VOLUME 8, ISSUE 5 | FEBRUARY 7, 2012

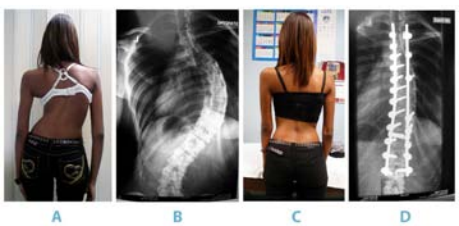
Orthopedics This Week

week in review

4 Inside the Wright DPA Meltdown ♦ Three former employees terminated by Wright Medical in the middle of the company's monitoring program with the feds have filed lawsuits against Wright Medical claiming they were terminated for reporting compliance problems to the Board. *OTW* read the complaints. Here's what we found.

8 Treace's Tricks to High Velocity Sales ♦ Want to know the secrets of one of the greatest of all medical product sales managers? We did. So we read John Treace's *Nuts and Bolts*. There are plenty of sales management books available but this is one of the best. Why? Think 30 years of medical sales management experience in a fast, practical read.

11 Heroes Among Us ♦ All around the world, orthopedists give their time for free. One of these surgeons is Dr. Vincent Arlet, Chief of Orthopaedic Spine Services at the University of Pennsylvania, who travels to Trinidad several times a year to help Dr. David Toby, the only spinal deformity surgeon on the island. Together they handle massive spinal curves of 90 degrees or more. Read their story.



14 Pagnano and Parvizi Debate Squeaking Hips ♦ "Lubricate the joint!" says Mark Pagnano, advocating for ceramic-ceramic...Jay Parvizi says that at the midterm, ceramic-ceramic and HCLP are essentially equivalent. This week's Orthopaedic Crossfire® debate is "The Squeaking Hip: Much Ado About Nothing."

breaking news

18 Korea FDA OK's **Stem Cell Drug**

Biologics to Fight **Psoriatic Arthritis**

$89 Million for **ConforMIS**

Dan Garen: **Wright's New Compliance Boss**

Value Pricing Leader IFS Now Marketing **Subtalar Implants**

Joint Replacement Blood Clot Threat Quantified

Industry/FDA Reach **$595 Million Agreement on User Fees**

Symmetry Settles SEC Inquiry

FRAX Use on the Rise

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: WMGI hit with a series of wrongful termination lawsuits emanating from last year's top executive exodus. Turmoil would not be an exaggeration. While WMGI tries to put its house in order, other ortho companies continuing to enjoy a warm Wall Street reception. Ortho equities, including WMGI, remain comparatively cheap.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Zimmer	27.75%	17.48%	2011 free cash flow was just under $1 billion ($907M). ZMH selling for just 12.5x free cash flow. Cheap.
2	2	Orthofix	14.72	18.40	Five out of six analysts covering OFIX rate it a BUY or Strong Buy. Still 3rd least expensive ortho stock overall.
3	3	Stryker	25.23	8.51	SYK's compliance program is among the industry's very best. Confirmed last week as court dismisses government's suit.
4	4	NuVasive	7.26	44.32	At Cedars Sinai meeting last week, positive report on NUVA's products and reputation among surgeons.
5	6	Medtronic	28.63	4.93	MDT appears to have hit bottom in terms of spine market share. 2012 will be the year MDT spine grows.
6	5	Conmed	9.65	15.24	Most analysts expect flat sales for the quarter to be announced in 10 days, but 10% earnings growth.
7	8	Smith & Nephew	22.80	3.96	SNN's continuing to report strong sales of VISIONAIRE and VERILAST knee systems. Outlook is for 8 % overall sales growth.
8	10	Johnson & Johnson	26.33	0.24	Looking for a mid-2012 closing of DePuy + Synthes. Musical chairs among spine reps likely to continue.
9	9	Exactech	7.69	4.66	Previewed Q4 sales and earnings. Bottom line, 2.5% sales growth which indicates a slowing rate as 2011 came to a close.
10	NR	Integra LifeSciences	14.81	0.94	As other ortho stocks have risen, IART has languished. This week it became, officially, the least expensive equity in orthopedics.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TranS1	TSON	$2.71	$74	44.92%
2	NuVasive	NUVA	$17.16	$725	44.32%
3	MAKO Surgical	MAKO	$35.87	$1,494	27.24%
4	Tornier N.V.	TRNX	$20.84	$818	19.29%
5	CryoLife	CRY	$5.85	$165	19.14%
6	Orthofix	OFIX	$41.25	$759	18.40%
7	Kensey Nash	KNSY	$24.23	$209	18.20%
8	Zimmer Holdings	ZMH	$62.51	$11,200	17.48%
9	Conmed	CNMD	$30.47	$851	15.24%
10	Bacterin Intl Holdings	BONE	$2.99	$121	15.00%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Symmetry Medical	SMA	$7.77	$282	-5.59%
2	RTI Biologics Inc	RTIX	$4.04	$223	-4.94%
3	Johnson & Johnson	JNJ	$65.64	$179,253	0.24%
4	Integra LifeSciences	IART	$31.04	$833	0.94%
5	Synthes	SYST.VX	$171.51	$20,371	2.24%
6	ArthroCare	ARTC	$32.24	$887	3.77%
7	Smith & Nephew	SNN	$50.70	$9,066	3.96%
8	Exactech	EXAC	$17.30	$227	4.66%
9	Medtronic	MDT	$40.20	$42,425	4.93%
10	TiGenix N.V.	TIG.BR	$0.96	$87	7.31%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$40.20	$42,425	12.07
2	Integra LifeSciences	IART	$31.04	$833	12.83
3	Zimmer Holdings	ZMH	$62.51	$11,200	13.00
4	Johnson & Johnson	JNJ	$65.64	$179,253	13.13
5	Stryker	SYK	$55.61	$21,280	15.11

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$17.49	$688	37.21
2	RTI Biologics Inc	RTIX	$4.04	$223	26.93
3	NuVasive	NUVA	$17.16	$725	25.61
4	ArthroCare	ARTC	$32.24	$887	22.55
5	Conmed	CNMD	$30.47	$851	21.92

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Integra LifeSciences	IART	$31.04	$833	0.51
2	Orthofix	OFIX	$41.25	$759	0.89
3	RTI Biologics Inc	RTIX	$4.04	$223	0.95
4	Stryker	SYK	$55.61	$21,280	1.40
5	Stryker	SYK	$54.90	$21,009	1.39

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$17.16	$725	3.64
2	Wright Medical	WMGI	$17.49	$688	3.32
3	CryoLife	CRY	$5.85	$165	2.46
4	Smith & Nephew	SNN	$50.70	$9,066	2.17
5	Johnson & Johnson	JNJ	$65.64	$179,253	2.13

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$7.77	$282	0.78
2	Alphatec Holdings	ATEC	$1.96	$175	1.02
3	Integra LifeSciences	IART	$31.04	$833	1.14
4	Conmed	CNMD	$30.47	$851	1.19
5	Exactech	EXAC	$17.30	$227	1.19

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix N.V.	TIG.BR	$0.96	$87	140.74
2	MAKO Surgical	MAKO	$35.87	$1,494	33.73
3	Synthes	SYST.VX	$171.51	$20,371	5.53
4	Bacterin Intl Holdings	BONE	$2.99	$121	4.61
5	Tornier N.V.	TRNX	$20.84	$818	3.60

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

Inside the Wright DPA Meltdown

By Walter Eisner

The Hagan Complaint/RRY Publications LLC

At 4:00 a.m. on the morning of May 4, 2011, David Stevens, chairman of the board of Wright Medical Technologies, Inc. picked up his phone and called Cary Hagan, the company's top executive for Europe, the Middle East and Asia. Stevens told Hagan he would be terminated if he did not resign immediately.

"Humiliating and Contrived Termination"

Hagan claims that Stevens made it clear that the only option in lieu of a humiliating and contrived termination was to sign a resignation letter.

The letter stated: "This letter shall serve as confirmation that my resignation… is not because of a disagreement with the company on any matter relating to the company's operations, practices or policies."

Hagan signed the letter but now says it wasn't true.

And so began the public disclosures of Wright's private struggles to comply with a deferred prosecution agreement (DPA) imposed by the U.S. Department of Justice (DOJ). Eight months later Hagan would blow the lid off Wright's struggles by filing a Breach of Contract and Retaliatory Discharge lawsuit against the company.

OTW has obtained and read a copy of Hagan's Complaint.

According to documents filed by Hagan's attorney in court, Stevens forced him to "resign" with no prior warning, notice or hint of suggestion that Hagan had failed to perform his duties. Stevens told Hagan the reason for the termination was "compliance issues."

"Retaliation" and "Scapegoat" Allegations

Hagan fires back that the charge was "bogus" and says his wrongful and forced resignation was in retaliation for his documented criticism of Wright's compliance failures and to placate the Department of Justice during its ongo-

ing investigation of Wright for the very type of compliance issues that Hagan had reported to the company's Board five months earlier.

In fact Hagan claims that Stevens had previously sent him an "unsolicited" personal note congratulating him on his "outstanding accomplishments". Stevens, according to the suit, "acknowledged Mr. Hagan's success at a level that 'historically did not appear achievable.'".

Hagan alleges that the early morning phone call was made to allow the company to file SEC papers later in the day and offer him up as a "scapegoat" to protect the board's reputation with prosecutors and investors for mishandling the monitoring program.

Hagan further alleges that Ed Steiger, Wright's senior vice president of human resources, who was also on the early morning call, told Hagan that if he didn't sign the letter, Hagan would be publicly mentioned "in what was clearly to be a negative, derogatory and defamatory manner" in an upcoming press release from Wright "in an identical manner as had been a case with the recent firing of another Wright senior executive, Frank Bono." Hagan signed the letter, but handwrote a note across the letter that stated, "By signing this letter I do not waive any recourse against Wright Medical, including rights to severance and bonus."

