

Orthopedics This Week

WEEK IN REVIEW

4 It's Not Homer's Stryker Anymore >> Kevin Lobo took over Stryker Corporation at one of the most critical junctures in the history of medicine. He took over from a boss who expounded steady and consistent growth. Lobo, however, wants transformative changes. Can he recreate this venerable stalwart of the orthopedics industry? Read what he has to say.

8 Chris Christie, We Knew Ye Well >> New Jersey Governor Chris Christie is being accused of punishing his enemies, rewarding his friends in a scandal called "Bridgegate." These allegations have a familiar ring to many orthopedic industry executives. They saw it first-hand six years ago.

12 \$1 Million to Rothman From DOD // You CAN Expect 30 Year Knee Survivorship // Mohit Bhandari, M.D. Receives Order of Ontario >> Researchers at Rothman Institute have received \$1 million from DOD to develop an antibody to help wounded warriors. New research indicates that 30 year knee survivorship is doable. Famed researcher Mohit Bhandari, M.D. has received the Order of Ontario for his research and years of dedication.



16 MacDonald v. Stulberg: Dual Mobility Poly Liner >>

"Dual mobility is an option for revision THA for instability, but not for primary THA," states Steve MacDonald. Not exactly, says David Stulberg, "There is evidence showing that for revisions and primary the dislocation rate was significantly lower than rates for non dual mobility liners."



BREAKING NEWS

20 Persona Knee Drives Zimmer's Quarter

DePuySynthes Hip on Knees in 4Q

MicroPort Acquires OrthoRecon From Wright

Titan Spine: Five New Patents

Unraveling Secrets When Hospital Buys Physician Practice

Political Theater Over Healthcare Job Numbers

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Big changes this week. Orthofix drops from #1 to #9. The wait for current financial reports is weighing heavily on investors. Recent resignations from the board don't help—although the departures appear unrelated to OFIX's continuing review of past financial reports. There is hope for OFIX—as this week's announcement that Smith & Nephew is buying ArthroCare illustrates.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	4	Stryker	15.71%	3.27%	This is not Homer's Stryker anymore. MAKO, China and other investments redefining SYK for years to come.
2	5	Globus Medical	28.29	15.96	Invests in surgical robotics. Given GMED's very practical and tight money culture, this is an interesting move.
3	8	Zimmer	27.31	0.84	Earnings for Q4 were up almost 10% and recon sales, buoyed by the knee implants, jumped 7%.
4	3	Conmed	10.37	(1.29)	A late reporter, most analysts think Q4 sales were down 2%. But the pattern this earnings season among ortho companies is upside surprise.
5	6	NuVasive	6.30	15.81	Big sales and earnings beat for the fourth quarter. Valuation is high, but with sales numbers like this, NUVA can grow into the valuation.
6	NR	Smith & Nephew	20.25	0.70	Agrees to buy ArthroCare for \$1.5 billion. Says that ARTC's products are highly synergistic with its own. Could raise sales growth rates.
7	9	Symmetry Medical	6.50	(3.57)	Most investors are looking beyond 2013. Right now, consensus is for 71% earnings growth in 2014.
8	2	Integra LifeSciences	11.77	(2.62)	Seals the Dura-Seal Deal. And, say the analysts, will report a solid 11% rate of sales growth in 2014.
9	1	Orthofix	16.25	(9.95)	Thurman leaves BOD. Reagan is interim chair. With no current financials, all of these BOD moves are unhelpful.
10	7	Medtronic	28.84	(1.45)	With K2M going public, the range of well funded MDT spine competitors grows. Could well set up an all out brawl for market share.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	\$1.17	\$189	63.86%
2	Aurora Spine	ASG	\$4.64	\$72	33.15%
3	Baxano Surgical Inc	BAXS	\$1.27	\$57	25.74%
4	Globus Medical	GMED	\$23.40	\$2,182	15.96%
5	NuVasive	NUVA	\$37.44	\$1,671	15.81%
6	ArthroCare	ARTC	\$45.38	\$1,288	12.77%
7	Bacterin Intl Holdings	BONE	\$0.54	\$28	8.00%
8	Alphatec Holdings	ATEC	\$2.17	\$212	7.96%
9	Stryker	SYK	\$77.60	\$29,365	3.27%
10	Zimmer Holdings	ZMH	\$93.97	\$16,067	0.84%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	RTI Biologics Inc	RTIX	\$3.10	\$175	-12.43%
2	MiiMedx Group	MDXG	\$7.84	\$811	-10.30%
3	Orthofix	OFIX	\$20.55	\$400	-9.95%
4	Exactech	EXAC	\$22.28	\$301	-6.23%
5	Symmetry Medical	SMA	\$9.72	\$362	-3.57%
6	Johnson & Johnson	JNJ	\$88.47	\$249,613	-3.41%
7	Tornier N.V.	TRNX	\$18.19	\$882	-3.19%
8	CryoLife	CRY	\$10.79	\$298	-2.71%
9	Integra LifeSciences	IART	\$46.46	\$1,493	-2.62%
10	Medtronic	MDT	\$56.56	\$56,467	-1.45%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	\$20.55	\$400	8.25
2	Medtronic	MDT	\$56.56	\$56,467	15.22
3	Johnson & Johnson	JNJ	\$88.47	\$249,613	16.15
4	Zimmer Holdings	ZMH	\$93.97	\$16,067	16.35
5	Smith & Nephew	SNN	\$72.24	\$12,901	17.70

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	\$37.44	\$1,671	98.53
2	Symmetry Medical	SMA	\$9.72	\$362	48.99
3	Integra LifeSciences	IART	\$46.46	\$1,493	29.65
4	ArthroCare	ARTC	\$45.38	\$1,288	29.06
5	CryoLife	CRY	\$10.79	\$298	27.86

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	\$20.55	\$400	1.18
2	Globus Medical	GMED	\$23.40	\$2,182	1.39
3	Exactech	EXAC	\$22.28	\$301	1.49
4	Conmed	CNMD	\$41.95	\$1,158	1.64
5	Zimmer Holdings	ZMH	\$93.97	\$16,067	1.70

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	\$37.44	\$1,671	8.01
2	CryoLife	CRY	\$10.79	\$298	6.96
3	Symmetry Medical	SMA	\$9.72	\$362	4.08
4	Integra LifeSciences	IART	\$46.46	\$1,493	4.04
5	Johnson & Johnson	JNJ	\$88.47	\$249,613	2.73

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	\$0.54	\$28	0.85
2	Orthofix	OFIX	\$20.55	\$400	0.86
3	Symmetry Medical	SMA	\$9.72	\$362	0.88
4	RTI Biologics Inc	RTIX	\$3.10	\$175	0.98
5	Alphatec Holdings	ATEC	\$2.17	\$212	1.08

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$1.17	\$189	46.17
2	MiiMedx Group	MDXG	\$7.84	\$811	29.98
3	Globus Medical	GMED	\$23.40	\$2,182	5.65
4	Baxano Surgical Inc	BAXS	\$1.27	\$57	3.94
5	Johnson & Johnson	JNJ	\$88.47	\$249,613	3.50

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

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It's Not Homer's Stryker Anymore

BY WALTER EISNER



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It's Kevin Lobo's now.

Lobo has been president and CEO of Stryker since October 2012. He was recruited in April 2011 to head the newly formed neurotechnology and spine group. He was then quickly appointed group president of orthopedics.

He became CEO while the company was working its way through the drama of his boss's resignation—former CEO, President and Chairman Stephen MacMillan. MacMillan fell out of favor with his board after a private matter became very public.

Lobo has been a different leader from MacMillan. “Mac” led like the baseball manager of the Kalamazoo Kings who played at Homer Stryker Field, often giving Wall Street analysts baseball metaphors of the company's strategy in hitting “singles and doubles” and executing basic fundamentals of business.

And Mac's results were great. He and his team posted up double-digit earnings growth.

Lobo took over at a time that Eric Topol, M.D., author of “The Creative Destruction of Medicine” calls the most disruptive period in the history of medicine as we enter the “Era of Big Data.” Technology is exploding, competitors are consolidating, payers are demanding more evidence, baby boomers are expecting more active lifestyles and Obamacare is bringing in millions of newly insured customers.



Stephen MacMillan

Reshuffled Leadership Team

Among Lobo's first acts as the new boss was to redeploy his top lieutenants and bring in new blood. One month after assuming the leadership reins, he brought in David Floyd, the former head of DePuy Orthopaedics to manage Stryker's orthopedics and spine businesses. In addition to heading up the company's MedSurg unit, Tim Scannell was also given neurotechnology. Lobo also hired a new CFO, Bill Jellison. The company's Vice President of Strategy and Investor Relations Katherine Owen remained.

Then Lobo and his board went swinging for the fences.

Getting Strategic

The company made strategic acquisitions in China, buying trauma and spine manufacturer, Trauson Holdings Company Limited for \$685 million.



David Floyd



Tim Scannell

They announced an agreement to buy Patient Safety Technologies, Inc. for \$120 million and jumped into robotics with the \$1.65 billion acquisition of MAKO Surgical Corp.

After the last quarterly analyst conference call, it was clear from Lobo's comments in the call that he is intent on being a transformational leader. Lobo left no doubt that he is imprinting a bold and aggressive strategic and operational vision on Homer Stryker's

company. He told analysts on January 2, 2014 that mergers and acquisitions are his top priority and with almost \$4 billion in cash—he has one of the largest war chests in orthopedics.

Lobo is embracing Creative Destruction. Case in point is MAKO which Lobo told analysts has the potential to transform orthopedic surgery.

And the results so far? The numbers of the company's last quarter tell the story.

