VOLUME 10, ISSUE 11 | APRIL 8, 2014

Orthopedics This Week

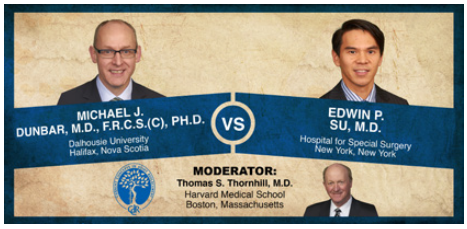
WEEK IN REVIEW

4 Alphatec's $49 Million French Adventure >> When Healthpoint Capital merged Alphatec and Scient'X in 2006, it stuck its finger into a festering litigation involving French spine companies, secret deals and a French doctor in Beverly Hills. When the dust settled, Alphatec agreed to pay $49 million to lance the boil. Is it over? Read here.

8 Short Stems in Primary Hip: Lombardi v. Whiteside >> "My message is that the short tapered titanium porous plasma sprayed femoral component is efficacious, with less than 1% stem revisions if we look at revisions related to the stem," says Adolph Lombardi. Leo Whiteside counters, "Despite the literature we must be careful here. I know a lot of good guys who have tried and failed with fractures, migration, and loosening. Let's avoid the learning curve."

12 Massive New Joint Registry Announced // "Jimmy" Andrews on Stem Cells in Sports Medicine // Zero Dislocation Risk with Dual Mobility Hip? >> Massive national consortium of hospitals studying best practices in total joint replacement. Sports medicine icon "Jimmy" Andrews, M.D. on stem cell rage. Does the dual mobility hip have "zero" dislocation risk?

15 Dunbar, Su Debate Surface Replacement Arthroplasty >> "Resurfacing is more invasive, has worse outcomes, and produces metal ions and pseudotumors," says Michael Dunbar. Edwin Su differs in opinion, saying, "Surface replacement is better because you get better bone preservation, greater stability, and a higher activity level."



BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Spent four days at Castellvi's Duck Key meeting last week. Plenty of time to catch up with companies and top spine surgeons in the United States. One takeaway—Alphatec Spine is different. Alphatec has been closer to Alpha-wreck more times than we can count. But Les Cross, Tom McLeer and the team have a very different vibe going on. We've seen it before. It's a winning team. ATEC on the Power Rankings at #7.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Zimmer	27.31%	(0.50%)	Persona Knee drove a 10% recon sales bump in Q4 and one of Wall Street's top analysts, Mike Matson, just raised his price target.
2	1	Stryker	15.71	1.87	Investors are looking for quality with growth and Stryker epitomizes that. Q1 estimates from Wall Street's analysts are for 6.20% sales growth.
3	3	Johnson & Johnson	26.58	6.30	To grow 6.30% in 30 days means that JNJ's market value rose by a whopping $17 billion! Our guess... dividend rising.
4	4	Medtronic	28.84	3.24	Analysts falling all over themselves to praise MDT's drug coated balloon. What about spine? Crickets chirping...
5	5	Integra LifeSciences	11.77	(5.15)	Interestingly analysts are signaling a large (50%) revenue growth pick up from Q1 to Q2.
6	NR	Orthofix	6.75	45.15	Finally, financials. And a new chairman. Whew! That took a while. Maybe now OFIX can get to the business of growing.
7	NR	Alphatec Spine	(5.21)%	13.28	Completely new vibe at Alphatec. More confident, relaxed and forward looking. Les Cross and team making a difference where it counts. Growing the biz.
8	8	Smith & Nephew	20.25	(3.51)	Strategically, SNN appears to be moving to wound care and MIS, Outpatient care. Scopes for knees, hips, shoulders...everything?
9	6	NuVasive	6.30	(3.83)	80 unique products, 3 major new product launches, expanding margins. But the Street is pricing that into the stock.
10	7	Globus Medical	28.29	(1.88)	Huge number of new products in the pipeline. Is sales force overwhelmed? Not quite yet. For investors, valuation is the issue. GMED is expensive.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Orthofix	OFIX	$33.18	$603	45.14%
2	Aurora Spine	ASG	$4.98	$78	27.69%
3	Bacterin Intl Holdings	BONE	$0.80	$44	16.36%
4	Alphatec Holdings	ATEC	$1.45	$142	13.28%
5	Johnson & Johnson	JNJ	$98.42	$278,364	6.30%
6	Tornier N.V.	TRNX	$20.64	$1,001	4.03%
7	Medtronic	MDT	$61.57	$61,620	3.24%
8	CryoLife	CRY	$10.15	$283	2.42%
9	Stryker	SYK	$82.60	$31,239	1.87%
10	ArthroCare	ARTC	$48.16	$1,655	-0.43%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc	BAXS	$1.01	$48	-39.16%
2	MiMedx Group	MDXG	$5.62	$593	-24.77%
3	TiGenix	TIG.BR	$0.75	$120	-14.77%
4	Symmetry Medical	SMA	$9.45	$354	-11.85%
5	ConMed	CNMD	$42.43	$1,154	-8.93%
6	Wright Medical	WMGI	$30.16	$1,503	-7.85%
7	RTI Biologics Inc	RTIX	$3.79	$214	-5.49%
8	Integra LifeSciences	IART	$45.28	$1,468	-5.15%
9	NuVasive	NUVA	$36.70	$1,707	-3.83%
10	Exactech	EXAC	$22.48	$307	-3.60%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$61.57	$61,620	16.70
2	CryoLife	CRY	$10.15	$283	16.79
3	Zimmer Holdings	ZMH	$96.67	$16,295	16.83
4	Johnson & Johnson	JNJ	$98.42	$278,364	17.92
5	Exactech	EXAC	$22.48	$307	18.72