Hagan says he was told in a cell phone call by another corporate officer on the same day that if he filed a lawsuit against Wright, its Board of Directors, or its Monitor under the DOJ proceeding, Wright would recommend Hagan for exclusion from participating in the U.S. Medicare and Medicaid programs. A death sentence for anyone trying to work in orthopedics.

Other Terminations

Hagan wasn't the only executive terminated on May 5. The company also accepted the resignations of Senior Vice President, General Counsel and Secretary Raymond Kolls as well as Vice President of Clinical & Regulatory Affairs Alicia Napoli.

All three executives were said according to a company statement to have resigned without "good reason.". Such a designation prevented the employees from collecting severance benefits. These terminations followed the resignation of former CEO Gary Henley and the termination of the company's Chief Scientist Frank Bono just one month earlier.

DPA Breaches

The terminations and SEC filings weren't all that happened on May 5. Later in the day the U.S. Attorney in New Jersey warned the company that it was out of compliance with their DPA. The feds, according to a company SEC filing, said Wright "knowingly and willfully committed at least two breaches of material provisions of the DPA."

The warning followed the company's disclosure to the feds on May 4 that it had discovered "credible evidence of serious wrongdoing."

Over the ensuing months, the company hired a new CEO, removed the chief compliance officer and extended their federal monitoring program for 12 more months. The company did its best to put this disruption behind it and get back to business.

Hagan, Bono, Napoli File Suits

But then came January 5 and 6, 2012, when Hagan and Bono filed separate

wrongful termination lawsuits against the company in the Chancery Court at Memphis, Tennessee. We have learned that a third executive, Alicia Napoli, has also filed suit.

Hagan wants to be awarded compensatory damages for non-economic harm (humiliation and embarrassment) and economic harm (including loss of salary, bonus, stock options and grants and all forms of compensation or remuneration) and punitive damages sufficient to compensate for his common law retaliatory discharge from Wright.

This week we review the history of Wright's DPA and monitoring program with the feds and look specifically at some of the allegations made by Hagan in his lawsuit. Next week we'll look at Hagan's action in trying to warn the Board of severe problems with the company's compliance program and allega-

tions made by Bono and Napoli in their lawsuits.

Wright's Compliance Gambit

According to Hagan's lawsuit, Wright had a history of "major" regulatory and legal compliance issues, resulting in civil and criminal claims made against them by the government after a major investigation by the DOJ beginning in 2008.

Wright entered into a DPA with the New Jersey U.S. Attorney on September 29, 2010, agreeing to a $7.9 million fine and accepted a federal monitor to oversee the company's compliance with the DPA for one year.

Wright picked James Tucker of Butler, Snow, O'Mara, Stevens & Cannada with offices in Memphis as the monitor and the U.S. Attorney agreed with choice.

Sources tell us that the agreement to complete a monitoring program in 12 months instead of the 18 months agreed upon by Wright's larger competitors the previous year, laid at the heart of the unraveling of Wright's DPA. The sources tell us that the company believed that it could complete a shorter monitoring period because of lessons from their competitors' programs.

Wright's Board of Directors went to "great and unreasonable" lengths to "placate" the Monitor and demonstrate their cooperation, states Hagan's suit.

The Board, at the "insistence" of the federal monitor, identified Lisa Michels, the company's chief compliance officer, as being "instrumental and critical" in appearing to be in compliance with the DPA. The result was the she was "shielded" from criticism.

Wikimedia Commons

Internal Criticism Over Michels

And criticism, lots of it, occurred.

According to Hagan, he and other Wright employees raised "documented" concerns about Michels' "inability" to manage the company's compliance program. The complaints cited "clerical errors, process communication errors, missed deadlines, and repeated failures to attend critical meetings," even when those meetings were scheduled to suit Michels' calendar.

Employees took a trans-Atlantic flight to attend meetings for which Michels "would" not appear. But the Board "repeatedly" ignored the concerns.

In fact, claims Hagan, the Board "wrongfully terminated" Hagan and others who raised concerns about Michels in order to "demonstrate its commitment" and "prove" to the Monitor that the company supported its compliance program.

"By blindly supporting Ms. Michels, in lip service to the dictates of the Monitor, and by dismissing the valid concerns raised regarding Ms. Michels and Wright's compliance program, Wright's Board of Directors demonstrated that it was far more concerned with the appearance of compliance than it was with actually complying with applicable laws and regulations, as well as the specific terms of the DPA."

"Inappropriate" Monitor Behavior

Hagan also claims the Board "abdicated" its responsibilities by permitting the

Monitor to "increasingly, and inappropriately, inject itself into areas of corporate governance.

The Monitor, according to Hagan, appeared to have influenced the Board to mandate that no terminated employees with "issues" could receive severance. Hagan says this was done despite the "compelling and direct protestations" by former CEO Gary Henley.

Hagan alleges that Monitor reports consistently described "dissatisfaction" with Wright's management's "tone at the top." Sources tell *OTW* that Henley's "resignation" occurred just before an unfavorable Monitor report to the U.S. Attorney in New Jersey.

DPA Extension-Michels Terminated

But despite the "hastily conceived efforts" to terminate officers of Wright in order to obtain the dismissal of the DPA, the DPA was extended for at least one year in September 2011.

The DPA was extended because of Wright's "serious continuing problems and deficiencies with its Compliance Program, exposing the tremendous irony of Wright's wrongful termination of Mr. Hagan due to 'compliance issues,'" states Hagan's suit.

Yet, despite two years of "repeated documentation of Ms. Michels' failure to perform," Michels remained in her job. Prior to the extension of the DPA, Wright knew that its "gambit of blindly supporting Ms. Michels in an effort to avoid extension of the DPA had failed," says Hagan.

Accordingly, says Hagan, on August 16, 2011, Wright finally terminated Michels presumably based on the company's "unreasonably delayed conclusion that she was not capable of performing her assigned tasks."

All this caused embarrassment to the Board and senior leadership (other than Gary Henley) and it then attempted to distance itself by directing "blame" onto others.

Next Installment: Board Warnings and Compliance Program Lessons

In the next installment of the Wright lawsuits, we'll look into the "serious continuing problems and deficiencies" with the company's compliance program described in the lawsuits and what the terminated employees said they did to warn the Board. We'll also look at the common threads of the multiple suits for lessons on running a corporate compliance program. ♦

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Treace's Tricks to High Velocity Sales

By Robin Young

Here's a great medical product sales management book by John R. Treace. It's called *Nuts and Bolts of Sales Management: How to Build a High-Velocity Sales Organization*. After I read it I called John up on his cell phone and said: "Now I know all of your secrets!"

John, his brother Jim Treace and Barry Bays were the core group of a team of especially successful managers who, collectively, built Xomed Surgical Products, Inc. up for eventual sale to Medtronic, Inc. Later, when private equity firm Warburg Pincus needed a team to take over near-bankrupt Wright Medical Group, Inc., these guys rolled up their sleeves and pulled that company back from the brink. So outstanding is the track record of these three guys that they are on speed dial for handling some of the most important or difficult business deals in orthopedics. Jim Treace, for example, was part of the team that provided early guidance to Kyphon Inc.

Nuts and Bolts by John Treace should be in every manager's top desk drawer. It's 30 years of sales management experience distilled to a practical, quick read.

What are John Treace's secrets for turning around or building a high velocity sales force?

Well…here are five of his best tips and tricks. But you'll have to buy the entire 194 page book to get the rest. Trust us—it'll be the best $20 you ever spent.

#5 Sales Tip

Lou Holtz, famed college and NFL football coach wrote in his book *Wins, Losses and Lessons* that there are three questions that people mentally ask about you. These are the questions customers must answer about each sales person or company before they buy:

"Can I trust you?"

"Do you care about me?"

"Are you committed to excellence?"

Those three questions frame up Treace's chapter on sales tips. For example, when you're a new rep in a new territory the customer has no frame of reference with

Nuts and Bolts of Sales Management: How to Build a High-Velocity Sales Organization by John Treace /RRY Publications LLC

which to judge you. And you're under pressure to rapidly establish a relationship with a busy, potentially antagonistic physician. It's a rough assignment. What do you do? Treace delivers with eight solid tips.

And, like all great coaches, Treace starts with the basics. Stuff your mother told you.

1. Make a good impression. Look sharp and speak intelligently and succinctly. For good or ill, people make snap judgments so those first impressions are not only critical but entirely under your control. Don't waste it.
2. Take notes. With good notes every sales rep won't forget a promise, a direction or critical piece of information and in, effect, make good on the promises of excellence and trust.
3. Show you care by remembering the little stuff. Study after study of customer buying habits show that four sales rep attributes rank higher than product price or quality—they are knowledge, helpfulness, speed and loyalty to the customer ("Do you care about me?").

#4 Sales Meetings

Sales people go to sales meetings to make money. Period. You might argue that they also want to have fun, hang out, tell stories. But says Treace, when they go home they must have new, solid information or skills that will put more dollars in their pockets. Or they wasted valuable selling time and wasted your company's money.

There is a right way and a wrong way, says Treace, to structure sales meetings. What does the master of ceremonies do? Here's the Treace battle tested checklist.

First. How should the corporate officer's presentation be organized? Treace provides a theme, an overview and an outline.

Second. What key morale issues should the meeting's organizer address from the podium? Treace offers three basic issues that are critical to any organization.

Third. What should the VP of Sales or Marketing present? Treace has the answer.

Finally, here is what Treace says about the VP of R&D's presentation:

> "Focus on strength, power and depth of the R&D groups. We probably have the largest specialty R&D group of any of our competitors; we need to tell them that, and let them know that it is going to be tough for any of the larger companies to catch us. This will help them understand why their time spent selling our products today is not wasted. Share with them the efforts we make to have a proprietary position (patents) in our new products; again, this tells them the business they develop with us is secure."

In fact, the VP of R&D may well be the secret weapon of every successful sales meeting.

#3 Awards Programs

Ever been to a sales award program where the end result was a *deflated* sales force? It happens more than you might think. Awards programs for sales people are difficult and nuanced—probably more than most executives realize.