The Numbers

Reconstructive net sales of \$1.1 billion increased 5.8% in the quarter, as reported, and 8.0% in constant currency. Net sales grew by 7.1% due to increased unit volume and changes in product mix and 2.8% as a result of acquisitions.

Most analysts expect that Stryker's organic sales growth in 2014 will be in the range of 4.5% to 6.0%.

In the U.S., reconstructive sales were up 9%, reflecting a 10% increase in hips and 8% growth in knees, in a tough year-over-year comparisons of 7% hip and 9% knees growth. And despite also facing challenging prior-year growth of 26%, which benefited from a competitor recall, sales of trauma and extremities products in the U.S. rose a respectable 8% for the quarter. Finally sales of

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foot and ankle products in the U.S. continued to roll, up an impressive 36%.

Lobo and his team were especially pleased with the knee unit's performance. Zimmer Holdings, Inc. and DePuy Synthes Companies have both introduced groundbreaking new knee designs and are reporting strong market acceptances. Despite those competitive headwinds, Stryker's own knee products did well. "We are still dealing with the absence from the market of our ShapeMatch Cutting Guides.... We believe [knee results] reflects the strength of both our Triathlon Knee and our highly motivated sales team," said VP Owen.

New Implants With MAKO

Lobo and his team believe MAKO, the crown jewel of their acquisition strategy so far, has the potential to

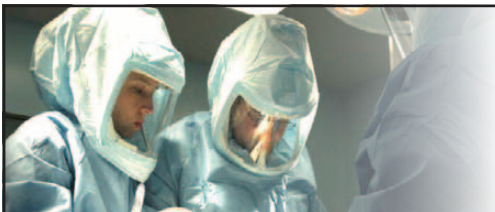
transform orthopedic surgery through procedural advancements, improved patient experiences and a new generation of implants. They point out that the MAKO robotic platform has already proven itself capable of achieving consistently reproducible surgical results.

They believe that robotic-assisted surgery will enable surgeons to improve bone preparation, geometry and precision. Indeed, the Stryker team believes that MAKO's approach is a significant improved over conventional manual instrumentation. "There's a potential to develop new implant designs that specifically enables robotics capability and functionality. In the near term, our teams are focused on leveraging Stryker's considerable sales and distribution capabilities to help drive adoption for MAKO's current applications. Two areas of initial focus, which we are currently evaluating, are enabling Stryker-mar-

keted implants to be put on the robot software and starting the trial for a total knee application in the first half of this year," said Owen.

Importantly, Stryker starts its integration of MAKO with an existing 20% market share in the unicompartmental knee segment. So layering MAKO over this existing market position has most analysts expecting excellent market acceptance of its partial knee application. And it could potentially build significantly from there as Lobo and his team talks about taking MAKO into total hips and total knees to leverage Stryker's reconstructive implants.

"That is the biggest opportunity that we see for robotic-assisted surgery. We're going to continue to use our sales and distribution capabilities to build on current indications, but the long-term potential really is around total knees,



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optimizing total hips and, longer term, the potential to introduce the next generation of implants that aren't feasible with the current instrumentation," added Lobo.

Transformative Leader

Lobo was asked by analysts whether or not the MAKO acquisition would lead to greater use of robotic surgery in orthopedics or whether it was just part a portfolio of advanced technology for the operating room.

Lobo said the move was made to really drive market share and become the clear leader in reconstructive surgery. "So I would not assume we're going to be passive about the way that we sell this technology. But surgeons take different times to convert. There are some that will convert very quickly, early adopters. There are others that will wait a little bit before they'll start to convert, and there are some that will be very stubborn and want to stick to their tried and proved approaches. So we will have approaches for all types of surgeons."

"Without a doubt, we plan to rapidly move the adoption of robotic surgery. This is a big play that we've made and we're not going to be passive about really taking this to the market. Certainly, our implant sales force is extremely excited about being able to sell the implants, so they can be associated with the robots, leveraging their own relationships."

"So make no mistake, we're going to be leaning forward," added Lobo.

Lobo on Healthcare Reform and Orthopedics

In a *Wall Street Journal* interview last October, Lobo said the move away from pay-for-service to paying for outcomes

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is a positive trend. He said he believes the knee replacement business could benefit from the [Affordable Care Act], because that's a more elective procedure. "We're hopeful that those patients will start to come into the healthcare system and the knee volumes would grow."

He told analysts, they won't have to wait long to find out.

He said that after a big fourth quarter of 2013, the first quarter of 2014 will tell whether or not there is an overall uptick in the market. "Since the middle of last year, I felt that the market has been gradually improving."

Generics and Reps

When asked about generic reconstructive joint implants and rumors of a "large" player entering the market by midyear, Lobo said he didn't see generic hips and knees as being really a viable option in the near term because the procedures are very difficult to do.

He said, "So until the procedures are de-skilled, which has been the case in some other parts of med-tech, when a procedure is very easy to do and you don't need a sales rep performing the high level of services that's required to enable patient outcomes, then generics take off."

"There's a reason why, in China, you have a low-priced segment that does not include hips and knees, and it does not include hips and knees because these procedures are very difficult to do. That low-priced segment, which we are now participating in through Trauson, is a spine and trauma market. And so, I don't really perceive this as a major threat. We're always going to keep our eyes open. But frankly, until you de-skill these procedures, the sales force representation is extremely important."

Kevin Lobo has laid it on the line. It's his team, his strategy and his vision of transformation. Welcome to Lobo's reconstructed Stryker. ♦

Chris Christie, We Knew Ye Well

BY ROBIN YOUNG

New Jersey Governor Chris Christie, blunt, aggressive, independent and, until just a few weeks ago, a favorite to run for President under the Republican banner, has stumbled into one fine mess called “Bridgegate.”

For a large number of executives and attorneys in the orthopedic industry the current allegations regarding Christie and “Bridgegate” have a familiar ring.

“Bridgegate” refers to actions by Chris Christie’s staff to create traffic gridlock in Fort Lee, New Jersey, after its Democratic Mayor Mark Sokolich refused to back Christie’s reelection bid. Lanes were closed for several days in September on the George Washington Bridge, the busiest bridge in the U.S. When state legislators held hearings and subpoenaed witnesses, emails were discovered which revealed that Christie’s deputy chief of staff, Bridget Anne Kelly, sent an email to a Christie appointee at the Port Authority, saying, “Time for some traffic problems in Fort Lee.”

The appointee, David Wildstein, responded with “Got it.” Bill Stepien, the strategist who managed Christie’s two gubernatorial campaigns, was implicated in the gridlock email chain describing the Fort Lee mayor as an “idiot.” Christie fired those three, but denied knowing anything about it, claiming he had been told it was simply a traffic study.

Later, a special New Jersey legislative panel issued 20 new subpoenas to try to get to the bottom of “Bridgegate.”

The issue is abuse of power by Christie.



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Just as it was six and a half years ago.

U.S. Attorney Chris Christie and Kickbacks

On September 27, 2007, the office of U.S. Attorney Chris Christie in New Jersey filed criminal complaints against Zimmer, Inc., DePuy Orthopaedics, Biomet, Inc. and Smith & Nephew plc charging them with conspiring to violate the federal anti-kickback statute through surgeon consulting agreements. According to Christie, these surgeon consulting contracts and the payments that were made had the effect of inducing surgeons to buy the company’s products.

Stryker cut their own deal with the Justice Department, and, due to their cooperation were dealt with separately by the government.

The Federal anti-kickback statute makes it illegal for doctors or medical facilities to receive financial incentives to increase the use of devices, which in turn increases the number of implant procedures, in patients covered by public health care programs.

Christie said in a press release at the time, “This industry routinely violated the anti-kickback statute by paying physicians for the purpose of exclusively using their products. Surgeons who had agreements with the companies were typically paid tens to hundreds of thousands of dollars per year for consulting contracts and were often lavished with trips and other expensive perquisites.”

In private meetings with each company and their attorneys, Christie and his staff hammered on these organiza-

tions—at times threatening jail time, at other times financial ruin—until they agreed to a harsh and punitive settlement.

To put this in even more perspective, these orthopedic companies represent hundreds of thousands of employees and routinely serve more than one million patients annually with the best orthopedic products in the world.

Balanced against the flow of money to surgeons is the reality that these companies are both medically and economically valuable to the broader global society.

Christie's proposed settlement to avoid prosecution was one the assembled companies could not refuse. The final price tag was \$311 million and required each company to overhaul their surgeon consulting contract practices AND

to agree to outside attorneys and monitors to scrutinize future contracts and behavior.

Specifically each company agreed to:

1. Put in place federal monitors to review compliance and all new and existing consulting relationships
2. Conduct a needs assessment to determine the reasonable needs for educational consulting services and new product-development consultants
3. Require physicians to disclose their financial engagements to their patients and require the device makers to disclose on the company website the name of each consultant and what they have been paid
4. Have outside attorneys review all current and future surgeon consulting contracts.

Then U.S. Attorney Chris Christie contacted his friends.

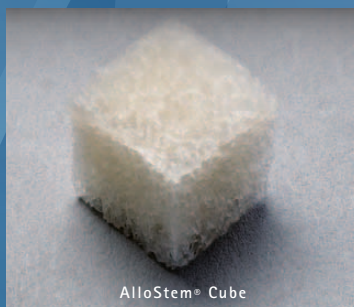
It Paid to be Christie's Friend

In effect, the settlement agreements set up a series of multi-million dollar contracts and, because many of these went to Christie's friends, it appeared that Christie used the settlement agreement as a form of patronage.