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$36.70	$1,707	97.81
2	Symmetry Medical	SMA	$9.45	$354	71.19
3	ArthroCare	ARTC	$48.16	$1,655	31.81
4	Integra LifeSciences	IART	$45.28	$1,468	28.54
5	Globus Medical	GMED	$25.63	$2,395	24.68

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Exactech	EXAC	$22.48	$307	1.04
2	Globus Medical	GMED	$25.63	$2,395	1.61
3	ConMed	CNMD	$42.43	$1,154	1.79
4	Zimmer Holdings	ZMH	$96.67	$16,295	1.84
5	Stryker	SYK	$82.60	$31,239	2.24

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$36.70	$1,707	9.42
2	Symmetry Medical	SMA	$9.45	$354	5.93
3	CryoLife	CRY	$10.15	$283	4.20
4	Integra LifeSciences	IART	$45.28	$1,468	3.36
5	Johnson & Johnson	JNJ	$98.42	$278,364	3.03

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.45	$142	0.69
2	Symmetry Medical	SMA	$9.45	$354	0.89
3	RTI Biologics Inc	RTIX	$3.79	$214	1.08
4	Exactech	EXAC	$22.48	$307	1.29
5	Bacterin Intl Holdings	BONE	$0.80	$44	1.33

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.75	$120	21.08
2	MiMedx Group	MDXG	$5.62	$593	10.03
3	Globus Medical	GMED	$25.63	$2,395	5.51
4	Wright Medical	WMGI	$30.16	$1,503	4.91
5	ArthroCare	ARTC	$48.16	$1,655	4.38

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

Alphatec's $49 Million French Adventure

BY WALTER EISNER

All allegations and statements contained in the feature below are from official court documents associated with various lawsuits. The cases have been settled. — Editor

After a month long trial this past January in a Los Angeles courtroom, a jury found Alphatec Holdings, Inc., and its owners, HealthpointCapital, LLC, guilty of transferring assets for less than fair market value and millions would have to be paid to OrthoTec, LLC, the injured party.

Before the dust settled and lawyers could sprint to the Appeals Court, Alphatec gave up and agreed to pay OrthoTec $49 million over the next seven years.

The characters are right out of central casting.

From Paris to Hollywood

In fact, the main character lives in Beverly Hills, has a French medical pedigree and once owned the rights to make and sell Playboy condoms. But that's another story.

