthused Dr. Coughlin notes, "No one

"If a child has an open fracture in sub-Saharan Africa, there is a good chance that he will develop chronic osteomyelitis and will require an amputation. This eventually impairs his ability to make a living, and he becomes a burden on his family. There are more instances like this than you can imagine…there are more of these cases than there are of HIV."

is doing this! IGOT is a far-reaching, sustainable enterprise which involves collaborating with smart, compassionate academic orthopedic surgeons from resource poor countries. We are helping empower these surgeons so that they can train their own people and start answering *their own* research questions. These are typically clinical questions such as, 'Is it more cost-effective to use a flexible nail for a pediatric fracture in a sub Saharan country?' or 'How long should someone stay in traction?' We are definitely not going there to figure out their questions and answers…that would be disempowering."

As someone who has experienced a range of ways to help others, Dr. Coughlin says that he could not stand by and do nothing about the larger problem (translation: he couldn't stay in the OR). Dr. Coughlin, who studied at the London School of Hygiene and Tropical Medicine and received his Masters in Public Health for Developing Countries, states, "I have been working abroad for 20 something years. When I see the well-heeled set complaining of tennis elbow or I have to deal with lawyers and excess paperwork, I am frustrated because then there is less time for impactful work. There are tremendous pathologies and disparities in the world, something that really 'came home' to me when I spent three months in South Africa and saw an extraordinary amount of trauma and a need that could never be filled by surgeons flying in and performing surgeries. While there is no question that this improves lives, it is just not the most impactful way of helping others."

Opening up about his philosophy, Dr. Coughlin states, "A bit under duress, last year I went to the Dominican Republic with a well established volunteer charity. By the end of the week we had seen a lot of trauma, but there was no education or training. I was almost embarrassed. As those from Médecins Sans Frontières (MSF) say, we physicians are the witnesses to trauma, atrocities, disparity, and injustice—and we must stand up and make changes."

"A bit under duress, last year I went to the Dominican Republic with a well established volunteer charity. By the end of the week we had seen a lot of trauma, but there was no education or training. I was almost embarrassed. As those from Médecins Sans Frontières (MSF) say, we physicians are the witnesses to trauma, atrocities, disparity, and injustice—and we must stand up and make changes."

A man of his word, Dr. Coughlin and the other exceptional IGOT staff have made concrete things happen for their less resourced colleagues. "Last year we were the host for a regional, soft tissue flap course along with SIGN, the Surgical Implant Generation Network. In all, 50 orthopedic surgeons from Pakistan, Nepal, and Africa came to UCSF for two days to work with plastic surgeons and learn how to do rotational flaps. The immediate feedback was stunning: we received emails from these surgeons within days saying that patients who had been stuck in the hospital for months had undergone the flap surgery and could go home! That is a pretty strong multiplier effect."

Harry Jergesen with collaborator Dr.David Oloruntoba at Bedford Orthopaedic Center, Mthatha, South Africa/Dr. Richard Coughlin

And the beat of Dr. Coughlin's "self sufficiency first" drum gets louder. "This year we are expanding the course, and adding a day long workshop on how to do clinical research. Twenty-five participants will learn the ins and outs of formulating a research question, etc., and will go forward to create a consortium that will address substantial clinical questions."

Like any decent researchers, the IGOT team wants to know the details. And those, says Dr. Coughlin, are "on the ground." "Our major goal this year is to determine the status of clinical research in sub-Saharan Africa, and then find out how we can help our colleagues there move forward. The work of these surgeons is hardly represented in the literature... looking at four major orthopedic journals over three years, we found that only .4% of the articles were from sub-Saharan Africa. It's a long-term project, but to start, we are sending a medical student to do qualitative interviews at three sites. We want to find out about attitudes toward clinical research, and see what the surgeons say are the barriers to clinical research. We also want to know what they consider to be the most important journals for them, i.e., is it better to publish in the *East African Medical Journal, the British Journal of Bone and Joint Surgery,* etc. Following this initial work, we can strategize and undertake a larger study that will involve as many sub-Saharan sites as we can enroll."

IGOT's specific GPS coordinates point toward the UCSF/SFGH Orthopaedic Trauma Institute (OTI). "Dr. Ted Miclau and I created the OTI ten years ago; now we are in a three floor building with ten full-time orthopedic surgeon faculty members and a host of physical medicine and podiatric professionals. When you look at the global inequities of musculoskeletal health, you see that the vast majority involve some sort of trauma. Having IGOT here means that we can more easily keep the focus on solving the capacity building issues that are related to trauma."

Because of its cadre of experienced academicians, IGOT can reach far and wide. Dr. Coughlin notes, "Dr. Ted Miclau, Professor and Vice Chair of Orthopaedics at UCSF, is on the IGOT board. He has led several large projects, such as a clinical research course in Havana that drew 135 Cuban surgeons last year. He also organized a course in Mexico where over 1,000 medical professionals had access to learning about clinical research."

Other examples of IGOT power? "We provided the financing for the first research in Uganda on the surgical impact of chronic osteomyelitis. Also, my wonderful co-director, Dr. Richard Gosselin—who is always 'on the road,'—is lead Orthopedic Consultant for MSF and is on the faculty at the University of California, Berkeley School of Public Health. Then there is Dr. Harry Jergesen, who has provided consultation to Nicaraguan educators about their orthopedic resident training. And we have Dr. Amir Matityahu, who has recently spent ten months traveling to all of the major trauma centers around the globe so that he can write a paper on the worldwide trauma system."