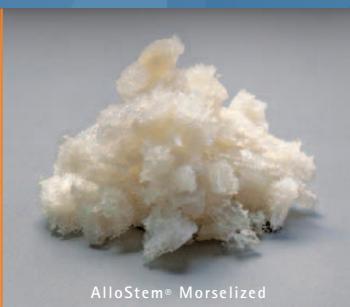
Debra Wong Yang, a former U.S. attorney in Los Angeles and Christie colleague with ties to former U.S. Attorney General Alberto Gonzales, landed the multi-million dollar contract to monitor DePuy Orthopaedics.

John Carley, former Cendant Corp. vice president and Federal Trade Commission lawyer under President Ronald Reagan and a Christie friend was awarded (no-bid contract) the contract

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to over-see the non-prosecution agreement with Stryker Orthopedics.

Christie's ex-boss and good friend, former U.S. Attorney General John Ashcroft, was selected—again, on a no-bid contract—to monitor Zimmer. The contract was worth as much as a whopping \$52 million for 18 months of work.

At one point Zimmer's lawyers objected to the Ashcroft Consulting Group's exorbitant charges. Ashcroft was planning to charge Zimmer \$1.5 million to \$2.9 million a month—with no receipts or invoices.

(By contrast, other independent monitors at other orthopedic companies were submitting 200-page bills. Ashcroft, however, sent a one-page note

with no billable hours or expenses, just an amount due.)

When asked about the matter during a congressional hearing, Mr. Christie said that his office was too busy to regulate every aspect of an agreement, and that news reports indicated that Mr. Ashcroft's fees were in line with what other firms charged to act as a monitor.

One Democratic New Jersey Representative, Frank Pallone, who was speaking at a New York University Law School forum characterized Ashcroft's bill this way: "This is a ransom note, not a billing statement. There was no question that the poster child for abuse was Mr. Christie."

Had Zimmer not paid the bill, theoretically Christie would have resumed

prosecution of both the firm and its executives.

Another member of Congress who reviewed Christie's no-bid contracts to monitor orthopedic companies, California Democrat Linda Sandhez, (who chaired the hearing where these issues were vetted) called Ashcroft's contract "a backroom, sweetheart deal."

Later in testimony to Congress, Christie acknowledged that one of the law firms that he had given a monitoring contract to had since made substantial donations to his campaign for governor.

Christie's Legacy

The pharmaceutical company Bristol-Myers Squibb was also the subject of a Christie investigation and eventual

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deferred prosecution agreement. In that case, it has been alleged, Bristol-Myers Squibb was pressured to endow an ethics chair at Christie's alma mater, Seton Hall University School of Law. The company had initially proposed to pay for ethics training at Rutgers but later switched to Seton Hall.

Then there was the \$12 million monitor contract Christie gave to former federal prosecutor, David Kelley, who had decided two years earlier not to seek charges against Todd Christie, Mr. Christie's brother, who had been accused of securities fraud.

Finally there is the case of Herbert Stern who was Christie's mentor and recipient of a \$10 million contract to monitor the University of Medicine and Dentistry of New Jersey, which had been accused of double-billing for services covered by Medicare. Members of Stern's law firm later gave \$23,800 in donations to Christie's campaign for governor. The donations were matched, 2-1, under New Jersey's campaign finance laws, bringing the total amount to \$71,400.

Because of the appearance of impropriety and, frankly, the smell of cronyism and financial kick-backs for these lucrative monitoring contracts, the U.S. Justice Department subsequently issued guidelines barring requirements such as the Seton Hall endowment as part of out-of-court corporate crime settlements. Furthermore, the Justice Department now requires that all monitoring agreements to be approved by the number two official at the Justice department.

In Retrospect

In retrospect Christie's investigation did a lot of good. It helped the major suppliers clean up their surgeon consulting



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contract practices. Because of Christie's investigation, the normal competitive fervor that supported much of the abuses with regards to surgeon consulting contracts was put aside.

In fact, Christie later told Congress that he saved the American orthopedic device industry by keeping them from receiving the Medicare "Death Penalty."

These investigations were a "come to Jesus" moment for the orthopedic industry. Today these five companies—Zimmer, Biomet, Smith & Nephew, DePuy and Stryker—appear to conduct their surgeon consulting practices at the highest ethical level. This year, due to requirements under the Affordable Care Act, these firms take this to an even higher level by posting for public view payments to surgeons.

The good news is that Christie made it possible for a level playing field so that ALL the firms could abandon the poor practices of the past without creating a competitive disadvantage.

But then Christie made that left hand turn which undermined much of the good he purported to represent. Christie's decision to steer these lucrative no-bid contracts to his friends and accept campaign contributions from one of those firms just plain stinks.

So, as many orthopedic executives and attorneys who went through the crucible of Christie's prosecution from 2005-2009 will say in their private moments, the current allegations regarding Christie and Bridgegate are depressingly familiar. For them, it's déjà vu all over again. ♦

\$1 Million to Rothman From DOD // You CAN Expect 30 Year Knee Survivorship // Mohit Bhandari, M.D. Receives Order of Ontario

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.



Mohit Bhandari, M.D., M.Sc., FRCSC

\$1 Million to Rothman From DOD For those who sustain traumatic combat-related joint injuries there may be new hope. A team from the Rothman Institute, at Thomas Jefferson University in Philadelphia has been awarded a \$1.1 million grant from the Department of Defense [DOD] to advance such treatment. Joseph A. Abboud, M.D., an orthopedic shoulder surgeon at the Rothman Institute, is one of the three primary investigators (PI) on the grant. He tells OTW, “This research is occurring in our basic science lab, at Jefferson, which is headed by my co-PI Andrzej Fertala, Ph.D. We are utilizing an antibody engineered in our lab to help inhibit excessive scar formation in a joint injury animal model. In vitro the antibody has demonstrated the ability to down regulate scar formation. In

the surgical arm of the study we are utilizing a validated rabbit model to create a post-surgical joint contracture. The rabbits in the treatment arm of the study will be treated with the antibody and eventually we will assess joint stiffness, modulus, ROM [range of motion] as well as histologic characteristics.”

“At this point my co surgical PI Pedro K. Beredjiklian, M.D. and I have finalized the surgical protocol and we are validating the delivery of the antibody through a specialized, subcutaneously implanted programmable delivery system. We expect to complete the surgical arm of the study within the next two years. This is a three year grant, and was the largest project funded by the Department of Defense in this funding cycle.”

“These are very disabling joint injuries, and if we can improve patient impairment by 20-40% then people may lead more normal lives.”

Mohit Bhandari, M.D. Awarded the Order of Ontario Mohit Bhandari, M.D., M.Sc., FRCSC has been invested with the Order of Ontario by The Honorable David C. Onley, Lieutenant Governor of Ontario. Dr. Bhandari, the Canada Research Chair in Musculoskeletal Trauma and Surgical Outcomes, was one of the 25 new appointees to the Order of Ontario, the province’s highest official honor. The Order of Ontario recognizes residents of Ontario who have demonstrated a high level of individual excellence and achievement in any field benefiting the people of Ontario or anywhere in the world.

Dr. Bhandari conducts research on many topics, including identifying optimal management strategies to improve patient-important outcomes in patients with multiple injuries, lower extremity fractures and severe soft tissue injuries. He has also tackled a subject that not many of his orthopedic colleagues have addressed: raising awareness of intimate partner violence.

Asked what this honor means to him, Dr. Bhandari told *OTW*, “I’m deeply touched by this honor, particularly because it honors those Ontarians who have been recognized for their contributions to the lives of citizens. The fundamental tenet of the work we have been doing in orthopaedic surgery over the past decade had its vision in helping people and making their lives better. For me, induction into the Order of Ontario is a profound recognition that our research may have transformed the lives of men and women suffering from injuries.”

“The selection committee aims to ‘recognize any current or former long-time resident of Ontario who has demonstrated a high level of individual excellence and achievement in any field benefiting the people of Ontario or anywhere in the world.’ The awardees spanned the sciences to arts and entertainment. I was particularly proud to be among the two surgeons in this year’s inductees. While I have little idea what specific selection criteria led to this award, I am reassured that our efforts to promote evidence in orthopaedics, transform research by large, global clinical trials, ask fundamental questions of importance to all people around the world, and become strong advocates for those causes that demand our action (violence against women, trauma in low and middle income countries, to name a few).”



Advertisement

Robert Talac, M.D., Ph.D. Named Top Orthopedic Surgeon

Robert Talac, M.D., Ph.D., of the Advanced Spine Institute, was recently voted Top Leading Physicians of the World for Top Orthopedic Spine Surgeon in Tennessee and Texas by The International Association of Orthopedic Surgeons. Dr. Talac grew up in Czechoslovakia, came to the U.S. to study at the Mayo Clinic, continued at the University of San Diego and the Center for Spine Health, Cleveland Clinic, and has focused his considerable intellectual talents and gifted hands on spine related problems. Using a 7-millimeter-wide endoscope with a camera on its tip, Dr. Talac is able to enter the back through that tiny 7-millimeter space while a patient is conscious under local anesthesia without cutting muscles or moving the spinal cord for quick recovery and one-day spine surgery.

30-Year Knee Survivorship: Expect It!

“But I can’t have a knee replacement yet because it will only last 10 years!” That, says a very experienced knee surgeon, just isn’t true. William J. Long, M.D., FRCSC is an orthopedic surgeon at Insall Scott Kelly Institute in New York. He tells OTW, “Our new research, which has just been accepted by the *Journal of Bone and Joint Surgery*, debunks the myth that a knee replacement isn’t very durable. We have found that a knee replacement—done well with a good component—and it doesn’t have to be state of the art—has

an 80-90% chance of attaining 30-year survivorship, when considering aseptic wear or loosening. Our team examined all knee replacements done on patients under 55 that were performed by Drs. John Insall and W. Norman Scott in the late '70s and '80s. It was incredible to see that the original IB-I monoblock design that Dr. Insall developed 40 years ago had a 30-year survivorship for wear or loosening of 92%.”