This story begins in France in 2006 when a French company by the name of Eurosurgical, S.A. sold some of its assets to another French firm called, Surgiview S.A.S. for $2 million. How did this transaction end up in a California court and how did Mortimer Berkowitz III and John Foster, the managing partners of Healthpoint and Alphatec end up paying $49 million for that $2 million transaction? It's a long and winding road. We dug into the lawsuit documents that provide the roadmap.

Photo Creation by RRY Publcaitons / Napoleon Bonaparte and Wikimedia Commons

Eurosurgical and Bertranou's OrthoTec

We'll begin with a French doctor named Patrick Bertranou living in Beverly Hills in 1998. He started a company called OrthoTec to sell medical devices made by Eurosurgical in the U.S.

Eurosurgical, a spine device company, was founded in France in 1992. Alain Tournier was the principal owner of the company. The managing partner, Guy Viart, was interested in having Bertranou find a U.S. distributor for their products. Bertranou agreed to give it a try, but after approaching 20 companies was basically striking out.

Exclusive Licensing Agreement

Eurosurgical and Bertranou then decided to enter into a licensing agreement in November 1997. The agreement granted Bertranou exclusive rights to market certain Eurosurgical products, as well as the right to use patent and trademark rights.



Left to right: Mortimer Berkowitz III, Alain Tornier and Guy Viart

Bertranou went to StelKast Medical, Inc., where he met a sales executive named Brad Harris. The two sides tried to negotiate a deal, but never got it done.

Bertranou and REO's Harris

Harris left StelKast and formed his own company, REO SpineLine, LLC.

In March 1999 Bertranou and Harris tried again and this time successfully entered into a licensing agreement to distribute Eurosurgical's products. In addition to the purchase price paid to OrthoTec by REO, Bertranou could buy 25% of REO for $1,000 and receive a royalty of 5% of the retail sales price of all products sold to any retailer.

Bertranou had finally secured distribution for Eurosurgical's products outside of Europe.

Under the deal, Bertranou would buy products from Eurosurgical and resell to REO after, of course, marking it up. For the remainder of 1999, OrthoTec sold approximately $1.3 million of Eurosurgical products to REO. That increased to $2 million in 2000 and $3 million in 2001. Bertranou, according to Eurosurgical's CFO, had become the largest and most profitable client for the company. By the end of 2000, the company had made almost $2 million in profits from OrthoTec's purchased.

So far, so good.

Unfortunately, the OrthoTec/Eurosurgical exclusivity agreement was due to end in March 2000. So Eurosurgical asked Bertranou to sign another contract.

Bertranou agreed on the condition Eurosurgical pay him $15,000 per month to improve his cash flow and help with operating expenses. So, effective April 1, 2001 Eurosurgical and OrthoTec entered into a partnership agreement under which OrthoTec granted Eurosurgical a further period of manufacturing exclusivity for the two-year term, plus an additional 36 months, and agreed to expand its marketing of the SCS and Claris spine systems to increase distribution of the products in North America. Eurosurgical, in turn, agreed to pay OrthoTec $15,000 per month for one year.

The agreement also said that it could be terminated if a proposed merger between Eurosurgical, OrthoTec and REO did not happen by April 2002.

An Expensive Middle Man

In early December 2001 Guy Viart, Eurosurgical's managing partner, came

to Los Angeles to meet with Bertranou. During that meeting, Viart told Bertranou he wanted to create a new company with Eurosurgical's and OrthoTec's assets and obtain the licensing agreement OrthoTec had with REO and the rights to all the products in the territory.

Viart said he would give Bertranou a 12.3% interest in the newly formed company. Bertranou told Viart the proposal was inadequate given that he had become Eurosurgical's biggest and most profitable client and Eurosurgical had made $2 million in profits from his sales to REO.

The middle man apparently became too expensive.

Eurosurgical Tries to Dump Bertranou

Eurosurgical, according to the court documents, wanted to get out from under the exclusivity of the agreement and wanted to make REO and Brad Harris understand that this was not the time to sign anything new with OrthoTec.

A business adviser named Maassen was hired by Eurosurgical. He proposed that the company rescind the April 2001 partnership agreement and inform Bertranou that Eurosurgical intends to enforce the assignment agreement's requirement that invoices be paid within 30 days. If he failed, Eurosurgical would repurchase the rights it transferred under the assignment agreement.