Fact is, the awards program is one of the best indicators of your sales force's morale and motivation.

Treace devotes an entire chapter to the awards program and dissects the issues well. "No one wants to work for an award that they feel will be given out based on even the smallest hint of favoritism."

This chapter is a blueprint for using awards programs to create a culture of achievement within the sales team. He describes how to build award consistency, set long-term goals and formulate the metrics that motivate, not deflate, a sales force.

Finally, he addresses the types of awards that work well and how to use them.

Here, for example, is Treace's "Product Champion's Award":

> **Description:** The top sales producer in each of the seven target products
> **Eligibility Requirements:** Minimum of six months tenure
> **Performance Requirement:** Highest combined rank of total annual sales dollars and total annual dollar growth for each target product (factors given equal weight)
> **Award:** $500 available for purchase of company stock
> **Number of Possible Winners:** 7

In total, Treace describes nine awards in *Nuts and Bolts* along with the presenter's script.

#2 Hiring and Firing

"If you start with a 'meatball' and train it, all you end up with is a trained 'meatball.'" In other words, says Treace, invest in hiring well (which is fun anyway) and you'll minimize firing poorly (which can haunt a company for years).

This chapter, as much as any other, springs from Treace's experience fixing bad decisions at companies who had not only hired poorly, but squandered valuable sales people and were virtually bankrupt. Having seen sales people over the years at their worst and their best, Treace has developed some tests (see "The Ultimate Golf Ball Test") and signs to looks for ("The Cadillac Salesman") when judging, hiring or, if absolutely necessary, firing sales people.

Given his 30 years in sales, it's perhaps not surprising that Treace thinks about sales management in terms of the different types of sales people. So much of his advice focuses on how to winnow "baggage handlers" from the high performers and how to sniff out a track record of customer success.

This chapter, in fact, may be his strongest since it comes from lessons learned in the heat of battle. Bottom line, says Treace, is that avoiding a problem is much, much cheaper than fixing it later.

#1 Compensation

You've hired like a champ, set up a great awards program and sales meetings but your compensation program neither motivates your sales force nor keeps your expenses manageable.

John has some advice for you.

"Powerful companies have sales teams that are compensated well and management that is sincerely joyous—and not at all envious—of the reps high pay." – John Treace.

Building a compensation program that motivates sales people and attracts and retains high performers takes an intelligent blending of the three basic forms of compensation: straight commission, salary, and a combination of the two. A key framework to keep in mind as you build your program, says Treace, is the current industry standard.

But wait, there's still more.

In total, *Nuts and Bolts* has 21 practical chapters on such key issues as:

- Morale, Execution and Teamwork
- Direct and Independent Sales Forces
- Who Should I Put My Money On?
- Practices to Avoid
- Managing the Expense Budget
- Metrics, What They Are and Why We Need Them
- Sales Forecasting
- Managing the Quarter
- When Sales Budgets Are Not Being Made
- Consultants
- Environment and Strategies for High-Velocity Organizations

After reading John's book, we called him and thanked him for giving us all of his hard-earned secrets. He laughed and said, "Well, frankly I could have written a book for each chapter. So I kept a few secrets."

Maybe so, but there are plenty of golden nuggets here for busy sales and management executives. ♦

For more information and to contact John, go to www.nutsandboltsofsalesmanagement.com
or see the book on Amazon (http://www.amazon.com/Nuts-Bolts-Sales-Management-Organization/dp/1934572764/ref=sr_1_1?s=books&ie=UTF8&qid=1328022585&sr=1-1)

Heroes Among Us

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

Twenty-six percent of us volunteer to mentor youth, raise funds, distribute food or offer our professional skills. Two states lead the country in this regard—Minnesota with 37% of its citizens volunteering (#1) and Utah where each volunteer gives 54.5 hours of their time annually (#1).

Then there are orthopedic surgeons.

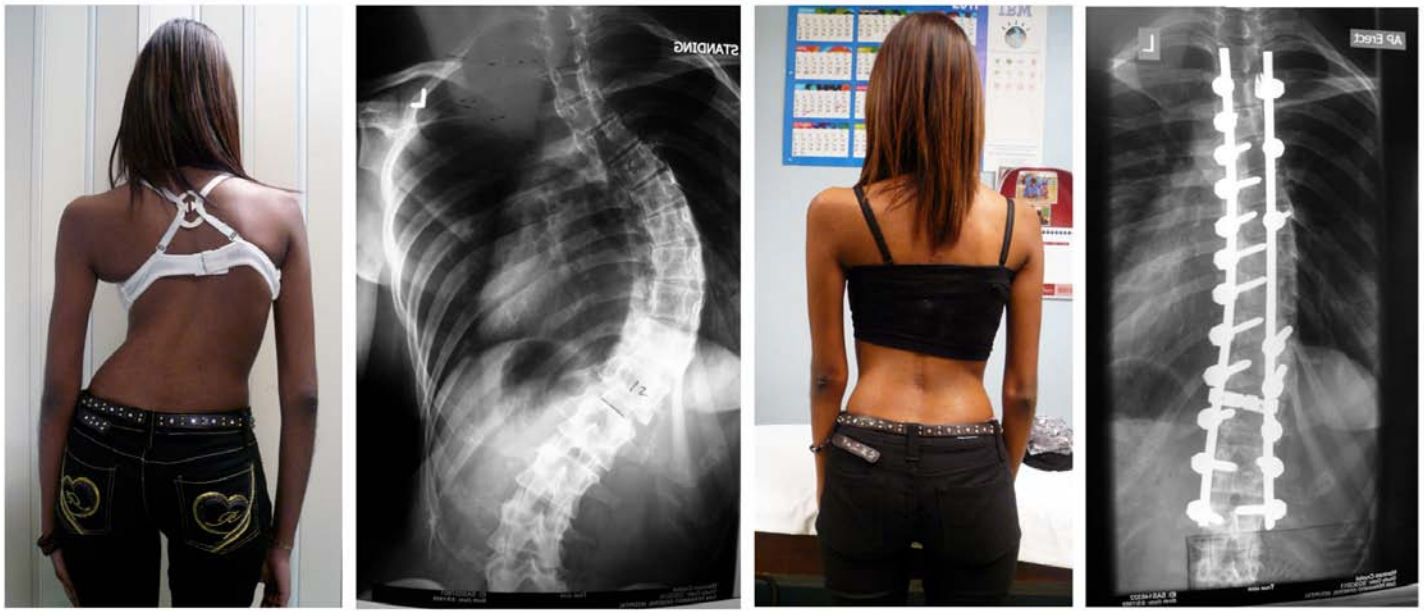
Since we started writing *OTW*, we've had the pleasure and honor to tell the stories of close to a hundred individual physicians, surgeons, nurses and techs who deliver volunteer surgical and other musculoskeletal care. No matter how complex the problem or rudimentary the operating theater, we've learned that hundreds of your colleagues have answered the call. Orthopedists will be there.

The percentage of orthopedists who volunteer their skills, we're certain, is higher than the national volunteerism average. At the University of Pennsylvania, for example, of the many surgeons we know, more than half volunteer routinely, quietly and profoundly.

Like Dr. Vincent Arlet, Chief of Orthopaedic Spine Services at the University of Pennsylvania.

Two or three times a year Dr. Arlet leaves Philadelphia to go to the 59-year-old Princess Elizabeth Center for Handicapped Children in Port of Spain, Trinidad. There he joins Dr. David Toby, an orthopedic surgeon from Trinidad who's been heading up the scoliosis program for the past 25 years. "When he asked me to get involved, I jumped at the chance, and have been working ever since in association with the Foundation of Orthopaedics and Complex Spine (F.O.C.O.S)." For free. As a volunteer.

The most exciting thing, says Dr. Arlet, is that he can make a concrete and lasting difference in the lives of these patients. "The scoliosis curve I see in Trinidad is so severe that I know that if I don't go, they will have no one to take care of them. Dr. Toby does his best, but he is the only spinal deformity surgeon on the island, and as such he gets referrals from all over the West Indies.



Pre (a &b) and post operative (c & d) photographs and x-rays of a 22-year-old girl with an 89 degrees scoliosis.

These deformities are primarily kyphoscoliosis with a Cobb angle measure of 90 degrees or more…and they require two surgeons in the operating room."

Dr. Arlet, who is committed to this project for life, describes the logistics: "We spend about six days there, four of which are in the OR. Trip dates are decided during the preceding visit to make sure that all members of the team will be available; we select patients for the next surgeries during the clinic preceding the next visit. It is challenging to prioritize the patients and surgeries… getting patients ready for the surgery is another issue that must be dealt with efficiently."

Andrew Huth/RRY Publications LLC

Prepping for these massive operations requires the talents of other skilled specialists. "Dr. Rodney Benjamin, our anesthesiologist, is trained in total intravenous anesthesia, which is necessary during such complex spinal deformities in order to achieve perfect spinal cord monitoring. We also have an electrophysiology technician and OR nurses. One of these nurses—Geeta Pollard—traveled to the U.S. three years ago and spent six weeks with us at The University of Virginia (UVA) to observe nursing and OR techniques involved in complex spine surgery."

So what is it like to do surgery without all of the bells and whistles of a U.S. operating room? Dr. Arlet notes, "As there is no ICU bed available in the center, we have to be very careful during the surgery that there will not be any need for this type of equipment. To decrease the blood requirement, we do an extremely meticulous dissection of the spine, use a cell saver, and plan our surgery such that we have a minimum of blood loss."

And sometimes, just when Dr. Arlet nearly had the rod in…surprise…water. "The OR has been flooded several times in the last few years. As a consequence, the c-arm fluoroscopy unit broke down, making it unreliable. This means that the majority of our scoliosis surgeries are done without a C-arm. Also challenging is that the overhead lights in the OR are relics from the 1950s. On two occasions we operated on 90 degree curves with only our personal head lamp. Every time we go there are improvements in terms of patient care, but we have setbacks because of local conditions. For example, we had a brand new Jackson spine table, but the flooding ruined it and we are left using a regular OR table."