“Additionally, we looked at their activity scores in 1997 and compared them to their scores in 2012. We found that if you didn’t have another joint that went bad and you were not medically comprised then your functional scores were the same at 30 years as at 15 years. Now we know that in a young, active, demanding population we can achieve durable long term outcomes.”

Promising New Stem Cell Suture

When it comes to stem cells the more direct, the better, says new research. Lew Schon, M.D. and colleagues have recently published work on a stem cell suture that improves Achilles tendon healing. Dr. Schon is director of foot and ankle services at MedStar Union Memorial Hospital in Baltimore. He is also founder and director of the Orthobiologic Laboratory at that facility. Dr. Schon, past president of the American Orthopaedic Foot & Ankle Society (AOFAS), tells OTW, “One of the well documented aspects of aging is the decreased level of mesenchymal stem

cells in our tissues with the result that we injure more easily and take longer to recover. Augmenting surgery with allogeneic stem cells has the potential to change medicine and be of great benefit to an aging population which wants to stay active. We were aware of studies on direct injection of large quantities of mesenchymal stem cells into tissue for various therapeutic effects, but we were concerned about other studies which showed a tendency for injected cells to migrate from the area of injection and lodge in the microvasculature of the organs. We used a rat model, and found evidence to suggest that the use of stem cells enhances healing after Achilles repair...and that embedding of stem cells directly into suture provides early healing benefits.”

“The concept of our *Stem Cell Suture*TM was to allow a surgeon to concentrate stem cells in a scaffold-like construct (suture) alongside and within the repaired damaged tissues to provide the desired therapeutic effect using techniques (sewing) already in the surgeon’s skillset. Perhaps the most surprising thing about this study was how well reality correlated with theory.”

“We are preparing a submission to the FDA for the *Stem Cell Suture*TM now; many more studies for that submission will occur. We had a substantial grant from the Maryland stem cell research fund to help us move through these studies and the process overall.” ♦



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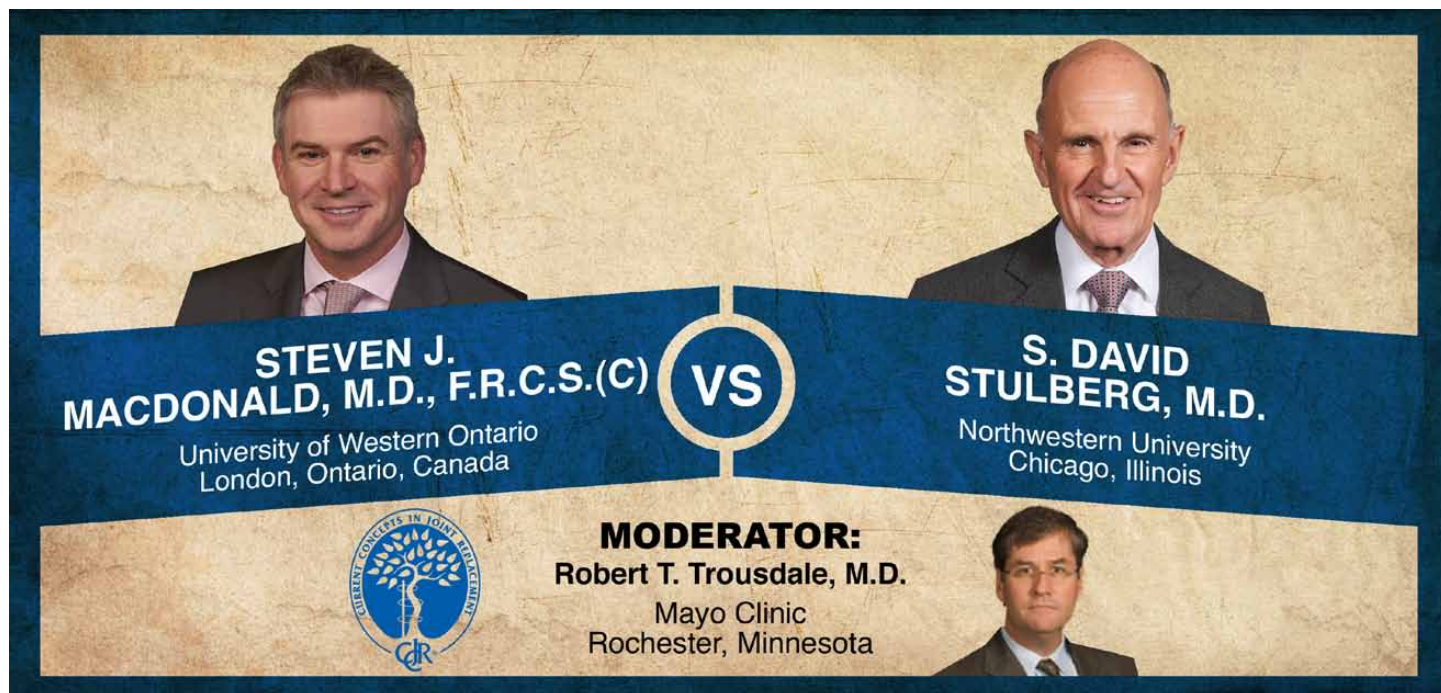
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MacDonald v. Stulberg: Dual Mobility Poly Liner

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.



Current Concepts in Joint Replacement/RRY Photo Creation

“Dual mobility is an option for revision THA [total hip arthroplasty] for instability, but not for primary THA,” states Steve MacDonald. Not exactly, says David Stulberg, “There is evidence showing that for revisions and primary the dislocation rate was significantly lower than rates for non dual mobility liners.”

This week’s Orthopaedic Crossfire® debate is “The Dual Mobility Poly Liner: Yet to Be Justified.” For the proposition is Steven J. MacDonald, M.D., F.R.C.S.(C) from the University of Western Ontario; against the proposition is S. David Stulberg, M.D. from Northwestern University in Chicago. Moderating is Robert T. Trousdale, M.D. from Mayo Clinic in Rochester, Minnesota.

Dr. MacDonald: “The original idea of dual mobility was a monoblock shell, a large poly articulation, a smaller head, and then a femoral component. In 2013

there are two options: the original ADM [acetabular dual mobility] and the MDM [modular dual mobility], which is the modular version.”

“Does it make sense? In a differentiated hardness bearing, the harder surface is normally articulating against the softer surface. So you have a metal or ceramic head articulating with a softer surface on the bottom. If you switch that around and make it soft-on-hard, it escalates the wear. So from a biomechanical point of view it doesn’t make a lot of sense.”

“Looking at the published basic science on this construct, I could only find one article (*Journal of Arthroplasty*, 2013, Loving et al.). It said that the dual mobility liner actually wore 75% less than a single articulating bearing. It makes sense if the dual mobility is highly cross-linked and is being compared to a conventional gamma/inert poly. The study was not ideally designed.”

“We do have advertisements in the literature that show a 94% reduction in wear with a 65 degree shell. So if you put your shells in like Rob Trousdale maybe you should use this construct. If you look at the design, the poly is free to go into a more closed position, but the potential is for edge loading and poly failure. And we have two articulating poly surfaces now, so there is a cumulative risk of increased wear and osteolysis. The claim is for improved ROM [range of motion] and stability, but we know from cadaver work that hip ROM peaks at around 36-38mm. Using larger and larger heads doesn’t give you ROM because you just reproduce bone on bone impingement.”

“We can achieve that same ROM and stability with current implants that have registry published data. So if you look at the design you have a monoblock shell. In the Australian registry monoblock shells have a higher revision rate;

fair enough, most are with metal-metal constructs.”

“So who is this being recommended for? It is unclear. In the technique manual it says, ‘OA, RA [osteoarthritis, rheumatoid arthritis], revisions, and patients with a dislocation risk.’ That could be every patient! So let’s assume that increased stability is the primary goal. David Stulberg has published an article (*Orthopedics*, 2010) looking at several series, and found a dislocation rate of 0.4%. There are similar published dislocation rates with conventional THA.”

“There is a recent report by Remi Philip-pot of a new complication (*CORR*, 2013). A large series showed a 0.4% incidence of intraprostatic dislocation

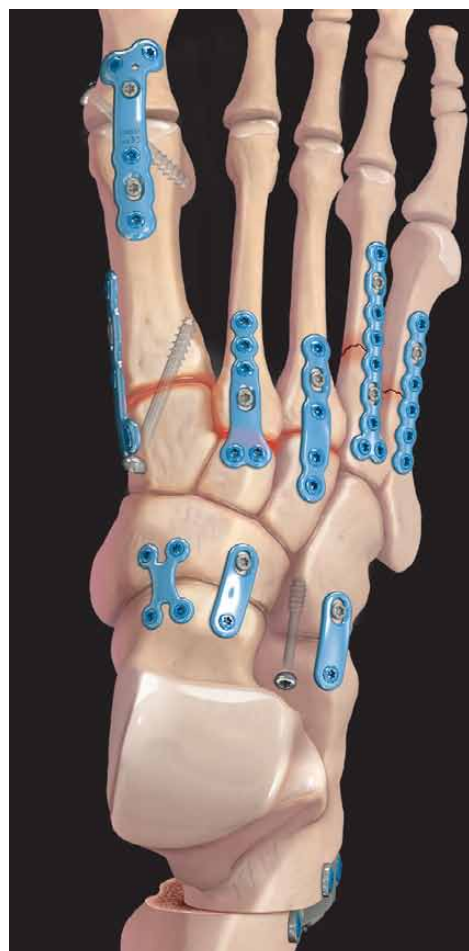
(ball from poly). A 2012 article (*CORR*, Hamadouche) showed a 7.5% incidence of intraprostatic dislocation. In these constructs they had larger heads, longer balls, no skirts, and they were creating impingement.”