Maassen testified he did not believe Bertranou had the ability to settle all outstanding invoices in that time frame and thus Eurosurgical would be able to terminate the assignment agreement.

But Bertranou paid his outstanding invoices.

A Deal With Harris

Viart and Maassen then went to see Harris.

On February 7, 2002, Harris and Maassen signed a nondisclosure agreement about negotiations concerning a possible merger between the two entities and agreed not to disclose any information discussed during the negotiations. Maassen understood the agreement as preventing Eurosurgical from disclosing to OrthoTec any information it learned about REO and did not inform OrthoTec that Eurosurgical had entered this agreement with REO.

On April 22, 2002, Viart sent Bertranou a letter stating he was terminating the partnership agreement because Eurosurgical, OrthoTec and REO had failed to enter into a three-party arrangement by April 1, 2002. A month later, he sent Bertranou a bill for alleged unpaid 1999 invoices.

Bertranou disputed the bill, so in June 2002, Viart sent him a letter exercising the company's option to repurchase for $100 the rights defined in the assignment agreement on the ground that Bertranou had refused to pay. Bertranou, under protest, paid up and returned Viart his $100 check.

By July, Bertranou signed a manufacturing agreement with Specialized Medical Devices, Inc.

Eurosurgical then stopped manufacturing any additional products for OrthoTec and REO cancelled all open purchase orders with Bertranou.

In October 2002, Eurosurgical signed a distribution agreement with REO and Harris. Bertranou demanded that REO cease using the rights that Eurosurgical had given to OrthoTec.

Bertranou Sues Eurosurgical and Wins

Bertranou also sued Eurosurgical. Eurosurgical countersued and it all went to a jury.

The jury found for Bertranou and awarded damages totaling about $9 million. The court also found that OrthoTec owned all rights conveyed under the assignment agreement and Eurosurgical's attempt to reacquire those rights was invalid. The court then ordered Eurosurgical to assign all intellectual property rights in the products and prohibited it from selling or marketing any of the products in the territory covered by the assignment agreement. The court also required Eurosurgical to turn over all product plans and specifications.

In January 2007, OrthoTec won a default judgment on the trademark and copyright issues and was awarded and additional $30.4 million.

So to recap. Bertranou (OrthoTec) sued Eurosurgical and won almost $40 million.

From Eurosurgical to Surgiview to Scient'X to Alphatec to Healthpoint

Enter the folks from Scient'X, Alphatec and Healthpoint.

Eurosurgical, after losing its case to Bertranou, entered into an agreement to sell some of its assets to a company

called, Surgiview. The parent company of Surgiview was Scient'X at the time of the $2 million asset transfer from Eurosurgical in 2006.

Eurosurgical created Surgiview as a subsidiary in 2000, and then sold its interest to Scient'X in September 2004, following OrthoTec's judgment in California.

Olivier Carli, a French citizen, was the CEO and two-thirds owner of Scient'X and the sole director of Surgiview at the time Surgiview acquired Eurosurgical's assets. Healthpoint owned the other third of Scient'X.

Eurosurgical's Disputed Asset Transfer to Surgiview

On May 17, 2006 Eurosurgical entered into a written agreement with Surgiview entitled "Partial Sale Agreement." The partial sale agreement said that Eurosurgical would sell all of the assets listed in a lease agreement to Surgiview. And Surgiview would deposit $2 million in an escrow account to be used by Eurosurgical to pay its creditors.

Alphatec acquired Scient'X in September 2006.

Bertranou alleged the $2 million dollars paid for Eurosurgical's assets was far less than their $47 million value and asked the court to add Surgiview to the judgment because he claims Eurosurgical created Surgiview for the sole purpose of transferring its assets to defraud OrthoTec. The court denied the motion.

Bertranou Goes Where the Money Is

Bertranou then decided to change course. Rather than pursue Surgiview as a judgment debtor, on May 6, 2008 OrthoTec sued Alphatec and Healthpoint, alleging claims for fraudulent transfer against all the people and entities it claims participated in the transfer of Eurosurgical's assets. Eurosurgical, which had initiated bankruptcy proceedings in France on July 6, 2007, was not named as a party in the complaint.