But the team knows that being organized can cut down on the chaos. "We schedule our most complex surgery for the first day; that way, if there are any issues postop we are there to take care of them. The surgeries are pretty grueling, and last anywhere from five to ten hours. The girl in the photo below underwent an 11 hour procedure; during her surgery we lost electricity and had to use our head lamps—not ideal because it gives us a limited field of vision…and there are lots of shadows 'flying around.'"

After the patient emerges from the OR, he or she does have postop care. "Following surgery, patients go to the recovery room, where a well trained nurse cares for their pain and monitors their vital signs. Typically a patient will spend three or four days on the Stryker frame and will be mobilized after this time; adult patients are mobilized earlier. One of the advantages of the Stryker frame—something that we no longer use in the U.S.—is that it helps to mobilize the patient's lungs."

To make all of this possible, locals help themselves and caring individuals from abroad step up as well. Dr. Arlet: "We have relied on the support of a local (Trinidadian) charity to fund a portion of these trips. They assist us with logistics, provide lodging, transportation, and meals, and raise money for patient care. Outside Trinidad, we receive support from F.O.C.O.S. (Foundation of Orthopedics and Complex Spine) for both transportation and the implants. F.O.C.O.S. is a 501c3, so people can donate and get a tax deduction. Several friends in industry have generously provided us with full support by giving the implants for free—this is especially important because it means that no expenses are incurred by the patient."

In an ideal world, says Dr. Arlet, every institution would have an outreach spinal deformity program. "More and more, universities are encouraging their residents and/or fellows to rotate overseas…even for a short period of time. When I was at the University of Virginia, I got this program approved through the school's graduate medical education office and it became part of the training. Typically, I bring along a resident or fellow who is interested in spine. They usually come back reinvigorated…and saying to their peers: 'Just go there. It is amazing.'"

To date, Drs. Arlet and Toby have performed 50 complex spine surgeries. "These are huge operations, with the average Cobb angle of these curves being 95 degrees. The correction rate has been 60%. Unfortunately, we have had a few complications: two infections that required local debridement, two transfers of our patients to the Port of Spain General Hospital where there is an ICU, and one cerebrospinal fluid leak that required a lumbar drain. We did not observe any neurologic complications. However, we lost the motor evoked potentials during the surgery on several occasions. None of the complications carried any long term sequellae."

Dr. Arlet states, "I am extremely grateful for the whole team at Princess Elizabeth Hospital. The establishment of a complex spine surgery program has been for me an invaluable experience. Without the help of an exceptional team in Trinidad nothing would have been possible."

We are grateful to Dr. Arlet and the thousands of other volunteer surgeons, nurses, technicians and companies who donate instruments, equipment and pharmaceutical products every year without fanfare or pay. ♦

For more information about F.O.C.O.S. go to http://www.orthofocos.org/

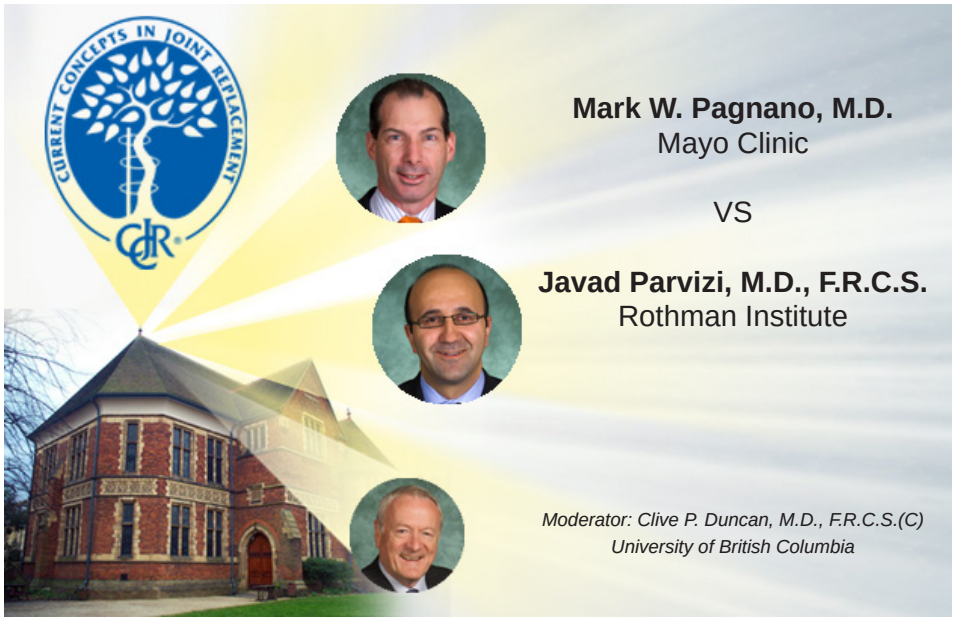
For more information about volunteering your skills go to http://www.ama-assn.org/ama/pub/about-ama/our-people/member-groups-sections/office-international-medicine/overseas-volunteering-opportunities-physicians.page

Pagnano and Parvizi Debate Squeaking Hips

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

"Lubricate the joint!" says Mark Pagnano, who says that the benefits of a superior wear couple as represented by ceramic-ceramic likely outweigh the potential risks. Jay Parvizi disagrees, pointing out that while we have a longer clinical experience with ceramic-ceramic components than we do with highly crosslinked polyethylene, at the midterm, they perform essentially equivalently.

This week's Orthopaedic Crossfire® debate is, "The Squeaking Hip: Much Ado About Nothing." For the proposition was Mark W. Pagnano, M.D. from Mayo Clinic. Against the proposition was Javad Parvizi, M.D., F.R.C.S. with the Rothman Institute in Philadelphia; moderating is Clive P. Duncan, M.D., F.R.C.S.(C) of the University of British Columbia.



Wikimedia - KaihsuTai and Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Pagnano: "I would like to take the position that squeaking hips after ceramic-ceramic are largely much ado about nothing. It's my contention that ceramic-ceramic bearings in total hip arthroplasty are the best bearing selection for a selected subgroup of patients. If we review the volumetric wear rates with different total hip bearing combinations, they are cobalt chrome against traditional polyethylene (120-200υm), cobalt chrome against crosslinked polyethylene (0-25υm), and then ceramic-on-ceramic (<1υm)."

"All bearing surface couples have risks. But at a certain young age the benefits of a superior wear couple of ceramic-ceramic likely outweigh the potential risks. In an extreme example, a 12-year-old patient with bilateral advanced hip problems…really nothing short of total hip arthroplasty is going to give this patient substantial pain relief. And a ceramic-ceramic hip is a reasonable treatment option for this person. Similarly, in an 18-year-old patient with bilateral avascular necrosis and disabling pain total hip arthroplasty is clearly the best option, and a ceramic-ceramic couple is probably the best bearing couple."

"There are risks with ceramic-ceramic, but they can be minimized. The potential disadvantages: there is a small risk of fracture of the ceramic head or chipping of the liner, a risk of runaway wear—you heard that earlier about metal-metal—same things with malposition and edge loading with ceramic-ceramic, an impingement risk, and then the squeaking phenomenon which has really dominated this discussion over the last three to five years."

"The fracture risk has decreased with modern technology. Improvements in the ceramic include smaller grain sizes, better burst strength, and with alumina ceramic the risk of fracture is now in the range of <1 in 2,000-10,000. Ceramic-ceramic is sensitive to cup position, however. If the cup is too vertical you can get edge loading and then runaway wear. If you have improper version you can have impingement of metal against ceramic or metal against metal in certain cup designs. The squeaking noise has received lots of attention. There is a spectrum of these squeaking noises, from intermittent nuisance type squeaks to more consistent reproduc-

ible squeaks in every step. But squeaking is typically not painful, and usually occurs with walking or changing position; prevalence is anywhere between 0 and about 6% in big series."

"About a year ago we had one of our fellows pull all the English literature that discussed hip component squeaking and it turns out that most of those reported cases are with a single acetabular component design, one in which there's a rim of titanium around a recessed ceramic bearing, leading to a potential for edge loading. We thought that there was potential to look at this on a basic science basis to try and figure out why squeaking occurs. We developed an in vitro study and looked at squeaking in the biomechanics lab at Mayo. Turns out that we could reproduce squeaking in dry conditions and so we had an effective model to look at this. In the dry condition, every potential pattern that we could think of will produce squeaking quickly and that squeaking will remain constant. If we add lubrication to the joint the squeaking goes away in almost every situation you can imagine. The only condition in which squeaking was reproducible in the lubricated condition was when there was titanium material transfer to the head."

"So it's our contention that squeaking occurs via a disruption of fluid lubrication in the joint. It will always occur in a dry joint, but in a lubricated joint it only occurs with metal transfer. Squeaking is commonly reported with certain designs."

"So in conclusion, in my own practice, metal-polyethylene bearings are applicable to the majority of total hips. Ceramic-ceramic is the best for a subgroup of young, active patients. I think we will see a resurgence in interest in ceramics as we better understand the interrelated aspects of design and surgical technique to avoid impingement."

Dr. Parvizi: "Like Dr. Pagnano, I use ceramic-ceramic in a select group of patients. Squeaking following ceramic-ceramic does happen, and the rate is between 0 and 29%. Part of the problem relates to what exactly we call squeaking. Our institution, as well as Dr. Ranawat, was the first to draw attention to the phenomenon of squeaking. We first noticed this in 2002, and the incidence of squeaking was around 3%. The incidence is affected by the definition and length of follow up. We did a study in which we looked at the natural history of squeaking and we found that some resolved, some were late start-

ers (happening up to two years after surgery)…and it did go up when the patients became aware of this phenomenon, especially if they were stimulated by some lawyers."