“So which patients should a dual mobility implant be used for? How about ones for which we don’t already have a good answer? Lachiewicz wrote an excellent review article (*JAAOS*, 2012) saying, ‘Caution is advised in the routine use of dual mobility in primary and revision THA. The greatest utility may be to manage recurrent instability in revision THA.’ A study by Hailer et al. (*Acta Orthopaedica*, 2012) found—using Swedish registry data—the exact same thing. They studied 228 revisions for instability using dual mobility.

There were 8% revised for any reason, but only re-revised for instability.”

“So conceptually there are challenges with the construct...and any new implant must show equivalence in wear, fixation, mid-term results, complications, and cost. We’re not there yet with dual mobility. Today it is an option for revision THA for instability, but not for primary THA.”

Dr. Stulberg: “While we’ll be discussing the femoral head, there are many causes for recurrent dislocation. So the rate of dislocation decreases with the use of larger head sizes. The problem is that it’s unclear whether these large heads have an adverse impact on polyethylene; the impact of using large heads in patients at risk is also



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unclear. You've also heard the concern about using large heads on the Morse taper. So is there a role for dual mobility when you're concerned about instability?"

"In the 1970s the French orthopedic community was beginning to worry about the issue of hip stability and poly wear. They were especially concerned about what they thought were causes of instability, things such as underlying diagnosis and cognitive dysfunction. But over the years the French have published many series where the dislocation rate in primary THA is very low (<0.4%)—lower than those published in general. The dislocation rate in revisions is very low (2.1%), much lower than those published in the same time period—before non dual mobility."

"The survival rate for a non-highly cross-linked poly dual mobility cup was surprisingly long (Leclerc, 1999, 94% at 15 years; Philippot, 2006, 95% at 10 years, etc.). When the French looked at this again last year (CORR, Delauney, 2012), they compared their registry data on dislocation to the dislocation rate in other countries. Use of the dual mobility cup in France is 30% or more; their dislocation rate is lower (Australia, 27.2%; New Zealand, 30.6%; Delauney study, 10.4%). When they compared the use of the dual mobility cup in France to other countries, this same data tended to flush itself out."

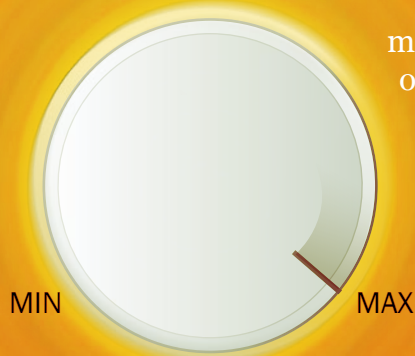
"But there are other ways of using dual mobility cups, such as with a cup cage construct. It's an interesting opportu-

nity in situations with acetabular deficiency, one that has been associated with a very low dislocation rate (CORR, Civinini et al., 2012). When Mike Mont reviewed all of the series—not just the French—he found that in both primary and revisions, the dislocation rate was significantly lower than rates for non dual mobility liners."

"But is the dual mobility cup just another large femoral head? On this we have more company data than non-biased data. Because of the construct, a dual mobility cup, for example, in a 54mm outer diameter shell, has a greater ROM than the largest femoral head you can put in that same 54mm outer diameter shell. And the 'jumping distance' for that construct is greater, so they behave differently than femoral heads of equivalent size."

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“What’s more interesting is whether you can improve wear by using this construct. Wear seems to be better when you compare it to conventional poly; when you use dual mobility cups with highly cross-linked poly the wear is even less. Then it comes down to this: if you have an unstable hip or an at risk patient, you want to use a large head and you have a relatively small acetabulum, are you going to use a large head with thin poly or will you use a dual mobility cup? There is an option. If you take this modular dual mobility operation and put the shell in, you can decide on the table what you want to do. This seems to be a reasonable approach.”

“So the dual mobility cup offers a safe, effective, versatile solution for hip instability.”

Moderator Trousdale: “So you agree in that in a routine primary total hip a dual mobility should not be utilized. Who would you use this with in a primary?”

Dr. MacDonald: “No one...I haven’t used it.”

Dr. Stulberg: “I would consider it in patients with dysplasia or large patients who have small outer diameter acetabular shells...where you may want the option of a large head, particularly in a young patient where you’re concerned about poly wear.”

Moderator Trousdale: “In a revision setting, Steve?”

Dr. MacDonald: “I’d use it in a case where other options have failed. In terms of all those primaries, for years we have been doing other things for those patients. There are other ways around it than having to go to a construct that doesn’t have broad spectrum registry data.”

Dr. Stulberg: “I’d like to have it in a situation where you have a revision and a recurrent dislocator, in particular a dislocator with significant acetabular bone loss. You might want to do a major acetabular reconstruction and in addition provide stability and not be constrained by the cage.”

Moderator Trousdale: “Steven, I presume you’re using constrained liners in that situation. Are those a better option than a dual mobility?”

Dr. MacDonald: “I don’t think we know the answer to that. The problem with a constrained liner in a younger patient is the cumulative risk of wear and perhaps increased stress and loosening. It depends on the surgeon and what they are used to.”

Moderator Trousdale: “David, is wear a real concern for these patients with a high risk of instability?”

Dr. Stulberg: “In the impingement situation it might be. If you have soft tissue impingement with these devices they can dissociate.”

Moderator Trousdale: “Steve, have patients failed from wear with the dual mobility?”

Dr. MacDonald: “No.”

Moderator Trousdale: “So it may be a theoretical concern?”

Dr. MacDonald: “Definitely. When you have small series of things they may look good, then we start seeing thousands and all of a sudden it doesn’t look so good.”

Dr. Stulberg: “Because of the way this technology is being ‘teed up,’ we need to think about in a patient with a 52mm

outer diameter shell in which you’re worried about stability then you can use a 36mm head with thin poly...or an equivalent or slightly larger head with a poly ball. At this point we still have to wait and see which one wins.”

Moderator Trousdale: “David, what is the etiology of an intraprosthetic dislocation with a dual mobility?”

Dr. Stulberg: “The predominant one is where you have impingement, so if that outer bearing isn’t moving so that the inner bearing starts to flex up and the outer bearing doesn’t have the opportunity to rotate, that’s where most dissociations occur.”

Moderator Trousdale: “How do you solve intraprosthetic dislocation?”

Dr. Stulberg: “It’s a theoretical question for me at the moment, but I would likely flip it and do a fixed head.”

Dr. MacDonald: “Not for long!”

Moderator Trousdale: “Steve, the modular dual mobility construct has a titanium shell and a cobalt chrome insert with a taper. Should we be concerned about corrosion?”

Dr. MacDonald: “We’re just exploring these things...that’s why I say that just because we don’t have data doesn’t mean it’s good.”

Moderator Trousdale: “Thank you.” ♦

Please visit www.CCJR.com to register for the 2014 CCJR Spring Meeting, May 18 - 21 in Las Vegas, Nevada.

COMPANY

Persona Knee Drives Zimmer's Quarter

Zimmer Holdings, Inc.'s 2013 fourth quarter sales of \$1.24 billion were up 6.6%, excluding currency.

David Dvorak, Zimmer's president and CEO, said the strong results were led by the successful commercialization of the Persona Personalized Knee System and its accompanying suite of next-generation instruments. Indeed, excluding a 2% currency hit, knees were up a whoppin' 10%.

On a reported basis, reconstructive sales were up 6% but hips were up only 1%. Trauma sales declined 4%, while spine dropped 2%. Extremities climbed 11%.

Dvorak said the "resoundingly positive clinical feedback" from Persona customers continues to "validate our bullish position for this truly differentiated knee replacement system. As in previous quarters, the accelerated growth of our knee business was further strengthened by our expanding portfolio of early intervention and joint preservation treatments, including Subchondroplasty and Gel-One."

Spine and Trauma Lag

Trauma and spine sales were disappointing.

Acknowledging that their trauma business faced challenges, Dvorak pointed to a promising 15.2% trauma sales increase in Asia Pacific. He said he was also encouraged by sales for the Natural Nail family and the NCB Periprosthetic Plating System. "We'll continue to focus

our execution and expand our presence in key U.S. markets, as well as in level 1 and 2 trauma centers. Looking forward, our comprehensive trauma portfolio continues to expand with new introductions for the hand and wrist market to increase our global competitiveness."

The company, said Dvorak, is preparing to recapture growth opportunities in spine in 2014. He said a "reinvigorated focus on our core fusion portfolio" continues to garner positive traction, with offerings such as the TM Ardis and TM-S Interbody Fusion devices. "In addition to the ongoing release of the APEX Spine System, which strengthens our ability to address degenerative deformity and complex spinal conditions, we also expect our introduction of the lateral interbody system to contribute a growing share of revenues in 2014. This differentiated offering delivers a unique support mechanism above and below the spinal interbody and marks our entry into one of the fastest-growing subsegments of the spinal market."

Dvorak on Ortho Markets and Healthcare Reform

During a conference call with Wall Street analysts on January 30, 2014, Dvorak addressed global market conditions. "In the fourth quarter, musculoskeletal markets were healthy in

the Americas and Asia Pacific, while stabilizing in Europe, Middle East and Africa. Increased procedural demand, particularly in the U.S., contributed to a strong performance in the quarter."

Dvorak said some of the procedural uptick during the quarter was driven by the implementation of healthcare reform and some of the perceived potential disruption to plans or access to particular surgeons.