With so much need, how does the IGOT team know where to invest its time and energy? "We have found that we get the biggest impact from working in locations where there is some history of orthopedic training or research. Partnering with Orthopaedics Overseas offers great synergy of mission. This enables us to spend more time helping to strengthen the orthopedic leadership capacity as opposed to just getting things off the ground. Uganda was a great 'bet' as it does have such a history; Orthopaedics Overseas started a residency program there and we have been able to send their Chairman to the AAOS Educators' Course and provide a Visiting Professor opportunity at UCSF."

So they must have an NIH (National Institutes of Health) grant for all of this work, right? No…they have a big-hearted bartender. "We raise money where we can. There is even a local bar owner who gives us $5,000 a year and likes to say, '*Drink Locally...Act Globally.*'"

"My goal is to be able to grow IGOT to the point where we have an improved infrastructure and even more sustainability. Having a dedicated development person and/or several full time researchers would allow us to pursue the larger NIH grants or substantial private grants."

A man on a very doable mission, Dr. Coughlin says, "Through academic partnering we are able to advance the training, clinical research capacity, and leadership development of those in the poorer areas of the world. Increasingly, our world is more connected… and medical students are having more and more global experiences. Instead of just having a 'buzz' about the latest unproven gizmo, why can't we create a 'buzz' about a new research facility in Tanzania that will change countless lives for generations?"

And there is the issue of sending signals…indeed, of being patronizing. "If we remain mired in the old model of helping, i.e., flying to XYZ country to do surgeries and leaving without having trained anyone, then we are sending the wrong message. We are saying, in effect, 'We have to do it for you.' Giving our orthopedic colleagues the tools to create the change their countries need means many things…one of which is that they will be more respected locally and then they can vie for resources themselves."

Dr. Coughlin: "We are a global family of orthopedic surgeons. Let's treat one another with the utmost respect and care." ◆

company

PRESS RELEASE-
Orthopedics This Week Now on Bloomberg

OTW now part of the global Bloomberg Terminal Network

June 13, 2011

Wayne, PA: Orthopedics This Week announced today that it has entered into an agreement with Bloomberg News to supply Orthopedics This Week, the #1 source for Orthopedic Industry News, to more than 300,000 Bloomberg terminal subscribers including some of the most prominent investors and decision makers around the world.

The Bloomberg network includes portfolio managers, central bankers, finance ministers and others. By adding Orthopedics This Week to its global news network, Bloomberg is providing its subscribers with critical and timely information regarding companies that supply or manufacture orthopedic products, technology trends, as well as expert analysis of the rapidly changing market for medical products generally.

The combination of Orthopedics This Week and Bloomberg dramatically increases the visibility of orthopedics companies to a well established global financial decision maker and investor customer base.

Using their Bloomberg terminal, customers around the world will be able to search Orthopedics This Week by company name, subject matter, product, technology category, geography or other search term and either read individual articles or download the entire newsletter.

Photo manipulation by RRY Publications. Source: OTW and Wikimedia Commons

"Bloomberg is the world's most trusted source of information for financial professionals and businesses. The combination of Orthopedics This Week and Bloomberg creates an unmatched analytical, data, news and analysis tool for healthcare and financial decision makers around the world." said publisher Robin R. Young, founder of RRY Publications LLC and Orthopedics This Week.

About Orthopedics This Week: Orthopedics This Week (OTW) is the four time winner of the MORE award which is presented annually by the American Academy of Orthopaedic Surgeons. OTW is published online to the broader community of healthcare providers, implant and instrument manufacturers, consultants and medical technology analysts. For more information please visit Orthopedics This Week online at www.ryortho.com or contact Robin Young, Publisher at robin@ryortho.com.

Orthofix's Milinazzo Steps Down, Vaters Promoted

He fought off pirates, hired his own replacement, managed the Blackstone Medical, Inc. acquisition, navigated a government investigation and guided Orthofix International, N.V. to the top of the *Orthopedics This Week Power Rankings*.

Alan Milinazzo led Orthofix International for six years as president and CEO, and as Mizuho analyst Mike Matson wrote in an investor note, "leaves with Orthofix in a much better position than when he started."

Alan Milinazzo (Top) and Bob Vaters (Bottom)

Vaters Promoted

Orthofix announced on June 16 that on August 1, 2011, Bob Vaters, the company's current chief operating officer will become its new president and chief executive officer. Milinazzo will remain on the Board of Directors.

"This is what succession should look like," Milinazzo told *OTW* after the announcement. He's proud of having been in charge of the company as revenue grew from $300 million to $600 million annually and positioning the company to compete effectively in a $12 billion dollar market. He hopes he'll be remembered for having made a positive impact on the orthopedic market, particularly on patients and surgeons.

Paul Keller, M.D., principal inventor of Orthofix's Firebird System, said Milinazzo was, "a heck of a leader that led the company through some challenging times. In doing so he grew the business, kept the wolves away from the door and increased shareholder equity. He was also the kind of guy a surgeon in the trenches could call and get something done pronto. The man following in his steps has big shoes to fill, indeed."

Scott Blumenthal, M.D., of the Texas Back Institute said that Milinazzo was the key figure in transitioning Blackstone Medical into the Orthofix culture. "He was the one that I could contact immediately (and he was always responsive). I would say that the acquisition would have not seen the success it has without him. He has become a confidant and a friend and his leadership will be missed."