"The etiology of this remains unknown. Some of these have not been proven to be scientifically sound such as—cup thickness initially was thought to be a problem. Patient demographic does not seem to have an influence on squeaking. We performed a bilateral total hip arthroplasty study in which we did not see any demographic factor that could be a risk factor for squeaking. Also, people have talked about malseating such as trying to put a ceramic liner that is encased in a jacket into the hip. There is difficulty seating the cup, perhaps due to the fact that the socket has deformed due to the hard bone of the patient. After impaction one is fairly certain that the socket is seated, but when you test the socket unfortunately it's not so. So this was thought to be one of the phenomenon related to squeaking, but that has not born out to be the case scientifically."

"Other theories…We know for a fact that if you've got a mismatched couple that a ceramic liner is likely to squeak—that has been born out by multiple papers, including a very elegant scientific study done in Italy and presented at the AAOS [American Academy of Orthopaedic Surgeson] two years ago."

"Dr. Walter drew our attention to possible malposition being a cause, and in his paper he found—in a small series—that component malpositioning was a risk factor for squeaking. We did a similar study in which we did a 2:1 match on all the patients, did a CT scan of the cup, looked at the version of the acetabular component. We didn't see a difference in the cup position, but one of our problems was that we could not measure the femoral anteversion…and one could argue that perhaps the combined version does have a role in terms of causing ceramic-ceramic squeaking. But what we did see is that the anteversion in the majority of the squeaking cases was excessive."

"Edge loading does lead to stripe wear and that has been implicated with squeaking, and I'm sure that is going to be proven even further. Dr. Capello and Dr. D'Antonio drew our attention to the importance of the femoral component, in particular the taper of the femoral stem. As they had not seen any squeaking with the C-taper design that they had used over a time period, whereas it happened that the TMZF, especially with the V-40 taper was a very significant risk factor. Dr. Walter also found that the most significant factor was the design of the femoral stem that they used in that study; now there have been multiple studies showing that the V-40 neck with the TMZF alloy is a risk factor for squeaking."

"I agree with Mark completely that some designs are more likely to lead to more metal transfer. Our retrieval studies published with Steve Kurtz on about 18 cases so far have shown metal transfer and impingement to be very common with one specific design. We followed that study, we've used Trident cups and non-Trident cups at our institution and we've found that amongst a large number of patients squeaking was around 8% in the Trident design and 0% amongst other designs. The incidence of squeaking was 7x higher with the use of TMZF so I agree with Mark that it happens that squeaking may be related to one particular design."

"So, you malposition the component, it leads to impingement. If you use a raised liner you might transfer more metal; perhaps the TMZF is more likely

to transfer metal. It gets into the bearing surface; then, if you have a good resonance such as what you might see with a TMZF alloy that leaks or squeaks."

Moderator Duncan: "Let's turn to something which we were not dealing with and that is the fracture. Bring us through management of the broken ceramic head. Jay?"

Dr. Parvizi: "They are extremely tough. I've had the misfortune of revising two cases with fractures—not the modern generation, the old generation…very difficult. Chit Ranawat talks about doing an extensive synovectomy through the front and the back. We haven't done that, but I can tell you that it's one of those cases that takes a long time, and I do actually choose a hard-hard bearing surface in that sort of a circumstance because regardless of how meticulous you are in trying to get all those particles, I'm sure there are some that are left behind that could put that soft bearing surface at risk later."

Moderator Duncan: "So what implant bearing surface did you put back into that patient?"

Dr. Parvizi: "I would use ceramic-ceramic."

Moderator Duncan: "Mark, what was that incidence again?"

Dr. Pagnano: "Probably somewhere between 2 and 10,000. Because the incidence is so low it's hard to get hard-core data because you don't know how many of these are reported back to central agencies that can accumulate the data."

Moderator Duncan: "There have been a small number of reports of revision for squeaking itself. How should we manage that patient?"

Dr. Pagnano: "I think it's an individualized decision and what we can say is that squeaking is a nuisance for a subset of patients, but it's rarely painful…and at this point we don't have data that squeaking leads to some catastrophic problem with the hip at a later date. That being said, if there's something with the X-ray where there's a major problem with cup position, it's markedly abducted…you're concerned about the potential for runaway wear, for instance, then that might be someone where you'd push them to surgery sooner rather than later. But for most patients the painless squeaking hip, it mainly comes down to whether it's a big enough nuisance on a daily basis to make it worth going through another operation."

Moderator Duncan: "Jay, if during the index arthroplasty you note during reduction, perhaps you've had to dislocate the hip again to ensure something, there is a stripe on the femoral head—will you throw that femoral head away?"

Dr. Parvizi: "That doesn't worry me and that has been shown in multiple in vitro studies not to significantly affect wear characteristics."

Moderator Duncan: "Mark, do you agree with that based on the Trousdale study? Do you keep that head or do you feel like it's going to interfere with lubrication?"

Dr. Pagnano: "There is the potential that that could lead to squeaking because it's some disruption of fluid film lubrication. But probably the negatives of changing that outweigh the positives."

Dr. Parvizi: "Because of the taper issues. If you pull that ceramic head off you've got a taper issue."

Moderator Duncan: "Thank you, gentlemen. It was excellent." ♦

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company

Dan Garen: Wright's New Compliance Boss

Wright Medical Group, Inc. has induced Daniel Garen to take over the organization's beleaguered compliance program and immediately become senior vice president and chief compliance officer of the company.

Garen has a lot of experience in implementing and managing corporate compliance programs, according to the company announcement on January 30. To induce Garen to join the company, the Compensation Committee of the company's board approved the grant of a stock option to purchase up to 50,000 shares of the company's common stock for the current trading price (around $17 per share).

The management of Wright's compliance program is getting public scrutiny as former senior employees terminated during the compliance program have sued the company, charging mismanagement of the program. Garen replaces Lisa Michels, the company's previous compliance officer, who was also removed from her position several months ago and left the company.

Robert Palmisano, Wright's new president and CEO noted that the organization has made "significant improvements" to the company's compliance policies and procedures "over the past several months."

Daniel Garen/Wright Medical Group, Inc.

Garen has more than 10 years of corporate legal experience. He has held senior compliance officer positions with Siemens Corporation and Bayer Healthcare. In addition, Garen served as chief compliance officer and senior counsel from October 2007 to August 2010 at Siemens Healthcare Sector U.S., where he most recently held the position of vice president, Healthcare Policy and Clinical Affairs until January 2012.

Garen holds a juris doctor degree and a master of laws in health law from the Loyola University Chicago School of Law and a bachelor's degree from the University of Michigan. He is a member of the Illinois Bar, the District of Columbia Bar, the Federal Supreme Court Bar, the American Health Lawyers Association, the American Bar Association and the Health Care Compliance Association.

The chair of the board's Nominating, Compliance and Governance Committee, John Miclot, said Garen's experience will be a great asset to the management team and "reflects our continued commitment to adhere to government laws and regulations."

Palmisano added that Wright has been and "continues to be committed to running our business in a manner consistent with the highest ethical standards....We look forward to continuing to enhance this critical area or our business under Dan's leadership."

Wright is operating under an extended Deferred Prosecution Agreement with the U.S. Attorney in New Jersey and continues to report to a federal monitor.

—WE (January 30, 2012)

$89 Million for ConforMIS

If new funds are like a hit of oxygen, then ConforMIS can breathe easily these days. The company is announcing today that it has raised $89 million in a Series E round of funding—more than in any prior fundraising rounds. The company indicates that the funds will be used to support ongoing sales and marketing expansion, R&D investment into new product lines, and build out of manufacturing infrastructure. The investments originated from private-equity and Sovereign-Wealth Funds in the U.S., Europe, Asia and the Middle East. AGC Equity Partners and Axel Johnson, Inc., along with Sovereign Wealth Funds from Asia and the UAE led the round.

Philipp Lang, M.D., MBA, Chief Executive Officer and Chairman of the Board of ConforMIS/ConforMIS

"ConforMIS' key objective for Series E funding was to work with investors who focus on high-growth opportunities around the globe and who see the value in funding differentiated technologies in markets with tremendous room for growth," said Philipp Lang, M.D., MBA, chief executive officer and chairman of the board of ConforMIS, in the January 30, 2012 news release. "This latest round of financing provides us with the resources to aggressively grow our business and invest in our scale up. It also provides us with the resources to pursue strategic initiatives in technology and intellectual property expansion."

Dr. Lang told *OTW*, "Our strategic initiatives include extending our technology into new offerings in other joints, as well as continuing our manufacturing scale up and integration with our supply chain. We believe both of these initiatives are critical to our long term value and strategic flexibility, and both efforts will generate a significant expansion in our intellectual property base."

—EH (January 30, 2012)

FDA Clears Medtronic Hemostatic Sealer

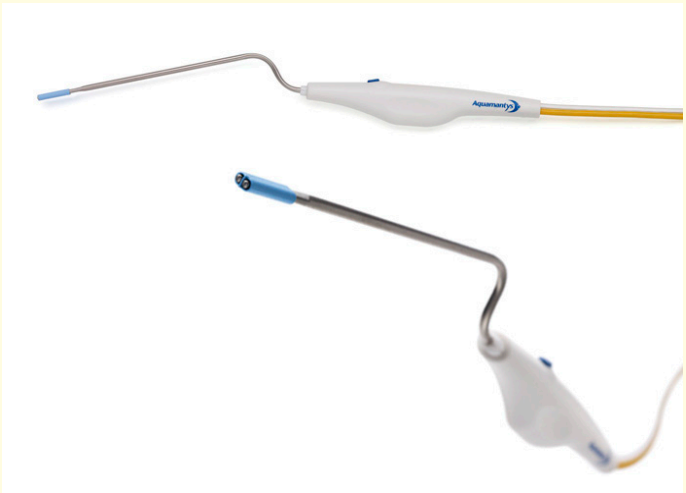
Medtronic, Inc. has received 510(k) clearance from the FDA for the Aquamantys SBS 5.0 Sheathed Bipolar Sealer. The company says the tool is an addition to the spine portfolio and the company's Advanced Energy business.