Zimmer 4Q13	Sales (\$ in millions)	% Change
Total Reported Sales	\$1,241.0	5.0%
Reconstructive	\$928.0	6.0%
Knees	\$523.0	8.0%
Hips	\$353.0	1.0%
Trauma	\$81.0	down 4%
Spine	\$53.0	down 2%
Extremities	\$52.0	11.0%

Source: Zimmer Holdings, Inc.



Persona Personalized Knee System
 Image Credit: RRY Publications LLC, Walter Eisner

He believes that, after the fundamental demographic drivers, there is an aging population out there. “These are procedures that have terrific clinical results. And relative to the knee, for joint replacement, the procedure is still underutilized and economically very beneficial to society.” He cited a publication in the August *Journal of Bone and Joint Surgery* regarding financial results and economic benefits to society of the 600,000-plus knee replacements that were done in the U.S. in 2009. “So that underlying demand is real. And with a little bit of an adjustment to the environment in which people are making those decisions, you can see how the procedural demand can increase in a short period of time. So I think it’s just more indicative, both from a long-term perspective, this is going to be a very healthy market and a consistently performing market.”

2014 Guidance

Full-year revenues for 2014 are expected to increase between 3.0% and 5.0% on a constant currency basis. Company officials believe that full year knee and hip markets will grow in the low- to mid-single-digits and expect global market conditions to remain relatively stable in 2014 when compared to the full year 2013.

BMO Capital Markets analyst Joanne Wuensch said that with most of the ortho companies having reported for the quarter, she estimates that on a constant currency basis, the hip market increased 4% and the knee market was up 7%. “What is at question is how much of the strength is associated with pent-up demand; improving economics; and dislocation associated the implementation of Obamacare,” added Wuensch.

—WE (January 30, 2014)

FDA Clearance for Kiva VCF System

Benvenue Medical, Inc.’s alternative to balloon kyphoplasty has been 510(k) cleared by the FDA for marketing in the U.S.

The Kiva VCF Treatment System is for the reduction and treatment of VCFs (vertebral compression fractures) of the spine. According to the company announcement on January 28, 2014, the clearance makes the Kiva the first new approach to the treatment of VCFs in over a decade. Also, according to the company, in the clinical studies provided for the 510(k) application, the system was shown to meet or exceed the performance of balloon kyphoplasty.

The implant is designed to provide structural support to the vertebral body and a reservoir to direct and contain bone cement during vertebral augmentation. The implant is delivered percutaneously over a removable guidewire in a continuous loop into the vertebral body through a small diameter, single incision. The amount of the Kiva implant delivered is physician-customized during the procedure.

Sean M. Tutton, M.D., FSIR, and co-principal investigator in the KAST Study (Kiva System as a Vertebral Augmentation Treatment - Safety and Effec-

tiveness Trial), which compared Kiva to the Medtronic KyphX System for balloon kyphoplasty, said he looks forward to presenting the results at the Society for Interventional Radiology meeting in March. Dr. Tutton is also a professor of radiology and surgery at the Medical College of Wisconsin in Milwaukee.

Per the January 28 press release, “Over the last 10 years, the approaches to treating VCFs have included conservative therapies or vertebral augmentation, traditionally performed with balloon kyphoplasty or vertebroplasty. The Kiva System features a proprietary, cylindrical implant made from PEEK-OPTIMA, representing a new approach to vertebral augmentation. The traditional approaches, according to the company, rely solely on a bolus of bone cement.”

Robert Weigle, CEO of Benvenue Medical, said the VCF segment has little Level I clinical data. “We are proud to have sponsored one of the largest randomized studies in this space to date.”

The press release also stated: “There are 700,000 osteoporosis-related vertebral compression fractures annually in the U.S. alone, representing a large patient population which is only expected to continue growing as the population ages.” The system received CE Mark in 2008 and it is distributed by Zimmer Spine in Europe.



The Kiva VCF Treatment System/Benvenue Medical, Inc.

“Founded in 2004, Benvenue Medical develops minimally invasive expandable implants for the spine. The company is privately held and funded by Versant Ventures, DeNovo Ventures, Domain Associates and Technology Partners. Its first products are designed for the treatment of vertebral compression fractures and degenerative disc disease.”

Long live the loop.

—WE (January 29, 2014)

Titan Spine: Five New Patents

Titan Spine is celebrating the awarding of five new patents from the U.S. Patent and Trademark Office. These patents relate to the unique design of the company’s Endoskeleton line of

interbody devices as well as various aspects of composite devices featuring a combination of metal and polymer materials, such as polyetheretherketone (PEEK). Titan Spine now has over 40 patents in their portfolio and currently under review.

One aspect of the Endoskeleton design that is covered by one of these new patents is the presence of transverse and anterior/posterior windows optimized for strength, visualization of bone graft integration and loading of bone graft for improved fusion.

Kevin Gemas, president of Titan Spine, told OTW, “The strength of titanium, unlike PEEK, allows us to create transverse windows on our devices that allow for multi-directional bone growth and an increased potential for a robust fusion. We are pleased to further protect this key feature of our implant design.”

Chad Patterson, director of Product Development and Operations for Titan Spine, said in the January 21 news release, “All of our current and pending patents will continue to bolster our position among the ever expanding number of companies that are beginning to realize the importance of surface technology. Our goal is to aid in faster patient recovery through advanced surface technology, implant design, and surgical technique methods.”

Titan Spine’s proprietary surface technology has been shown to promote a superior osteogenic environment when compared to smooth titanium or PEEK. This surface technology, which contains unique topographies at the macro, micro, and sub-micron levels, is featured on the company’s line of Endoskeleton interbody devices for the cervical and lumbar spine.

—EH (January 23, 2013)



Titan Spine

DePuySynthes Hip on Knees in 4Q

Good news in knees, continued Synthes integration challenges in spine and an improving orthopedic market dominated Johnson & Johnson Alex Gorsky's fourth quarter conference call with analysts on January 21, 2014.

J&J's DePuySynthes orthopedic unit reported a 4.2% rise in revenue for the fourth quarter of 2013, excluding currency. The company said strong growth for knees and hips drove results, partially offset by slower sales in spine.

Excluding currency, knees led the way with an 8% increase, which was attributed to the launch of the Attune fixed

bearing knee system. Hips were up 5% and trauma rose 7%, with sales impacted by a nail recall. A 2% decline in spine was attributed to pricing pressure, a soft market and "disruption in the commercial sales organization" as the company continued to struggle with integrating Synthes.

Spine Salesforce Turnover

Gorsky, J&J's chairman and CEO, said integrating Synthes has been the company's number one priority, adding, "We've made good progress on that."

"And we clearly acknowledge we still have some more work to do, but I've been very encouraged, particularly as of late, to see some of the steps we're doing in things like cross-selling initiatives that we had envisioned from the onset, as we see these things starting to take hold, as well as revenue and cost savings synergies that are going to make this business extremely competitive going forward."

He added that in looking at the overall integration of DePuySynthes, spine was clearly going to be the challenge. "And we did see higher sales force turnover, frankly, than we would have liked to see."

"I think Michel [Orsinger] and Gary Fischetti and his team have done a nice job of addressing many of those concerns. I think our performance in Q4, while still not where we want it to be, is showing some improving trends, in fact outside the U.S we're actually positive. And also, with some of the complementary nature of some of the underlying technology that we have in the other orthopedic segments, that scientifically, commercially, contractually, it will be an important piece of our business. And we're confident that we'll get that back to a growth rate that may not be reflective of the growth rate that you saw several years ago, that we saw several years ago in spine, and nonetheless is a healthy and sustainable one for the business."

But Gorsky much preferred to talk about knees.

Attuned to Knees

Attuned to Knees

Gorsky said the ability to readily develop and launch new products is ultimately what drives the business, noting that in the last two years alone, DePuySynthes has invested approximately \$3.5 billion in research and development to advance the ortho portfolio. "And it's brought some strong, dynamic products to the market over that time span, including things like the Attune knee system, which now we have over 23,000 implanted worldwide. It's off to a very successful start."

To better serve customers in knee replacement procedures, Gorsky

DePuySynthes 4Q2013	Sales (\$ in millions)	% Change*
Total Reported Sales	2,456	4.2%
Knees		8.0%
Hips		5%
Spine		down 2%
Trauma		7%

Source: Johnson & Johnson
 * Constant Currency



Image created by RRY Publications, LLC

focused on two company initiatives. First, Care for Today Orthopedic Solutions focuses on improving continuity of care and recovery through patient education and empowerment, as well as by providing post-surgery support both in the hospital as well as at home.

Second, True Match, according to Gorsky, brings a new level of personalized total knee replacement surgery to the OR, “based on the proven philosophy of mechanical alignment with customized patient instruments and systems that are designed to really aid in knee implant positioning and to increase the efficiency of the procedure as well.”

Gorsky’s Optimism and Cash

He was also upbeat about the orthopedic recovery citing some early signs of improvements. “Overall, we believe that as economies recover, healthcare reform starts taking hold here in the U.S. and abroad, utilization rates are going to increase, and we remain very confident in the long term prospects for this market.”

Utilization data is still somewhat mixed overall. But he said if one looks at the hospital data, patient procedures, surgical procedures, outpatient procedures and lab tests, they remained essentially flat through the end of the year. “We saw physician visits up slightly, and of course we saw improvements in hips, knees, and trauma in the fourth quarter.”

While not exactly a throw away-line, the company noted it generated significant free cash flow of \$13.8 billion for the year. No wonder Gorsky is optimistic.