Bertranou then won the case and Alphatec decided to settle.

"While we continue to believe strongly in our position with respect to this litigation, this settlement removes a future uncertainty in our business and eliminates further distraction and extensive investment of human and financial resources associated with continuing with a lengthy legal process," said Les Cross, Alphatec's CEO.

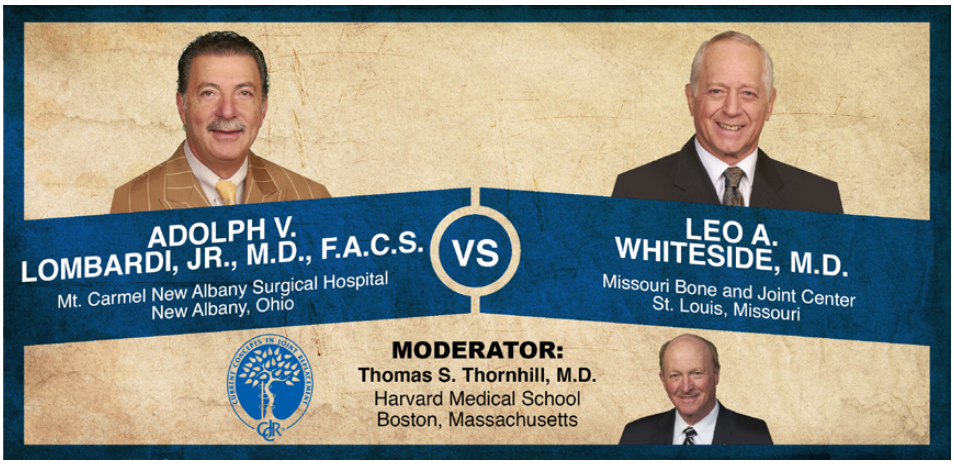
On to New York

But this may not be the end of it as Bertranou, through his attorneys, asserted that OrthoTec will now look to New York, where the same issues are slated to be tried later this year against Foster, Berkowitz, and Healthpoint. ♦

Short Stems in Primary Hip: Lombardi v. Whiteside

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

"My message is that the short tapered titanium porous plasma sprayed femoral component is efficacious, with less than 1% stem revisions if we look at revisions related to the stem," says Adolph Lombardi. Leo Whiteside counters, "Despite the literature we must be careful here. I know a lot of good guys who have tried and failed with fractures, migration, and loosening. Let's avoid the learning curve."



Current Concepts in Joint Replacement/RRY Photo Creation

This week's Orthopaedic Crossfire® debate is "The Short Stem: Emergent Solution for Primary Hip Problems." For the proposition is Adolph V. Lombardi, Jr., M.D., F.A.C.S. from Mt. Carmel New Albany Surgical Hospital in Ohio; against the proposition is Leo A. Whiteside, M.D. of the Missouri Bone and Joint Center in St. Louis. Moderating is Thomas S. Thornhill, M.D. from Harvard Medical School in Boston.

Dr. Lombardi: "Not all short stems are created equal: there are short and bulky, short tapered, the 'Mayo Influence' stems, and the neck sparing stems. There are multiple reports showing short term follow-up (2.7 years and 8 years on an ultra-short stem) but no stem revisions. For the DePuy Proxima Stem it was the same in different studies (1.7, 2.2, and 4.5 years). The Mayo Stem didn't do as well—even in the hands of the designer (9% stem revisions). So we're seeing small series in the literature, but what's emerging is more and more stems that are FDA approved."

"A 2013 review article by Banerjee included 22 articles; the researchers found that 'midterm survivorship of short stems has thus far been comparable to traditional stems'. Follow-up was four years. In a 2012 article by Rometsch there were 14 articles reviewed involving 7,000 devices; they had a revision rate of 0.38 per 100 component years."

"What's the length of a standard stem? If the goal of the tapered stem is to preferentially load the proximal femur, then why do I need a long stem? Short stems comply with that proximal loading theory of tapered stems. In McLaughlin's 2010 series he used a device known as 'reduced distal' so that he wouldn't get the stem impinging distally."