Milinazzo once told us that hiring the right people is perhaps the most important decision a company's CEO makes. If that's the case, then Milinazzo's decision to hire Bob Vaters in 2008 as chief financial officer was a home run. Matson wrote that Vaters and Milinazzo were the key players in fixing the numerous problems that Orthofix was dealing with after its acquisition of Blackstone Medical. Milinazzo had to fight off a very public attempt by a dissident shareholder investment fund as it attempted to oust him and board members for acquiring Blackstone in 2006. He won that battle.

Vaters is highly respected by Orthofix insiders and is expected to lead the company's operating margins back to where they were before the Blackstone acquisition. The news of Vater's promotion and Milinazzo's departure was not surprising given the company's March 15 SEC 8-K filing which telegraphed the eventual change of leadership.

Jim Gero, Chairman of the Orthofix Board of Directors said, "We're very thankful to Alan for everything he has done for Orthofix over the past six years and delighted that he will remain an essential advisor to us as a member of the Board."

Jeffries analyst Raj Denhoy wrote that the company's recent shift of most of its operations to Austin, Texas, from Boston and the resultant increased travel demands and time away from his family, precipitated Milinazzo's decision to step down. And the Bruins won the Cup.

Well done Alan Milinazzo.

—WE (June 17, 2011)

Synthes and Eli Lilly Collaborate for Bone Healing

Orthopedic devices containing pharmaceuticals have been under development for some time and have slowly made their way to the FDA for approval. Now, Synthes, Inc., a device maker and Eli Lilly and Company, a pharmaceutical company and maker of the osteoporosis drug Forteo, have agreed to work together to develop site-specific bone healing (osteoinductive) products based on Synthes biomaterials combined with Lilly's biologics and pharmaceuticals.

SYNTHES®

Source: Forteo/Eli Lilly and Synthes

The exclusive worldwide collaborative agreement announced on June 9 promises to address needs of orthopedic patients suffering from osteoporosis and bone fractures.

Joint Development, Licensing and Promotion

The agreement calls for the joint development and licensing of early stage compounds from Lilly to Synthes for use within orthopedic trauma, spine, craniomaxillofacial and reconstructive areas. The compounds, according to a joint press release from the companies, already have pre-clinical and in some cases, clinical data packages.

One development program calls for the two companies to jointly conduct and fund the evaluation of Lilly's Forteo (teriparatide [rDNA origin] injection) for additional orthopedic uses. The companies say a Phase II study that Lilly has already completed will be a first step to conduct additional clinical studies to evaluate potential future indications for Forteo, including fracture healing.

The collaboration also includes co-promoting Forteo to orthopedic surgeons throughout the world.

Michel Orsinger, president and CEO of Synthes, said, "Strategic collaborations between medtech and pharma companies represent a new and promising avenue to develop and market true innovations in a changing, dynamic market environment."

"Many orthopedic surgeons are in the position to diagnose and treat osteoporosis when their patients present with fractures, and we believe it is imperative to treat the underlying cause of the initial fracture," said Johnston Erwin, Bone/Muscle/Joint global development platform leader, Lilly Bio-Medicines, Eli Lilly and Company. "Our collaboration will also explore ways to treat fractures with Forteo in older patients

and/or those who have osteoporosis and, longer term, will look for new ways to deliver medicine locally to the fracture site."

Financial terms of the agreement have not been disclosed.

Forteo

Forteo is a treatment for postmenopausal women with osteoporosis who are at high risk for fracture and to increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture.

Last summer Lilly announced that the FDA had given the company the go ahead to promote the use of Forteo to treat osteoporosis associated with sustained, systemic glucocorticoid therapy in men and women at high risk of fracture.

As *OTW* reported at the time, because this was a new indication that extends the use of the drug to patients who may be younger than those currently receiving the medication, the company updated the language in the existing boxed warning section of the label regarding the risk of osteosarcoma to reinforce that Forteo should not be used in pediatric and young adult patients whose bones are still growing. In addition, due to the increased patient population, Lilly established a voluntary Forteo Patient Registry to further evaluate the long-term safety of the drug.

—WE (June 13, 2011)

biologics

More Players Requesting Cell Therapy

The semi-experimental stem-cell therapy, (reported by *OTW* on June 7), that Bartolo Colon, a pitcher for the New York Yankees, underwent last spring in the Dominican Republic has increased interest in the procedure from other injured athletes.

Bartolo appeared in just 19 games after 2005 when he partially tore the rotator cuff in his pitching arm. Bone spurs in his elbow caused him to miss the entire 2010 season. In a last ditch attempt to repair and regenerate the torn tissue and salvage his pitching career, last spring Bartolo agreed to have stem cells extracted from his bone marrow and fatty tissue and re-injected into his elbow and shoulder.

This January Bartolo signed another contract with the Yankees, for $900,000, and is back on the pitcher's mound throwing baseballs across the plate at 95 miles an hour.

According to Leonel Liriano, one of the doctors who assisted in the procedure on Bartolo, ten other pitchers have expressed interest in the surgery. Liriano is the medical director of the Florida-based Regenocyte, which does most of its work in the Dominican Republic.

Major League Baseball has launched an investigation of the stem cell procedure in order to determine whether the application of Colon's own stem cells in this manner qualifies as a performance enhancing drug. Joseph Purita, an orthopedic surgeon from Boca Raton

Wikimedia Commons and Brandonrush/

who was part of Colon's medical team, thinks it does not. "This is not hocus-pocus. This is the future of sports medicine, in particular," he says.