—WE (January 23, 2014)

MicroPort Acquires OrthoRecon From Wright

MicroPort Scientific Corporation has recently announced that it has acquired OrthoRecon business from Wright Medical Group, Inc. The transaction establishes MicroPort Orthopedics as the sixth largest multinational hip and knee reconstruction company, with global headquarters in Arlington, Tennessee. As a result of the acquisition, MicroPort now holds U.S. manufacturing, global infrastructure, logistics and operations in the top four global orthopedic markets, as well as established hip and knee franchise brands.

MicroPort Orthopedics Chief Executive Officer Ted Davis stated in the January 13, 2014 news release, “This is an exciting transaction for the MicroPort Orthopedics team, our partners, our customers, our patients and the communities we operate in. We will be building upon 60 years of innovative leadership in the hip and knee industry to grow our orthopedics business segment and establish MicroPort as a worldwide pro-

vider of effective and affordable orthopedics management solutions.”

“MicroPort’s commitment to growth and research and development is the engine that drives our leadership position in the cardiovascular market in China today,” said Jonathan Chen, VP International Business & Investor Relations, MicroPort Scientific. “This philosophy extends to MicroPort Orthopedics as well as shareholders, patients and partners who can expect that our orthopedics business will be just as innovative.”

Regarding first steps as they integrate this new business in the overall structure, Davis told OTW, “One of the advantages of this transaction is that there is little ‘integration’ required. The entire management and commercial team is in place already, our manufacturing facility remains in Tennessee, and the support functions have been re-staffed. We have already established key communication lines in the obvious areas of finance, scale up of the domestic China business and corporate governance. Our focus is now on executing our turnaround plan!”



MicroPort Scientific Corporation Headquarters

He added, “One year from now, we want to have re-energized the business, both culturally and on business fundamentals. We are off to a great start. Our goals for 2014 center around reinvigorating the growth drivers of the business, including R&D, marketing and medical education investment, with the additional effort to ensure our global sales teams embrace the opportunity with MPO. Our goal is to exit 2014 having stabilized the business, thus setting the stage for growth in 2015. There are also some specific investments we need to make in 2014 that will begin to contribute in 2015, most obviously, building out our infrastructure in China to leverage MicroPort’s market leading position in the cardiovascular segment.”

—EH (January 21, 2014)

LEGAL

Unraveling Secrets When Hospital Buys Physician Practice

Pricing contracts between device manufacturers and their hospital customers aren’t the only transactions in healthcare where pricing transparency is lacking. It’s also hard to get financial information when large health systems attempt to acquire physician practices.

According to *healthjournalims.org*, news organizations in Idaho are asking a federal appeals court in San Francisco to unseal pricing information that health insurers pay to hospitals and providers in an antitrust lawsuit over Boise, Idaho-based St. Luke’s Health System’s acquisition of a physician group named Saltzer Medical Group.

In March 2013, the Federal Trade Commission (FTC) and the Idaho attorney general sought to unwind the acquisition of the 44-member Saltzer physician group based in Nampa, Idaho. Before the health system completed the acquisition on December 31, 2012, Saltzer was the largest independent, multispecialty physician practice group in the state. A not-for-profit health system, St. Luke’s owns and operates seven hospitals, the FTC said.

The FTC and the attorney general’s office joined a lawsuit filed by two of St. Luke’s competitors: Saint Alphonse Health System and a small surgical hospital in Boise. The competitors sued in November 2012 alleging anti-trust violations. St. Luke’s and Saltzer moved to keep all the pricing data sealed before the start of the trial. The news organizations filed their request for transparency after the trial judge refused to consider argument for keeping the information sealed.

Audrey Dutton of the *Idaho Statesman* reported last October that the documents reveal details about the acquisition, compensation that St. Luke’s and its main rival proposed for independent doctors and other particulars about the Saltzer purchase.

Molly Gamble reported in *Becker’s Hospital Review* that the news organizations claimed more than half of the first seven days of testimony occurred behind closed doors and more than 575 exhibits were sealed.

The case could define how antitrust regulators view hospital acquisitions of doctor practices for years to come, according to *Modern Healthcare*. Although the FTC seeks to identify anti-competitive deals involving hospitals and doctors, the trial in Boise marked the first time the agency has litigated such a deal in a courtroom, the news magazine said.

—WE (January 27, 2014)



RRY Publications LLC

Bone-Stim Podiatrist Lied, Pleads Guilty

Seven months ago, a Virginia podiatrist named Ilene Terrell, D.P.M., was indicted for manipulating patient medical records and then lying about it to a grand jury. The indictment also claims Terrell lied to Orthofix, Inc. auditors. On January 15, 2014, Terrell was convicted.

Terrell pleaded guilty to four counts of making a false declaration to a grand jury. She faces a maximum of five years in prison. Sentencing is scheduled for April 17, 2014.

Lied to Grand Jury

According to the U.S. Attorney's Office in Massachusetts, Terrell lied to the grand jury about her role in falsifying patient medical records to induce Medicare to pay for claims for Orthofix bone growth stimulator medical devices that did not meet Medicare's payment guidelines.

Falsified Patient Records

On numerous occasions, says the government, Terrell prescribed a stimulator for a patient where the claim would not have met Medicare's guidelines. When this occurred, the Orthofix territory manager, Terrell, and an employee at Terrell's direction often falsified the patient's medical records, making it appear as though the stimulator was not prescribed until three months had elapsed without healing, when that was untrue and Medicare should not have paid the claim.

Fictitious Prescriptions

On some occasions, according to the prosecutors, Terrell prescribed a stimu-



Ilene Terrell, D.P.M.
Podiatry Management Online

lator for a patient and the patient's bone healed within the prohibited three-month window. When that occurred, Terrell, an Orthofix representative, and an employee at Terrell's direction deleted references in chart notes that the patient was using the stimulator and was healing, and they created a new, fictitious note at the end of the 90-day period stating that the bone was still broken and that a stimulator would be ordered. Terrell also created fictitious prescriptions to support the bogus claims.

On May 22, 2012, Terrell testified before the grand jury and was asked several times if she was aware that patient records had been manipulated. Terrell lied to the grand jury, emphatically denying that she manipulated patient records or that she was even aware that anyone had done so. The government said Terrell lied about other matters as well, including her communications with an Orthofix representative about the government's investigation. Terrell discussed the government's investigation at length with the Orthofix representative and instructed him that "you and I have not talked."

Threatened Orthofix Rep

She also threatened the Orthofix representative, stating: "If you guys take

me out you are never going to live to hear the end of it. If I roll on this, I am serious, heads are going to roll, heads are absolutely gonna roll." In the grand jury, Terrell was asked if she had recently spoken with the Orthofix representative. Terrell lied, stating that she only spoke with him briefly and that the sum total of the conversation was that the representative stated that he did not know what the investigation was about.

"The Foot Doctor of Rappahannock"

Last June we reported that according to Terrell's website, "The Foot Doctor of Rappahannock, Ltd.," she is board certified in foot surgery by the American Board of Podiatric Surgery. She provides conservative as well as surgical management of foot and ankle ailments for children, teens, adults and seniors, including diabetic patients.

She has been practicing in the Fredericksburg area since 1986 and has maintained Board certification in foot surgery since 1995. Terrell maintains privileges at Mary Washington hospital and the Fredericksburg Ambulatory Surgery Center. She has served as chairman of the podiatry department at Mary Washington Hospital.

Terrell attended the Pennsylvania College of Podiatric Medicine and the Surgical Residency programs. "She is committed to providing the highest level of care, taking the time to explain your ailment and address your concerns. She believes that ongoing training and product knowledge assists her in her efforts to remain current with new trends in podiatric medicine and surgery," states the web site.

Orthofix is under new management.

—WE (January 21, 2014)

LARGE JOINTS

Mortality Drops for Joint Replacement

It is a lot safer getting a hip or knee replacement now than it was 20 years ago, according to a study by Dutch researchers of the experience in Denmark. Overall, the death rate in the two months after surgery fell from about 3.4% each year between 1989 and 1991 to 1.4% per year between 2003 and 2007. The length of time the patients stayed in the hospital following their surgery also dropped—from more than two weeks, to about one week.

Amy Norton, of *HealthDay Reporter*, wrote that the lead researcher, Arief Lalmohamed, PharmD, of the Utrecht Institute of Pharmaceutical Sciences in the Netherlands, attributed the drop in deaths to new blood-thinning medications that help prevent patients from developing potentially dangerous blood clots after surgery. Also significant is the fact that patients start physical therapy much sooner than they did in the past.

While the study was based on data from only one country Lalmohamed said he expected to see a similar pattern in other countries that, over the years, made the same changes in medical care as had Denmark. In the United States, more than 1 million people have a hip or knee replacement each year, according to the U.S. National Institutes of Health.

Dr. Richard Iorio, chief of adult reconstruction at New York University Langone Medical Center in New York City, said “We get people out of bed and moving on the first day after, or on the day of, surgery.” That mobility is important, he said, because it lowers patients’ risk of developing blood clots. He added that doctors also have gotten better at managing the chronic health conditions that many patients have. That, in turn, lowers the risk of complications.

Iorio, who was not involved in the study, agreed that the drop in mortalities trend would be similar in the United States.

—BY (January 21, 2014)



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TRAUMA

Overuse Cause of Youth’s Sports Injuries

The emphasis on competitive success in youth sports has led to burnout and a rise in overuse injuries, according to a new clinical report by the American Medical Society for Sports Medicine. The report provides guidance to professionals who provide care to young athletes.



Wikimedia Commons and Thomas Sorenes

The researchers, through a literature search, found that overuse injuries comprise 50% of sports injuries. “Not only are overuse injuries in young athletes likely much more common than is realized, these injuries can require lengthy recovery periods, and in some cases, they can result in long-term health consequences,” said John P. DiFiori, M.D., chief of sports medicine and non-operative orthopedics at UCLA and president of the American Medical Society for Sports Medicine. “Children grow and mature at different rates, making chronologic age a poor barometer for parents and coaches to set expectations and gauge progress.”