"Why do you need a stem? Maybe to prevent varus…but in our series varus stems did as well in this porous plasma-sprayed device as did the straight stems that were neutral. Also, if you use a varus stem you can accommodate some femoral deformities, as well as a proximal-distal mismatch. Also, they violate less bone and revisions are easier. Short stems facilitate a shorter incision surgery as well as procedures like the anterior supine intermuscular."

"Our experience in over 2,450 cases has been excellent. Also, when I looked at my series of long stems compared to my short stems I found that I was having a few more problems interoperatively with my longer stems than with my short stems. From January 2006 to April 2013 we did 2,457 of these surgeries. We had to revise 35; our biggest nemesis was infection (15 of the 35). The second biggest issue was periprosthetic fractures. In some patients we noticed a distal hypertrophy, so we modified the stem to reduce the distal part. We looked at 100 of these short stems that were the standard and then 100 that were reduced distal, and we classified the amount of distal canal fill. We found that by reducing the distal portion we had now decreased the amount of what I call 'grade three' canal fill (distally) down to 12%."

"So my message is that the short tapered titanium porous plasma sprayed femo-

ral component is efficacious, with less than 1% stem revisions if we look at revisions related to the stem (i.e., not including infections)."

Dr. Whiteside: "Remember that the femoral forces are high: 250Kg of axial load offset and 2.5 KgM of torsional load. Bone ingrowth occurs only if you keep the micromotion less than 20 microns at that interface. It's achieved primarily by proximal fixation (wedge or collar). Fixation depends on a tight distal diaphysis, and the length of the stem. It also depends on torsional load bearing, the femoral neck, and diaphyseal cortical interlock."

"Total surface area is very important. I have settled on a tapered rough porous proximally coated implant that is rectangular and long enough to engage the diaphsys and support the implant. Whether you have a wedge or collar, tight or loose fit distally makes the difference at low and high loads. Tightness or looseness distally controls axial motion. Torsional micromotion is another matter. One of my fellows found that torsional micromotion is very poorly controlled by the standard round stems that you see all time. Part of that is because of the resection of the neck. Michael Freeman showed us that if you resect the neck you lengthen the lever arm that the load is applied to and you shorten the lever arm that resists it. A quick lab test will show that torsional load to failure is much higher if you keep the entire neck and much lower if you resect the neck."

"If you cut the stem in two you get three times more micromotion at the interface. I lean more toward a rectangular stem that has various sizes that allow me to get that tight distal fixation. Even in Dorr type C bone if you concentrate on getting tight distal fixation, torsional micromotion is minimized well below the 20 microns of interface motion."

"Preserve the neck and don't worry about incision length. Preserve the bone, not the skin. Even in soft bone you can still preserve the neck and end up with excellent fixation. Continue to compact and fit proximally first, maintaining the neck—especially that medial and posterior cortex. Then size distally. The final implant is made to fit that broached cavity…rectangular for scratch fit distally…proximally porous coated and made to fit in a femoral neck. Then you get a short lever arm that applies the load and a long lever arm that resists the load…and a tight fit in the canal. You do end up with a little proximal stress relief, but you don't end up with a varus femur even if you try to varus it."

"The literature looks good for short stems. However, with a few phone calls I found out that we have a problem. I know a lot of good guys who have tried and failed with fractures, migration, and loosening. That suggests that we need to be careful; let's avoid the learning curve here…and avoid 'minimally invasive' anything. Use an extensile approach, and use an implant that is fixed proximally and distally for both axial and torsional loads that you can do right *every time*."

Moderator Thornhill: "Adolph, now that people are pushing anterior hips and other minimally invasive approaches. Do you think it's right to shorten the implant because of your approach?"

Dr. Lombardi: "Leo is right…don't do a minimally invasive procedure because of the implant. If you're driven to make a shorter incision I suggest you get comfortable with whatever device you're going to use in that shorter incision

with your standard approach and then go to your different approach. I've done many of these shorter stems through a direct lateral approach, and now I'm doing an anterior supine intermuscular on about 25% of my patients. But I can still use the longer stem…the incision would have to be longer.