According to the January 23 announcement, the device gives spine surgeons the ability to optimize speed and continuity in surgical cases by providing hemostatic sealing capabilities for both incised soft tissue (e.g., cut muscle) and epidural veins with a single device. The SBS 5.0 uses transcollation technology, a combination of radiofrequency energy and saline that, according to the company, has been shown to reduce blood loss and improve visualization when used during spine procedures. Reductions in blood loss during surgery have been linked to reduced blood transfusion rates and decreased surgical time.

Paul Santiago, M.D., a surgeon at Washington University School of Medicine said the tool is a "great combination tool that will allow surgeons to treat cut muscle planes as well as compress and treat epidural veins with a single device. This will be particularly useful in cases like 1-2 level TLIFs/PLIFs in which you want the ability to address both of these needs but the economics can make using multiple devices difficult."

Mark Fletcher, president of Medtronic's surgical technologies business, promises that the SBS 5.0 "will deliver considerable value to surgeons, patients, and hospitals alike."

—WE (January 30, 2012)



Aquamantys SBS 5.0 Sheathed Bipolar Sealer/Medtronic, Inc.

legal

Symmetry Settles SEC Inquiry

Symmetry Medical Inc. has reached a settlement with the U.S. Securities and Exchange Commission (SEC) to settle a previously reported informal inquiry conducted by the federal agency.

According to a January 30 announcement by the company, the SEC initiated an investigation in 2007 related to matters arising from the discovery of certain accounting irregularities at Symmetry's Sheffield, UK operating unit. A former employee at that location had, according to the company, colluded to falsify records. The company said it discovered the irregularities in 2007 and reported the matter to the SEC.

The company says it cooperated fully with the SEC and there are no allegations of any issue related to the company's financial reporting since 2007.

Under the settlement reached on January 30, the company consented to an administrative cease-and-desist order to comply with relevant provisions of the securities laws. There is no fraud charge against the company, nor was any civil penalty or other financial obligation imposed by the SEC.

Moore, Hite Resolve Claims

Simultaneous with the company's settlement, Brian Moore, Symmetry's former CEO and current president of Business Development, and Fred Hite, Symmetry's CFO, resolved claims under Section 304 of the Sarbanes-Oxley Act through the repayment of certain incentive-based compensation they earned between 2004 and 2007. Section 304 requires the repayment of, among other things, performance-based compensation earned during a time when the company filed inaccurate financial statements, and does not reflect any allegations of wrongdoing on their part in connection with the inaccurate financial statements. Hite also agreed to the payment of a civil penalty stemming from internal control deficiencies. There was no allegation, according to the company, that Hite knew of or participated in any of the wrongdoing by the Sheffield employees.

Relative to this settlement, Craig Reynolds, chairman of Symmetry's Board of Directors, stated, "This investigation followed the discovery that individuals formerly employed at our Sheffield UK plant misrepresented that business' financial performance. We believe this settlement is consistent with the company's conclusion that their misreporting was concealed from the company's current management. We note that the SEC expressly recognized the remedial acts that were promptly undertaken by the company upon the discovery of this misconduct, and its cooperation with the SEC's investigation. We are glad that this matter is resolved on terms that we believe are in our shareholders' best interests, including the lack of any penalty imposed on the company."

Hite Vote of Confidence

Thomas Sullivan, Symmetry's president and CEO, and a member of its Board of Directors, reiterated his strong support for Fred Hite. "I have worked closely with Fred since joining Symmetry last year and have the highest regard for his professional ethics, financial acumen, and leadership as a member of the Symmetry management team."

Reynolds added his own support of Hite saying, "We are rigorously committed to strong corporate governance and compliance with all legal and financial reporting requirements. Fred is a strong proponent of those goals as well. The experience of responding to the discovery of the issues in our Sheffield unit has strengthened the company, and we have now implemented even stronger internal controls. We have complete confidence in our current reporting processes and staffing under Tom and Fred's leadership."

—WE (February 3, 2012)

Symmetry Medical and Wikimedia Commons/RRY Publications LLC

Industry/FDA Reach $595 Million Agreement on User Fees

Octaviolopez/morguefile.com

The FDA said on February 1 that the agency and industry have reached an agreement in principle for the reauthorization of the medical device user fee program.

If Congress accepts the agreement, the agency will collect $595 million over the next five years from industry. At that funding level, the agency says it will be able to increase its staff by over 200 employees and reduce the average time it takes to review device applications. The agency has been criticized by industry for taking too long to make decisions and by some consumer advocates for approving devices too quickly.

Review Times

The FDA took 73 days on average in 2010 to complete reviews of 510(k) devices, down from 80 days before companies paid fees in 2001, according to a Bloomberg study. More than 90% of devices are reviewed under the 510(k) program. The FDA's premarket approval application (PMA) program web page says that as of December 27, 2011, there were 81 original PMAs under review. The agency took 177 days to make a decision in 2011 from the time an application was submitted by a company.

Details of the agreement are expected to be finalized soon.

$595 Million

According to the last available public minutes from meetings between the FDA and industry, industry had proposed a user fee package of $447 million over five years, which would equate to 26% of the medical device review budget in FY2017. A 2007 reauthorization of the program had industry contributing $295 million. The FDA was reportedly seeking as much as $805 million from industry.

It looks like they pretty much split the difference.

So for an extra $370 million over five years, the public gets 200 more reviewers and a promise of faster decisions by the agency.

The 2007 reauthorization mandated that the agency submit a new agreement to U.S. lawmakers by January. 15. They missed that deadline but it looks like they reached the agreement in time to meet the February. 15 U.S. House of Representative hearing date on the law.

User Fee Program

Under a user fee program, industry agrees to pay fees to help fund a portion of the FDA's device review activities while the FDA agrees to overall performance goals such as reviewing a certain percentage of applications within a particular time frame. The FDA has been under severe criticism by industry and legislators for not meeting previously agreed upon performance goals.

The agency says the new use fee level will result in greater accountability, predictability, and transparency through such improvements as a more structured pre-submission process and earlier interactions between FDA and applicants.

The Advanced Medical Technology Association (AdvaMed), the Medical Device Manufacturers Association and the Medical Imaging and Technology Alliance were some of the industry associations who negotiated the agreement with the agency.

Congress first established the user fee program 10 years ago with the Medical Device User Fee and Modernization

Act of 2002 (MDUFA I), prompted by growing concerns about the capacity and performance of the medical device review program. The five-year program was reauthorized with the Medical Device User Fee Act of 2007 (MDUFA II) and is set to expire on September. 30.

MDUFA II authorized FDA to collect user fees for certain medical device applications, for the registration of certain medical device establishments, and for certain other purposes. Small businesses may qualify for a waiver from fees on certain submissions or may qualify for a reduced fee.

The FDA held a public meeting in September 2010 on the device user fee program with industry, scientific and academic experts, health care professionals, and representatives from patient and consumer advocacy groups. Stakeholders provided their assessment of the overall performance of the MDUFA program and their opinions about which aspects of the program should be retained, changed, or discontinued in order to further strengthen and improve the program.

—WE (February 1, 2012)

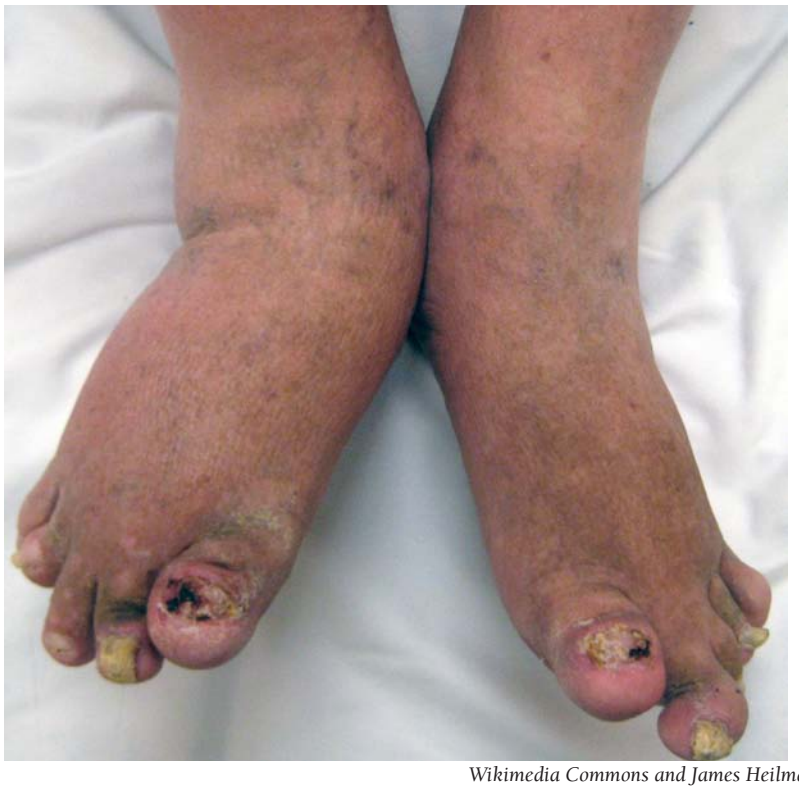
biologics

Biologics to Fight Psoriatic Arthritis

A new review article in the *Journal of the American Academy of Orthopaedic Surgeons (JAAOS)* is shedding light on how medications or biologic agents that target T-cells appear to offer significant benefit to patients suffering from psoriatic arthritis (PsA).

"Although these new immunosuppressive agents are expensive, they are the only agents that have demonstrated a decrease in radiologic progression of peripheral arthritis, and can be used to manage associated types of inflammation, as well as skin and nail disease," said lead study author Michael S. Day, M.D., M.Phil., a resident orthopedic surgeon with the Department of Orthopaedic Surgery at NYU Hospital for Joint Diseases, in the January 18, 2012 news release.

"When patients in dermatology clinics are screened for evidence of inflammatory arthritis, many have evidence of joint inflammation that they did not report, suggesting that many of these patients are undiagnosed and untreated," said study co-author, Dr. Susan M. Goodman, an assisting attending rheumatologist and internist at Hospital for Special Surgery (HSS). The other


Wikimedia Commons and James Heilman, M.D.

authors of the study are HSS rheumatologist Susan Goodman and HSS orthopedic surgeons Dr. Edwin Su and Dr. Mark Figgie.