Researchers recommended that a history of prior injury should be a part of each injury assessment and pre-participation examination. Because early sport specialization may increase risk for overuse injury and burnout, parents and physicians should encourage sport diversification among younger athletes.

Researchers also recommended limited weekly and yearly participation time and limited sport-specific repetitive movements; scheduled rest periods; and careful monitoring of training workload during the adolescent growth spurt, as injury risk seems to be greater during this phase. Injury rates also can be reduced with pre-season conditioning programs and pre-practice neuromuscular training, the report noted.

—BY (January 21, 2014)

REIMBURSEMENT

Political Theater Over Healthcare Job Numbers

The U.S. healthcare industry reported its first monthly loss of jobs in 10 years. Politicians and economists were quick to place blame and credit.

According to a January 10, 2014 Bureau of Labor Statistics (BLS) report, 6,000 jobs were lost in December 2013 in the sector. Overall the U.S. added 74,000 jobs during the month.

Ambulatory healthcare services had the biggest hit, dropping 4,100 jobs; home healthcare services dropped 3,700 jobs while hospitals cut 2,400 jobs. Outpatient care centers and nursing and residential care centers posted gains of 3,600 and 500 jobs, respectively.

Marcia Frellick of *Medscape.com* reported December was a steep departure from the healthcare sector's pattern over the rest of the year. Jobs in healthcare averaged a monthly gain of 17,000 in 2013. In 2012, the average monthly gain was 27,000 jobs. Not since July 2003, when 9,000 jobs were lost, has the sector reported a monthly decline.

The year was one of sluggish job growth for healthcare as only 208,000 jobs were added, down sharply from the 321,000 added in 2012.

For the year, home health services for aging baby booms added 68,000 jobs, followed by physicians' offices adding 43,000 jobs, and outpatient care centers adding 42,000 jobs. The nursing care facility sector was the only sector registering a loss with 15,000 jobs going away as seniors spent less time in those facilities.

Overall, spending on healthcare grew only 3.7% in 2012, which was less than the overall growth of the economy. It was the fourth consecutive year of slow growth, according to the Centers for Medicare & Medicaid Services.

Still, according to the BLS, the employment outlook is strong for healthcare for the next decade.

In December, the agency released projections that the healthcare and social assistance employment sector will grow at an annual rate of 2.6% and will add 5 million jobs between 2012 and 2022. That projected growth accounts for nearly one third of the projected increase in all jobs, in part because of the need for workers to care for an aging population.

Blaming Obama

Republicans in Congress, led by Representative Cathy McMorris Rogers, chair of the House Republican Conference were quick to blame Obamacare. "The healthcare sector lost jobs, at the very time that we need more people; we need more doctors, we need more nurses, we need more therapists, across the board. We're seeing people lose their jobs...it's another impact of the president's healthcare law on healthcare in this country and on people's jobs. We can do better," said McMorris Rogers.



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Bureau of Labor Statistics/bls.gov

According to *Factcheck.org*, citing the BLS report, there were 14,661,300 health care employees in December. So a loss of 6,000 jobs is a drop of just over 0.04%.

American Political Virus

“I think reading anything into a one month dip is silly,” Uwe E. Reinhardt, an economics professor at Princeton University, told *FactCheck*. “Statistical error alone could account for a good part of it.”

Robert Farley of *FactCheck* noted that healthcare spending has slowed in recent years, a fact President Obama has frequently touted even though experts have said the main reason for slower growth in spending is the once-faltering and still-recovering economy, not the Affordable Care Act. As a result of that trend, economists say we should expect a commensurate slowing in the growth of healthcare jobs.

Reinhardt told *FactCheck* that McMorris Rodgers appears to suffer from “some uniquely American virus” that prevents people from seeing both sides of an economic equation—in this case, that lower healthcare spending is tied to healthcare jobs.

Bending of the Cost Curve

“For decades now we have thundered that we must control health spending and that healthcare breaks the federal budget. For reasons that have little to do with Obamacare, and that are still being researched and debated among health economists, the healthcare cost curve (really the annual growth in total and per capita health spending) has been bent downward, starting in 2002 and accelerating after 2007. Most economists now believe growth will

not return to pre-2002 rates,” added Reinhardt.

Whoever gets the credit or blame, healthcare spending growth is slowing and adding jobs at a slower pace than in the past.

—*WE (January 24, 2014)*

CMS Covers PILD for Studies

Percutaneous image guided lumbar decompression (PILD) for lumbar spinal stenosis (LSS) will now be paid for by the Centers for Medicare and Medicaid Services (CMS) for patients enrolled in an approved CED (Coverage with Evidence Development) clinical study.

That’s great news for patients and companies like VertiFlex, Inc. and Vertos Medical Inc.

Treating Spinal Stenosis

In a Decision Memo published on January 9, 2014, CMS determined that PILD

for LSS is not reasonable and necessary for general use.

According to CMS, spinal stenosis is the most common reason for lumbar spine surgery in adults over the age of 65 years. (Weinstein et al. 2008) Spinal stenosis often results from the normal aging process. Surgery for spinal stenosis was reported to be the fastest-growing type of lumbar surgery in the U.S. from 1980 to 2000. Rates of surgery for lumbar stenosis declined slightly from 2002-2007, but use of more complex procedures has increased substantially. (Deyo et al. 2010)

PILD

PILD is a posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area. “The use of a cannula and trocar provides a portal that allows access to the anatomic area for instruments used for resection. This is a procedure proposed as a treatment for symptomatic LSS unresponsive to conservative therapy. This procedure is generally described as a relatively non-invasive (compared to open surgery)

The screenshot shows the CMS.gov homepage with a search bar and navigation tabs. The 'Decision Memo for Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (CAG-00433N)' is highlighted. A dropdown menu is open, showing 'Decision Summary' as the selected option.

CMS.gov

procedure using specially designed instruments to percutaneously remove a portion of the lamina and debulk the ligamentum flavum. The procedure is performed under x-ray guidance (e.g., fluoroscopic, CT) with the assistance of contrast media to identify and monitor the compressed area via epidurogram,” stated the agency.

Endoscopically assisted laminotomy/laminectomy, which requires open and direct visualization, as well as other open lumbar decompression procedures for LSS are not within the scope of this Decision Memo.

Pathway for Reimbursement

Earl Fender, VertiFlex’s president and CEO, said, “There now exists a pathway for reimbursement for PILD procedures and Totalis [VertiFlex’s system] for Medicare beneficiaries. We appreciate CMS’ leadership in allowing CED, and look forward to working with them to finalize a robust clinical trial protocol.”

The agency said it has a particular interest in improved beneficiary function and quality of life, specific characteristics that identify patients who may benefit from the procedure, and the duration of benefit. The clinical study noted by Fender must address one or more aspects of the following questions in a prospective, randomized, controlled design using current validated and reliable measurement instruments and clinically appropriate comparator treatments, including appropriate medical or surgical interventions or a sham controlled arm, for patients randomized to the non-PILD group.

Study Protocols

“The study protocol must specify a statistical analysis and a minimum

length of patient follow-up time that evaluates the effect of beneficiary characteristics on patient health outcomes as well as the duration of benefit.

- Does PILD provide a clinically meaningful improvement of function and/or quality of life in Medicare beneficiaries with LSS compared to other treatments?
- Does PILD provide clinically meaningful reduction in pain in Medicare beneficiaries with LSS compared to other treatments?
- Does PILD affect the overall clinical management of LSS and decision making, including use of other medical treatments or services, compared to other treatments?”

VertiFlex’s procedure involves a small working cannula about the size of a dime, providing physicians the ability to remove targeted ligament, bone, and facet capsule material. A company statement said this broad decompression involves minimal collateral tissue disruption and can be performed under local anesthesia. Totalis was 510(k) cleared by the FDA in November 2012, and has been launched in the U.S.

To read the entire CMS decision memo, click here: <http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=269>

—WE (January 21, 2014)

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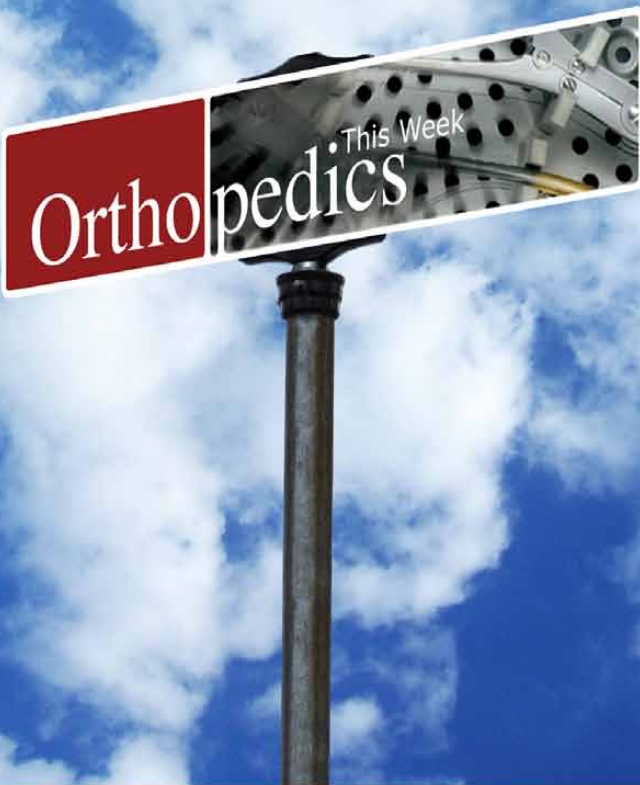
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