Dr. Whiteside: "If you have a longer stem and you decide you're not getting enough fixation then you can put in a longer stem. I'd suggest some corners on that stem of yours. Round is kind of dangerous in the femur because it can slide around. I like to see edges that get cortical purchase distally."

Dr. Lombardi: "I use a porous plasma spray stem that's been on the market for almost 25 years. It's got a roughened surface, it's rectangular, and the amount of porous coating in the short stem is identical to the amount of porous coating in the long version of it."

Dr. Whiteside: "The amount of porous coating is important."

Dr. Lombardi: "I would challenge you on that grit blasting distally. That is a pain in the rear. Why do we need that? And if you ever have to remove one of those stems you'd better know that it's grit blasted distally because you're going to have to do a very long osteotomy."

Dr. Whiteside: "You need that because it improves fixation and if you get osteolysis proximally then it's nice to have a well fixed implant that you can salvage."

Dr. Lombardi: "If you didn't have that grit blasting distally you wouldn't have to worry about that osteolysis because you'd have bone up there. But because you put that grit blasting distally it got fixed distally and the proximal bone has melted away."

Dr. Whiteside: "Fixation distally does not cause proximal osteolysis; other issues do. If you have a fixed stem it's likely to stay fixed if it's fixed proximally and distally. Flexibility of that stem gives you bone preservation proximally."

Moderator Thornhill: "Adolph, occasionally with an uncemented implant—and certainly with a cemented implant or a modular implant—you can change version. What do you do in those cases with your short stem?"

Dr. Lombardi: "If I have an issue with version, the flexibility of using a tapered stem that's rectangular…you can maybe change 5/10 degrees. If you must do more than that then you have to go to a different design. I use the one Leo showed that has both proximal and distal fixation so that I can dial in the rotation I want."

Moderator Thornhill: "Leo, what about impingement?"

Dr. Whiteside: "That's important. You have to be careful and trim the edges of that proximal femur—especially anteriorly so that it doesn't impinge in flexion. If you're concerned about it you can put your finger on the front, flex the hip, and if it requires more trimming you can do that. But if you just flatten off that osteophyte it clears fine, especially with a 32mm head."

Moderator Thornhill: "A question from the audience here. Adolph, did distal hypertrophy mean thigh pain in these patients?"

Dr. Lombardi: "No. It was more of a radiographic finding that was bothersome to some of us who were using this device. And so we do what was done in the standard line, and that is to come up with a reduced distal. We need a few more years under our belts with the reduced distal to tell you that we're not going to have that distal hypertrophy. What I found by reducing distal is that we increased the size. I would broach with my standard stem broach and then broach with my reduced distal broach, and found that I was able to push up one or two sizes."

Dr. Whiteside: "That distal hypertrophy is part of a shorter stem. The stresses are huge when you have a short stem; a longer stem mitigates those stresses to the point where you don't see nearly as much distal hypertrophy."

Dr. Lombardi: "I saw it with our longer porous plasma sprayed stems."

Dr. Whiteside: "Of course…if they're ingrown and big distally."