Purita has commented in the press that, to his knowledge, the exact mechanism of action underlying the use of autologous stem cells in sports medicine is still largely unknown. In his view, either Colon's stem cells became new tendon and muscle tissue themselves or they released a cocktail of proteins and peptides, including various growth factors that encouraged resident tendon and muscle cells to proliferate at the injured site. The published record, said Purita, is limited with respect to using autologous stem cells in sports medicine indications like Colon's where the treatment actually improved tendon or joint performance beyond pre-injury abilities.

There are, however, more published studies regarding the use of autologous stem cell therapies in equine athletes. Specifically, a recent study showed that when horses with tendon injuries receive conventional treatment, between 50% and 60% re-injure themselves. But in 141 racehorses who received stem cell therapy, the rate of re-injury dropped to 27.4%. This study was published in *Equine Veterinary Journal* in May 2011.

—BY (June 14, 2011)

large joints

Wrinkles Predicting Fracture Risk?

New use for old skin…Researchers from Yale School of Medicine have found that wrinkles might actually be able to predict a woman's bone fracture risk. Specifically, the severity and distribution of skin wrinkles and overall skin quality could tell the story of bone mineral density in early menopausal women.

In the June 5, 2011 news release, Dr. Lubna Pal, associate professor in the Department of Obstetrics, Gynecology & Reproductive Science at Yale School of Medicine, noted, "Skin and bones share common building blocks—proteins, and aging is accompanied by changes in skin and deterioration of bone quantity and quality." They hypothesized that in postmenopausal women, the quality of an individual woman's skin—the degree of wrinkling and hardening—will reflect the status of her bones.

The investigators assessed skin wrinkles at 11 locations on the face and neck, and assessed skin rigidity at the forehead and the cheek. Skeletal mass and density were studied by dual X-ray absorptiometery as well as by a portable heel ultrasound device.

"We found that deepening and worsening skin wrinkles are related to lower bone density among the study participants," said Dr. Pal. "The worse the wrinkles, the lesser the bone density, and this relationship was independent of age or of factors known to influence bone mass."

Tomas Castelazo-derivative work: Dobromila/Wikimedia Commons

As for what led to this work, Dr. Pal told *OTW*, "I had first explored the relevance of tissue collagen for skeletal fragility in the postmenopausal women enrolled in the WHI-Estrogen Plus Progestin trial and had demonstrated that postmenopausal women with a common gynecological condition—pelvic prolapse (a condition recognized to be related to comprised tissue collagen)—were at an enhanced risk for low bone density and fracture compared to women without or with minimal prolapse. That study then led to the next question…are there any

clinically more obvious manifestations of tissue collagen deterioration (other than pelvic prolapse) that may identify women at fracture risk? The most obvious tissue to study was the skin!"

Dr. Lubna also commented to *OTW*, "We have reported on baseline data for early menopausal women enrolled in an ongoing clinical trial—the Kronos Early Estrogen Prevention Study (KEEPS) study. We are continuing to follow these participants on a yearly basis for the duration of the parent trial and will be able to assess if women with worse skin wrinkles at baseline lose bone at a faster rate than those with fewer wrinkles. We will also be able to assess if higher skin rigidity relates to slower rates of bone loss in early menopause. Future analyses at the completion of the KEEPS trial will thus better clarify the observed relationship between skin and bones."

—EH (June 15, 2011)

New Osteoarthritis Treatment Popular in UK

Orthopedic surgeons in the United Kingdom are treating some of their younger patients who suffer from osteoarthritis with a new procedure that involves cementing metal to the damaged parts of the knee. This approach allows the younger patient to receive a partial knee replacement surgery but with fewer or none of the usual negative side effects associated with a more traditional joint replacement.

Osteoarthritis affects 8.5 million people in the United Kingdom and each year the National Health Service carries out more than 70,000 knee-replacement procedures. (Osteoarthritis of the knee develops when the cartilage that coats the bone wears away, either because of wear and tear, injury or genetic predisposition—leading to the bones grinding against one another and deteriorating.)

The particular surgical technique targets only the areas of the knee that have been damaged by the effects of osteoarthritis and, according to the surgeons who've written about this surgical technique, provides patients with greater post-operative mobility as compared to more traditional and invasive joint replacement surgery.

The new procedure requires the surgeon to clearly identify and map out which areas of the knee cartilage have become worn down due to osteoarthritis. Then, under general anesthetic or an epidural, the surgeon makes a small (3.5 inch wide) incision on the inside of the knee.

After filing down the rough sections of the knee the surgeon cements a thin shell of cobalt chrome to cover the affected part of the knee. To keep the metal surface from grinding against the bone or other sections of metal, a small plastic bearing is attached to the top of the tibia to replicate the role of the cartilage in the natural knee. Over time, bone tissue grows around the implanted surfaces to make them an integral part of the joint.

Source: Wikimedia Commons

"We have patients who do very strenuous activities that they would not be able to do with a full knee replacement," says David Barrett, professor of orthopedic engineering at Southampton University, who has been performing the operation since October. He says that with this procedure more of the original joint is conserved, none of the ligaments around or inside the knee are disturbed and the plastic insert can be renewed. Additionally, further compartments or areas of the knee can be resurfaced if the arthritis begins to affect other parts of the joint. Barrett has found that patients can get up and walk the same day and usually can go home after a few days.

One successful patient is a fireman at Southampton airport who was also a cyclist and jogger. He had an operation to clear out the bony debris that had accumulated since he developed osteoarthritis in his knees. The surgery worked for his left knee but not his right.