The first line of treatment for PsA includes nonsteroidal anti-inflammatory drugs (NSAIDs), but going forward, said Dr. Goodman, drugs aimed at providing more targeted therapy will allow more PsA patients to avoid progressing to end-stage arthritis and joint destruction. Surgery may also be considered for patients who have joint deformities as a result of PsA, but so far there have been few large-scale, high-quality clinical trials, Dr. Day added.

The authors told *OTW*, "We preferentially care for these patients in the Comprehensive Arthritis Program, or CAP Service, which is a collaborative service of rheumatologists and orthopedists dedicated to treating patients with systemic rheumatic diseases and inflammatory arthritis. Dr. Day began his study while a medical student rotating on the CAP service at HSS. We meet weekly to formally present our patients, and additionally get input from other involved participants including social work and physical therapy."

"Our research group—which was an outgrowth of our clinical group—has a project underway to study the psoriatic arthritis patients in the HSS arthroplasty registry and compare outcomes to OA patients undergoing arthroplasty. We have wondered if the poor results historically described still apply, given current medical therapy and changes in surgical technique. We have hypothesized that better control of the inflammatory process with more aggressive medication regimens, better control of skin disease, and current surgical technique might have decreased both surgical adverse outcomes such as infection, as well as decreased medical complications such as cardiac or thromboembolic disease."

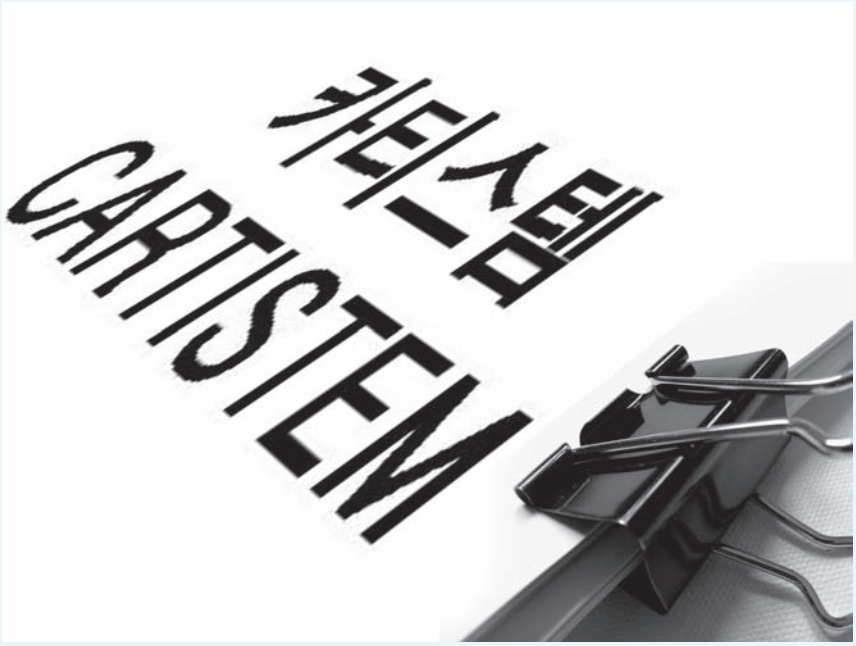
—EH (January 31, 2012)

Korea FDA OK's Stem Cell Drug

As Seoul-based Medipost officials predicted a few weeks ago, the Korea Food and Drug Administration has approved commercial sales of its drug using stem cells developed from newborn's umbilical cord blood. Medipost developed the drug, called Cartistem, to help regenerate knee cartilage. It can be injected into a patient's knees.

"Cartistem is...the world's first approved allogeneic (taken from different individuals of the same species) stem cell drug, that can offer new opportunity for treatment of patients with degenerative arthritis," a Medipost administrator said in a statement. He added that clinical trials have been under way in the United States since last year.

Medipost officials reported that $23.8 million, from private investors and government funds, has been invested since 2001 to develop Cartistem. Company officials report that two of the world's top 10 drug-makers are in talks with Medipost to seek a worldwide license to make the drug - adding that final trials involving a large number of people would likely begin in the US in 2015.



Courtesy Medipost

—BY (January 29, 2012)

large joints

Study: RA Patients Often Inactive

Have rheumatoid arthritis? Get on the treadmill, slopes, etc..... A new study has found that two in five adults (42%) with rheumatoid arthritis (RA) were inactive. The results are now available in *Arthritis Care & Research*, a journal published by Wiley-Blackwell on behalf of the American College of Rheumatology (ACR).

"While there is much evidence of the benefits of physical activity, RA patients are generally not physically active, and physicians often do not encourage regular physical activity in this patient population," explained Dr. Jungwha Lee, an Assistant Professor in the Department of Preventive Medicine at Northwestern University Feinberg School of Medicine in Chicago, Illinois, in the January 26 news release. "Our study aims to expand understanding of the risk factors associated with inactivity among adults with RA and encourage clinical interventions that promote participation in physical activity."

The study, funded by the National Institute for Arthritis and Musculoskeletal and Skin Diseases, involved 176 RA patients, 18 years of age or older enrolled in a randomized controlled trial to assess the effectiveness of an intervention promoting physical activity. A full 42% of RA patients were found to be inactive (participating in no moderate-to-vigorous physical activity periods of at least ten minutes during a seven-day period of objective activity monitoring). Researchers found that 53% of study participants lacked strong motivation for physical activity

National Institutes of Health

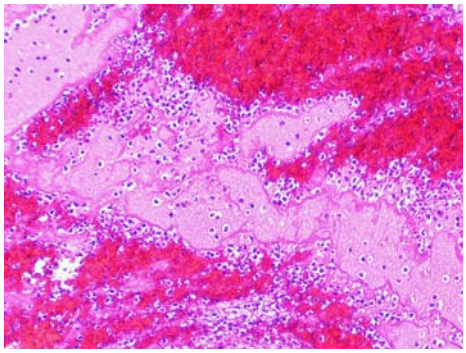
and 49% lacked strong beliefs in the benefits of physical activity.

When asked how to alter patient and doctor behavior, Dr. Lee told *OTW*, "People with arthritis need to weave physical activity into their lifestyle. Walking is a wonderful way to increase activity: for example, park your car at the far end of the parking lot instead of taking the closest spot. Go for a walk with a friend instead of meeting for coffee. The Arthritis Foundation is a wonderful resource, and sponsors water aerobics, walking activities, and classes to promote healthy behaviors. Certainly if you have questions regarding what is safe for you, talk to your healthcare provider. We are currently working on interventions on changing patient behavior suggesting moderate intensity, low impact activities. For healthcare providers, we are working on providing a workshop at the annual ACR meeting to spread the word that physical activity is good for everyone. When it comes to physical activity for people with arthritis, there is good evidence that the benefits far outweigh the risks. The bottom line is that physical activity is good for everyone, including people with arthritis."

—EH (February 3, 2012)

Joint Replacement Blood Clot Threat Quantified

It has long been known that blood clots are a risk factor for patients undergoing replacement of their hips or knees. But just how great that risk is has been quantified by research out of the University Hospital of Lausanne, Switzerland.



Source: Wikimedia Commons and Yale Rosen/ Caption: The blood clot consists of erythrocytes (red areas) and plasma admixed with leukocytes (pale areas).

Jean-Marie Januel, Ph.D., M.P.H., senior researcher at the Institute of Social and Preventive Medicine, has found that 1 in 100 patients who have knee replacement surgery and 1 in 200 who have hip replacement surgery will develop a blood clot while they are still in the hospital. The numbers do not reflect those patients who develop blood clots *after* leaving the hospital.

Called a venous thromboembolism, this is a situation in which a blood clot forms in one of the deep veins of the body and then breaks away, sometimes lodging in the lungs or brain. Surgeons routinely prescribe anti-clotting drugs to help prevent blood clots from forming following the surgical procedure.

Januel and his colleagues evaluated the results of 47 studies that included

approximately 45,000 patients. Some of the studies were clinical trials; 21 studies involved patients who were having hip replacements; 20 included patients having their knees replaced; and six included patients who were having both done.

The researchers were surprised to find that the number of blood clots following knee replacement surgery were twice as high as were those for hips. According to Kathleen Doheny on WebMD, other studies have found that, when the period after the hospital stay is included, the clots after hip surgery occur with greater frequency than is reported in this study. The risk of blood clots is probably greater than the numbers reported because the risk persists beyond the period of the study. The Lausanne report is published in the *Journal of the American Medical Association*.

—BY (January 29, 2012)

extremities

Value Pricing Leader IFS Now Marketing Subtalar Implants

Internal Fixation Systems, a Miami, Florida, company founded in 2006, has received 510(k) clearance from the FDA to market its subtalar implants. Made of stainless steel, with a cylindrical shape and tapering on one or both ends, the devices are designed to preserve motion at the ankle joint and deal with arthritis as well as whatever trauma the patient has experienced.

IFS's CEO, Stephen Dresnick, M.D., says that his firm also currently offers a full line of mini-cannulated screws for small bone fixation as well as a Modular Locking Small Fragment System for treatment of bone fractures and osteotomies.

In describing IFS, Dresnick said that the company takes products that have been around for a long time and made by various companies, such as subtalar implants, and figures out how to make them better. He presents the established designs to his panel of recognized surgeons for analysis and modification and the addition of doctor—recommended enhancements. Dresnick then manufactures and sells the devices for 40% to 60% less than the competition.

"We are a value-priced company," Dresnick told *OTW*. "We try to build our products inexpensively. They presently cost too much. Medicare is no longer willing or able to pay separately for implants." IFS customers include ambulatory surgery centers, hospitals and orthopedic surgeons.