"Professor Barrett suggested that I try a new resurfacing treatment for my right leg and the results were fantastic," said the patient who returned home from the hospital after just four days. Three weeks of physiotherapy later he was back at work and enjoying pain-free cycling again. "If I had been given a full knee replacement with much less mobility, I would have lost my job. It's been a lifesaver," he said.

—BY (June 14, 2011)

Busy Hospitals Better For Joint Surgery

For joint replacement surgery, busy hospitals are better. A study published on June 7 in *Arthritis and Rheumatism*, a peer-reviewed journal of the American College of Rheumatology, found that patients who undergo elective total hip or knee arthroplasty at hospitals with lower surgical volumes had a higher risk of venous thromboembolism and one-year mortality following the procedure.

The authors theorize that the causes of complications at low-volume hospitals could be connected to hospital procedures and peri- and post-operative care processes. One example cited by the authors is the different types and levels of medication prescribed by physicians to prevent blood clots following elective joint replacement surgery. The authors also suggest that the outcome of surgery may well be affected by how much time elapses between initiation of clot prevention therapy and its cessation. Dr. Singh Jasvinder, M.D., M.P.H. of the University of Alabama, lead author of the study, concluded, "Further studies are needed to investigate whether the underlying reasons for poor surgical outcomes at low-volume hospitals are modifiable and which interventions may reduce complications for patients at these facilities."

Researchers used the Pennsylvania Health Care Cost Containment Council database to identify the number of patients who underwent total hip replacement (n=10,187) and total knee replacement (n=19,418) surgery in 2002 in the state. The mean age of patients in both groups was 69 years, and men comprised 43% of the total hip replacement cohort and 35% of the total knee replacement group. Hospital volume was categorized by less than 25 surgeries, per year, for low-volume hospitals and 200 or more surgeries per year for high volume hospitals.

—BY (June 14, 2011)

RRY Publications LLC

extremities

FDA Clears Arthrocare's New Rotator Cuff Anchor

ArthroCare Corporation, a manufacturer of minimally invasive surgical products, has just received clearance from the U.S. Food and Drug Administration for its Spartan 6.5 Needled Anchor. The Spartan device is a preloaded threaded anchor for physicians to use when fixing soft tissue to bone—for example, during rotator cuff repair surgery.

The needled version of the Spartan line of anchors was developed by ArthroCare's engineers for use by surgeons in the open rotator cuff repair surgery. The non-needled version of the Spartan line is already cleared by the FDA and it is meant to be used by surgeons in arthroscopic repair cases. The company believes that its Spartan anchor complements its line of other anchors which can be used by surgeons with the company's suture passing technology, such as the FirstPass suture passer. The Spartan anchor has a 6.5mm, screw-in design and can be used by surgeons to perform single and double row repairs. (A 5.5mm version of the Spartan received FDA clearance in February 2011.) ArthroCare's marketers estimate that more than 400,000 patients undergo rotator cuff surgery annually in the U.S.

ArthroCare Corporation

—BY (June 13, 2011)

trauma

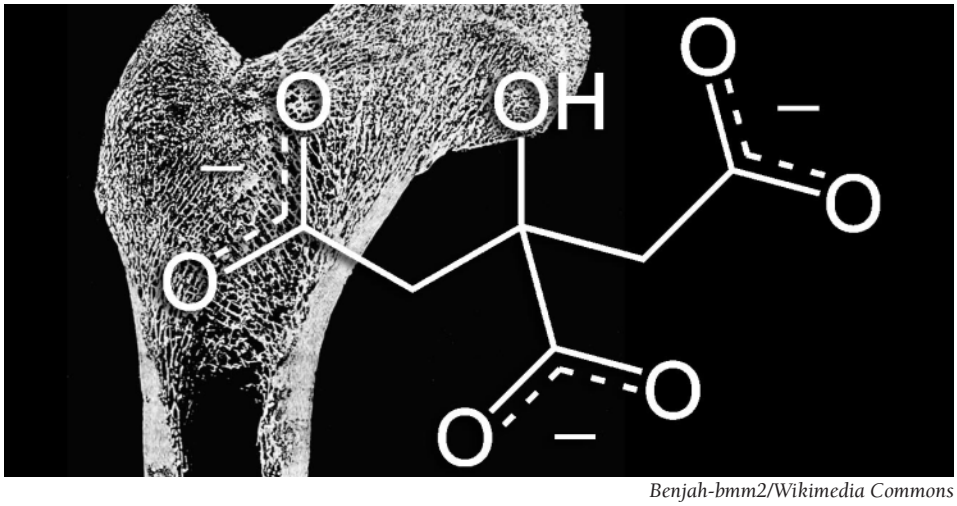
Bone Strength: Now We Know

So THAT's what's going on with those bone nanocrystals…Researchers at the U.S. Department of Energy's Ames Laboratory have identified what gives bone its outstanding properties and the important role citrate plays, work that could benefit those with osteoporosis and other bone diseases.

Using nuclear magnetic resonance (NMR) spectroscopy, Ames Laboratory scientist and Iowa State University chemistry professor Klaus Schmidt-Rohr and his colleagues studied bone, whose stiffness is provided by thin nanocrystals of carbonated apatite, a calcium phosphate, imbedded in an organic matrix of mostly collagen. They noted that how these apatite nanocrystals form and what prevents them from growing thicker was unknown. While some research pointed to sugars being involved, Dr. Schmidt-Rohr wasn't convinced.

In the June 8, 2011 news release, Dr. Schmidt-Rohr stated, "We can see all the peaks clearly," referring to a spectral graph which shows the points at which specific components in bone samples resonate; these specific signatures are the key to NMR technology, "even those at the organic-inorganic interface, where the organic material's signal strength is relatively weak."

"We had gotten some crystalline collagen samples to study," he continued, "and it turned out that the supplier, Sigma-Aldrich, had used citrate to dissolve the collagen. And the citrate signature in the collagen samples matched the signature we were seeing in bone."



Benjah-bmm2/Wikimedia Commons

Then graduate research assistant Yanyan Hu was able to extract citrate from cow bone and replace it with carbon 13 (C13)-enriched citrate, resulting in a 30-fold enhancement of the NMR signals of the bone sample. The peaks matched exactly, confirming the presence of citrate on the surface where the apatite nanocrystals had formed. Schmidt-Rohr further hypothesized that, since citrate is too large to be incorporated into the apatite crystal lattice, it must be bound to the nanocrystals' surface where it stabilizes the nanocrystals' size by preventing their further growth.

"Based on the old literature, we looked at the citrate levels in a variety of types of bone and found that herring spine had the highest citrate concentration—about 13% by weight," Schmidt-Rohr said. "So it should hold that the citrate signal for herring spine should be three times higher than for cow bone, and indeed it was."

They then found that the higher concentration of citrate, the thinner the apatite nanocrystals in bone. This was further confirmed on bone-mimetic nanocomposites in a collaboration with Ames Lab faculty scientists Surya Mallapragada and Muffit Akinc, using a polymer template with various concentrations of citrate to synthesize apatite nanocrystals. At higher concentrations, the nanocrystals that formed were thinner and should therefore be more resistant to crack propagation.

"At this point, we feel that citrate probably also has a role in the biomineralization of the apatite," Schmidt-Rohr said. "It's also been noted in the literature that as an organism ages, the nanocrystal thickness increases and the citrate concentration goes down," Schmidt-Rohr said, "and there's also support from clinical studies that citrate is good for bones," adding that one of the leading supplements for bone strength contains calcium citrate.

—EH (June 16, 2011)

Fracture Risk and Menses

New research from Mass General has found that young female athletes who have stopped menstruating have a weakening in the quality of their bone structure that may predispose them to breaking a bone—despite getting plenty of weight-bearing exercise.

Madhusmita Misra, M.D., the study's principal investigator, is a pediatric endocrinologist at Massachusetts General Hospital in Boston. She told *OTW*, "The study was prompted by our previous observation of low bone density despite weight bearing activity in teenage athletes who lose their menses in the course of endurance training, raising concerns regarding fracture risk. We were also concerned about teenage athletes who have normal menses and apparently normal bone density, and yet develop stress and other fractures. Studies in post-menopausal women indicate that assessment of bone microarchitecture can provide information regarding fracture risk above and beyond that provided by DXA measures of bone density. Hence, we decided to assess bone microarchitecture using high resolution peripheral quantitative computed tomography (HRpQCT) at

Werner100359/Wikimedia Commons

both a weight bearing site (the lower end of the shin bone or tibia), and a non-weight bearing site (the lower end of one of the forearm bones)."

"We found differences between the study groups at the tibia (weight bearing bone) that appeared to be specific to athletic activity, and other changes that appeared to be more specific to the state of amenorrhea (absence of menses). At the tibia, both groups of athletes had an expansion of the total cross-sectional area of bone and the inner trabecular (spongy) component of bone, likely from weight bearing activity. An increase in cross-sectional bone area would be expected to improve bone strength. However, the spicules of trabecular bone were thinner and further apart in athletes who had stopped having menses compared with those who were still having menses and non-athletes, which would be expected to be deleterious to bone strength. Also, while bone density for bone as a whole (cortical and spongy) was lowest in athletes who had stopped having menses, bone density of the outer rim of bone (the cortex) was lower in both groups of athletes compared with non-athletes, suggesting a lag in mineralization of cortical bone, concerning for poor bone strength in both groups of athletes despite weight bearing activity."

She also commented to *OTW*, "We are following our study subjects prospectively to determine how bone microarchitecture changes over a year-long period in athletes who are or are not having menses compared with non-athletes. We are also performing an intervention study examining the impact of estrogen replacement on bone density and bone microarchitecture in athletes not having menses."

—EH (June 15, 2011)

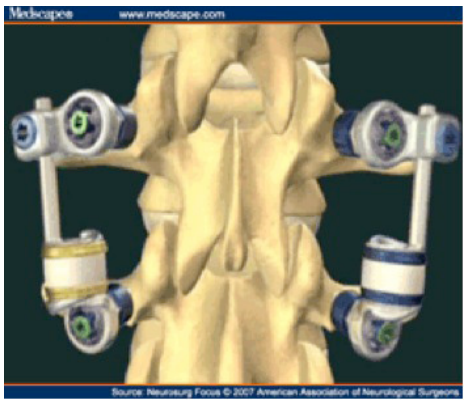
spine

Stabilimax Rising From the Ashes

The Stabilimax Dynamic Spine Stabilization System is still alive.

But a June 13 press release from Boston based Rachiotek LLC announcing receipt of a U.S. patent (patent number 7,931,675, B2), titled, "Dynamic Stabilization Device including Overhanging Member," showed that Dr. Manohar Panjabi's spine stabilization technology was alive and expanding.

Photography by Aaron Sesker



Stabilimax NZ System

When Applied Spine Technologies (AST) closed its doors last year and auctioned off its assets, it all but appeared that years of clinical, legal and commercial work may go down the drain.