—BY (January 29, 2012)

Courtesy of Internal Fixation Systems, Inc.

trauma

FRAX Use on the Rise

FRAX, a fracture risk assessment tool now available in 18 languages, is being used by an increasing number of physicians around the world. The online version alone is used to calculate 10-year probability of fracture in approximately 2.8 million patients annually. FRAX, which is country-specific, can be used with or without the input of bone mineral density (BMD) values measured at the femoral neck. It is available free online at http://www.shef.ac.uk/FRAX/

World Health Organization

The recently launched version 3.5 of the tool now includes new models for Ecuador, Norway, Russia, Slovakia and Sri Lanka. The model for Sri Lanka is the first surrogate model, built by combining national mortality data with hip fracture data from a representative, surrogate country. Revised epidemiological data have also been incorporated into the models for Belgium, Czech Republic, Italy and Lebanon.

Dr. Eugene McCloskey, a co-founder of FRAX and Professor in Adult Bone Disease and Honorary Consultant at the Metabolic Bone Centre, University of Sheffield UK, told *OTW*, "For any new model of FRAX, we need the best available information on the incidence of fractures in men and women within and across age-groups in the population. The most easily collected data usually come from hip fractures as these are usually hospitalised. It is important to exclude double counting (e.g., one hip fracture event counting more than once, for example if admitted in one hospital but transferred to another for therapy). It is also important to know the size and characteristics of the catchment area; this is obviously easier if the hip fracture data are captured at a national level. If not, a judgment has to be made about the repesentativeness of the data compared to national fracture rates. If well-validated information on other fractures is also available, e.g., forearm or humeral fractures, this can also be incorporated in the new model. Finally, the model requires good data on mortality within the population and this is most easily captured at the national level and available through organisations like the UN."

He added, "The assessment of fracture risk should be undertaken in all men and women with a prior fracture, especially when aged 50 and over. In older individuals, fracture preventative therapy should be strongly considered as long as no contraindication to therapy exists. In younger individuals, the use of the FRAX tool can target therapy to those at highest risk who will gain the maximum benefit."

—EH (February 2, 2012)

spine

Eden Spine's Giza Receives Clearance

Eden Spine LLC has received FDA 510(k) clearance for its new corpectomy device called the Giza.

The company announcement on February 2, states the device is an expandable titanium VBR (vertebral body replacement), with rotatable endplates that provide multiple angulation options by simple endplates rotation.

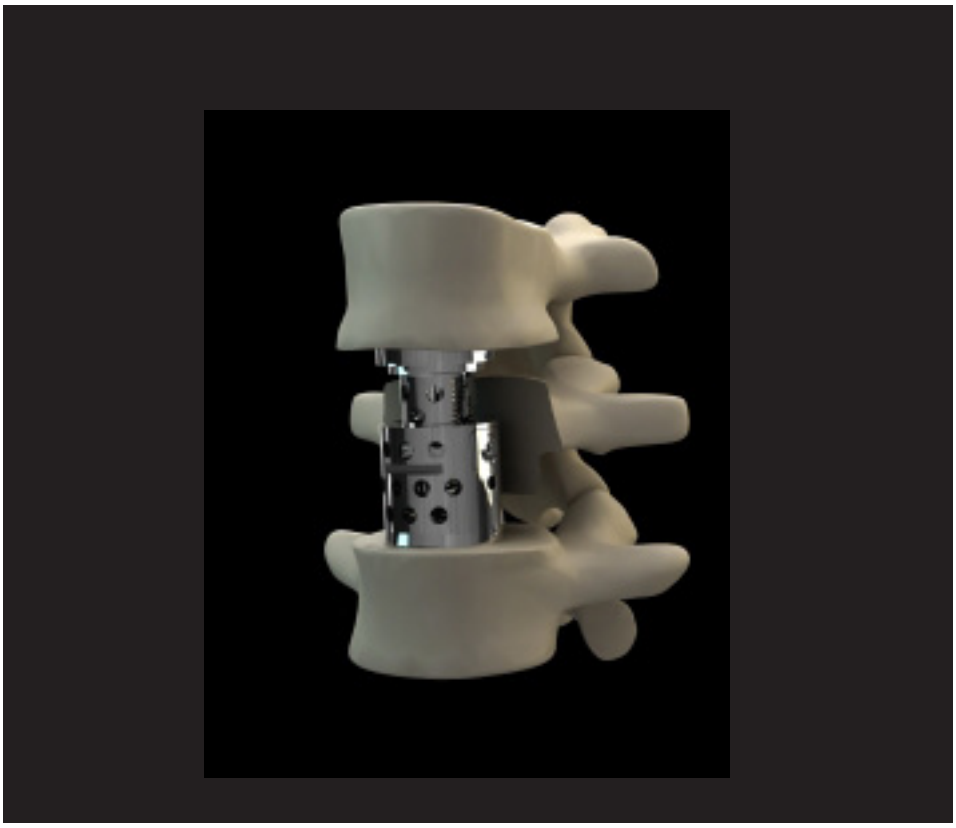
According to the company, the device is indicated for vertebral body tumors and anterior column fractures and work with the patient's anatomy in a modular fashion. Each implant comes fully assembled, and offers multiple angulation options by quick and simple endplates rotation. Adjustment of the implant height is securely achieved in situ with a simple and reliable locking mechanism that maintains it in distraction and avoids compression. The device also features an open architecture to allow for bone growth.

"Its beauty is its simplicity," said Mourad Ben Mokhtar, head of Eden Spine's R&D efforts. He added, "What we did with the Giza is to create an intuitive spinal system designed to help the surgeon easily implant the device, swiftly adapting its height and its angulation to the patient's characteristics, hence maximizing the chances of a positive clinical outcome."

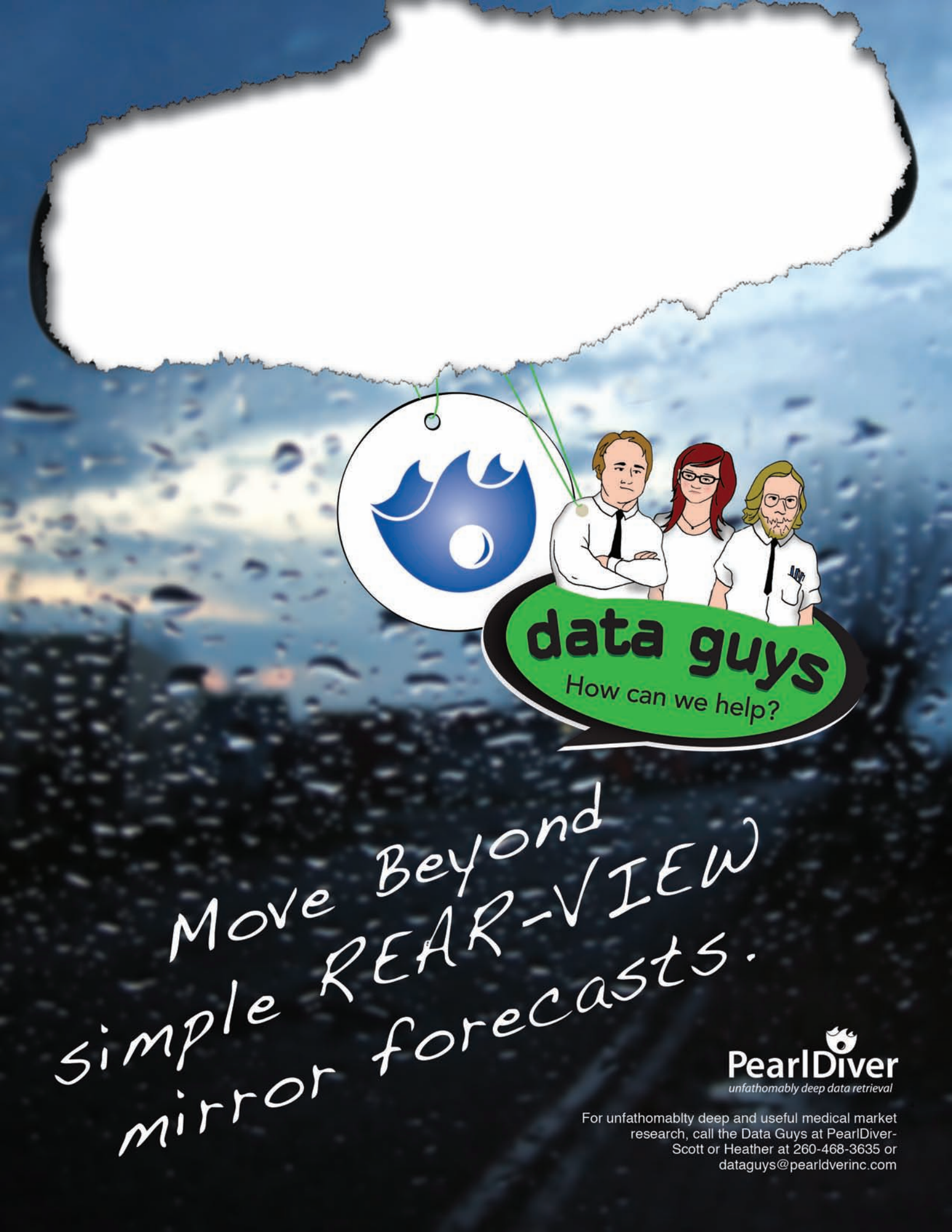
The device, according to company CEO Guillaume Viallaneix, is patented, trademarked, CE Marked, and now, FDA cleared. The Giza "enhances the company's technological footprint and ideally positions Eden Spine for long-term growth," added Viallaneix. The company's objective is to have the Giza available clinically both in the U.S. and internally via a dedicated network of stocking distributors and strategic partners.

The company is privately held and headquartered in Florida, with a wholly owned subsidiary in Geneva, Switzerland. Its portfolio is composed of five proprietary technologies: the Wwlldisc Total Disc Replacement; the Perfx-2 Dynamic Stabilization System, the Wellex Interspinous Technology, the Giza VBR and the Numis Lumbar Plating System.

—*WE (February 3, 2012)*



Giza VBR/Eden Spine LLC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