Rachiotek is the entity formed by the venture fund, BioVentures Investors, to acquire AST's assets last October. BioVentures was a Series A investor in AST. The fund also includes HydroCision in its portfolio.

Peter Feinstein, Chairman of Rachiotek and co-founder of BioVentures, said, "One problem with many dynamic stabilization devices is a lack of space between the pedicles. This lack of space limits the amount of motion allowed by the device and is thought to be critical to clinical performance." Feinstein added, "To gain space Rachiotek's new patent describes an overhang of the rod beyond the upper or lower screw

of the construct. The overhang 'creates space' between the pedicles, potentially increasing the amount of motion that the device permits and enabling clinically relevant motion."

Feinstein told *OTW* that Rachiotek will continue to collect Stabilimax clinical data and enhance the patent portfolio of the technology. The company may return to the FDA in the future with a new PMA (premarket application) for the Stabilimax system.

—WE (June 15, 2011)

people

Ekdahl Promoted to DePuy Orthopaedics President

Indiana-based DePuy Orthopaedics, Inc. has promoted Andrew Ekdahl to be its new president. He replaces David Floyd, who left the company at the end of March.

Andrew Ekdahl/DePuy Orthopaedics, Inc.

Ekdahl is no stranger to DePuy. He joined the company over 20 years ago and has worked on orthopedics, trauma, sports medicine, neurosciences and spine. Prior to his new appointment, he was Franchise Vice President, DePuy Europe, Middle East and Africa. He had held positions in sales, marketing and distribution in the U.S., Canada and abroad.

He received his undergraduate degree in Economics from the University of Manitoba and his MBA from Wilfred Laurier University, both in Canada.

DePuy Orthopaedics, headquartered in Warsaw, Indiana, makes devices for the hip, knee, extremities and trauma, as well as bone cement and operating room products. Having served DePuy in Europe, he should be well situated to help DePuy and Synthes integrate over the coming months. One of his challenges will be to rebuild DePuy's hip business, which saw an erosion of market share to its cross-town rival, Zimmer, due in part to the metal-on-metal ASR hip system recall in 2010. The company regained some of that market share in the first quarter of 2011. In knees, the company gave up some market share in the first quarter.

In his role as president, Ekdahl will serve on the DePuy Franchise Global Management Board of the DePuy Family of Companies of Johnson & Johnson.

—WE (June 13, 2011)

THE PICTURE OF SUCCESS

Dr. Vincent Arlet

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

Dr. Vincent Arlet

When Vincent Arlet did his training, the words he heard in class were "une ostéotomie" and "l'osteonécrose." Born in Paris in the late fifties, Dr. Vincent Arlet, the Warren G. Stamp Professor of Orthopedic Surgery and Professor of Neurosurgery at the University of Virginia (UVA), has come to see his dual worldview as particularly helpful when it related to orthopedics.

Importantly, Dr. Arlet is also the inventor of Scolisoft, an essential software database tool that has changed the way surgeons treat patients with scoliosis. What motivated such an esteemed professor of orthopedics to become a database developer? "My mom was a homemaker and my dad was an engineer. I found his work stimulating, and had my sets set on following in his footsteps."

But he temporarily lost sight of that engineering goal when he lost sight of his skis. "I had a ski accident in high school that almost killed me. I had severe intra-abdominal bleeding and the only surgeon in the local hospital was an orthopedist…he saved my life. Because I missed three months of classes, I couldn't get into any engineering schools. As I interacted with my doctors, I thought, 'Medicine looks interesting. These people are intense and get to make truly important decisions.'"

Now a seasoned surgeon, researcher and accomplished database innovator, Dr. Arlet helps others get started. As Chair of Spinal Deformity Research at King Saud University in Riyadh, he is laying the groundwork for Saudi surgeons who want to pursue a career in research. "Saudi Arabia has a population of 25 million, but only a handful of spine surgeons. Two years ago the Chief of Spine, Dr. Abdulmonem Alsiddiky, asked me to help establish their research program and assist with complex spine surgeries. Twice a year I travel to Riyadh both to operate and to help clinician researchers establish the framework for their research and spinal deformity program. The extremely challenging pathology I see there is usually only something found in textbooks."

Deputy editor of the *European Spine Journal*, Dr. Arlet has a deep appreciation for the value of learning from others. "I was fortunate to have superb mentors, including Dr. Jean Paul Padovani, who had such an extensive knowledge of pediatric orthopedic pathology that even specialists—such as geneticists—would consult with him. I must also credit Dr. Max Aebi, Chairman of Orthopaedics at McGill University. His ability to conceptualize the entirety of a surgery taught me how to understand the surgical problem and how best to 'attack' it. Without him I would never be where I am today."

In perhaps the first case of "orthopedic stalking," the determined Dr. Arlet often sought the advice of Dr. Jean Dubousset. "I never trained with Dr. Dubousset, who developed the most famous method of spinal instrumentation ever invented. But I would seek out meetings where I knew he would be in attendance…and I would bring my X-rays of particularly difficult cases. Once I found him, I would scribble his recommendations on the folders."

As an established surgeon, Dr. Arlet would use his skills in diplomacy to lead orthopedic departments. The insight needed to manage this task began in his early years, with the dawn-

ing realization that politics is everywhere. "European career pathways are very hierarchical. This means that to attain academic milestones you have to contend with an extraordinary amount of politics. In American medicine, for example, when there is a position available, there is usually a nationwide search; in Europe they usually don't look beyond the hospital grounds. I saw many instances of those who were better qualified not even being considered for jobs. I was frustrated with the system, and was planning on entering private practice in France. That is when I was offered a position at McGill University in Canada."

Dr. Arlet remained a member of the McGill community for 13 years, during which time he became director of the spine division, as well as head of the spine fellowship. "I started out doing 50/50—half of my surgeries involved children and the other half involved adults. The Chair, Dr. Aebi saw an evolving need for a vertical concept of spine treatment from birth to the elderly, so I altered my practice and began to work more with adults. Once I moved to UVA my practice began to consist of about 90% adults."

And the young residents and fellows who trail behind him on rounds are often surprised by what seem like radical words. "When I tell trainees to 'Forget the X-rays and listen to the patient' they are rather shocked. I explain, 'If you have someone with complex adult scoliosis—with an obvious curve—but the only thing he complains of is leg pain, then you probably shouldn't do a big surgery. The rest of the disease is not important enough for him to want to undergo such an extensive procedure. So you can do a big operation, get the spine perfectly straight and feel proud of yourself, but the patient isn't happy because he has had a major surgery and he now has post operative complications."

Orthopedic trainees who want to learn more about the nervous system come to see Dr. Arlet at UVA. "There are only several places in the U.S. that have a combined orthopedics/neurosurgery fellowship…we are one of them. We learn from neurosurgeons how to handle nerve tissues and they learn certain aspects of biomechanics from us. It's interesting to see a young surgeons' thinking evolve. Right after they have completed their training, they think that they are the only ones who know the truth. Then they see others doing something different and getting good outcomes and think, 'Well, they are not *wrong*.'"

So what is Dr. Arlet especially proud of? Scolisoft. "I have established an online database of scoliosis cases that can be used by any surgeon worldwide. The impetus for this goes back to my mentor, Dr. Padovani, who had several cupboards filled with slides. When a challenging case came in we would go to his cupboard and find an identical case. Years later at McGill I commented to a resident how nice it would be to have a clinical answer on the other end of a mouse click. He got to work and we soon had an embryonic software…now there are 300 cases. We only include those cases that have been documented extensively. The biggest challenge is to get surgeons to submit cases. But those who get involved really benefit…they can find cases that are identical to the one they are dealing with."

When asked about his favorite research, Dr. Arlet discusses a study that shows "more is not always better." "We had cases from Scolisoft reviewed by scoliosis surgeons and then laypeople, all of whom were blinded to some part of the procedure. The tendency is for people to think that more screws, etc. results in better outcomes; our study showed that when blinded, surgeons do not think this is true. For example, if I have a patient with a 55° right thoracic curve, 30 years ago we would have used a Harrington rod and two hooks. Fifteen years ago we would have used two rods and eight implants; now, some surgeons would put in two rods and 24 screws!! Our study showed that with a middle grade curvature, it is unlikely that you need such an extensive number of screws."

As for how his European background and North American experiences contribute to his success, Dr. Arlet says, "When there is a new trend in spine I

try to have a critical appreciation of it. The first reaction of North Americans is to be open to new things, whereas Europeans tend to criticize first. Then if something doesn't work North Americans are the first ones to drop it (Europeans may keep it for a longer time, especially if this has become a tradition!) We all need to be wary of things that are unproven. On the other hand we must be ready to abandon techniques that do not work."

Dr. Arlet is unusually honest about the experience in his career that most changed him. No, it wasn't any sort of accolade. It was failure. "Like everyone, I have had surgical failures. Having a complication in spine surgery is devastating…it was your own hands that didn't do the job right. This is when you really learn how to talk to patients—you must look them in the eyes and tell them the whole truth. Then you do everything in your power to ensure that it doesn't happen again."

Several times a year, Dr. Arlet takes his experience and skills to Trinidad. "There is one pediatric orthopedist—Dr. David Toby—for this island of 1.2 million people. I started helping him with the big cases—those with over 100° curvature—in 2006. While Trinidad has a fairly high GDP, the resources for specialized surgery aren't available. I'm proud to be part of this effort, which is affiliated with FOCOS, the Foundation of Orthopedics and Complex Spine."

As an academic surgeon, there is little room for downtime. Especially when you have four children. "My wife Anne and I have a 26-year-old daughter who is a family medicine resident at McGill, a 24-year-old son who just graduated from Columbia, a 20-year-old at Virginia Commonwealth University, and our 'baby,' who is in high school. We find as much time as we can to get out on the water and do some sailing. My wife has been invaluable in helping me find balance; as academic surgeons we have the tendency to throw ourselves too heavily on the side of work."

Dr. Vincent Arlet…a critical eye plus an honest heart equals success. ◆

Rearview Mirror Forecast

+

PearlDiver reports:

- Available in spreadsheet and written report form
- Bottom up analysis starting with diagnostic and procedure codes
- 1.7 Billion patient records in database (HIPPA compliant)
- Every zip code and virtually every hospital covered

PearlDiver co-founder Robin Young has been at the forefront of virtually every major technology trend in orthopedics. He organized PearlDiver's research to give senior marketing executives the most actionable market data possible.

Detailed market analysis (in spreadsheets) from $1,950.

Specific indication analysis (in pdf) from $950.

PearlDiver

unfathomably deep data retrieval

For unfathomablty deep and useful tmedical market research, call the Data Guys at PearlDiver- Scott or Heather at 260-468-3635 or dataguys@pearldverinc.com.

Orthopedics This Week | RRY Publications LLC

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

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

Biloine W. Young
Writer
bgwy@msn.com

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Production Coordinator
jayme@ryortho.com

Dana Bader
Graphic Designer
dana@ryortho.com