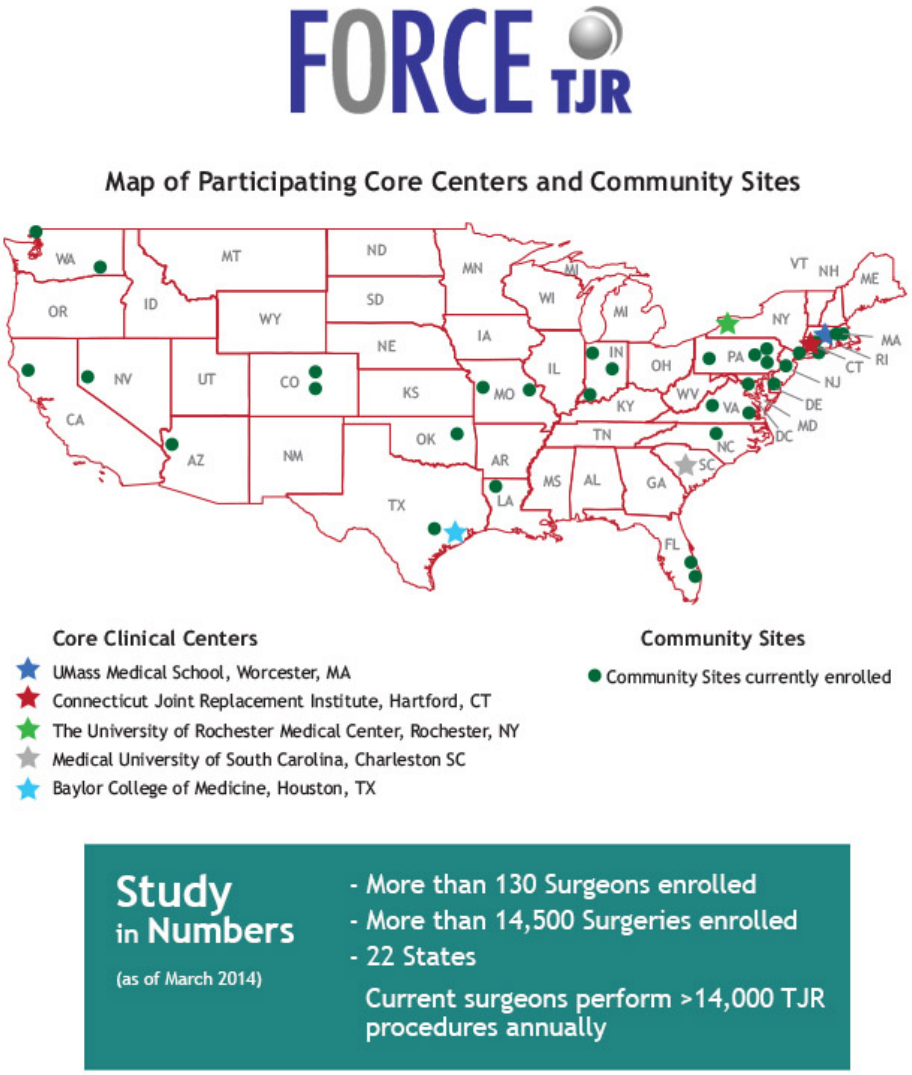
Moderator Whiteside: "Thank you, gentlemen." ♦

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

Massive New Joint Registry Announced // "Jimmy" Andrews on Stem Cells in Sports Medicine // Zero Dislocation Risk with Dual Mobility Hip?

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

Incredibly Comprehensive Total Joint Registry Consortium Researchers at the University of Massachusetts are working on what is likely the most comprehensive effort to date to develop and implement a total joint research registry. This project—Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR)—is a national consortium of hospitals focused on studying best practices. At the helm is David Ayers, M.D., Chair of the Department of Orthopedics and Physical Rehabilitation and director of the Musculoskeletal Center of Excellence at the University of Massachusetts Medical School. Dr. Ayers tells *OTW*, "FORCE-TJR was initiated when we received a $12 million grant from the Agency for Healthcare Research and Quality. This research registry is more in depth than other registries, and includes a patient's complete operative record, adverse events, and surgeon and institutional characteristics, among other variables. At this point we have collected patient reported pre-and postop outcomes from nearly 40,000 TJR patients via 130 orthopedic surgeons—and there is a waiting list of surgeons who want to join. A big differentiator is that these surgeons represent all regions of the U.S. in varied hospital and surgeon practice settings (e.g., urban/rural, low and high volume). With such immense diversity we will certainly have data that is representative of typical clinical practice—not just the experience of academic centers."



www.force-tjr.org

"For the first time ever we are able to statistically identify the point at which most patients and surgeons come together to decide to proceed with a total knee or hip replacement. This is a real coup and will allow us to establish and utilize national benchmarks that patients and surgeons can use in shared decision-making. As for researchers, investigators worldwide will be able to collaborate with the registry in order to further academic-private partnerships to expand the research scope."

James Andrews, M.D.: 'Stem Cell Use Lags Science' Sports medicine icon Dr. James Andrews has often been in the forefront of innovation in his specialty.

Reflecting on the past and future of sports medicine, Dr. Andrews tells *OTW*, "The major revelation in sports medicine through the years has been the arthroscope. I was a young doctor at the time it was introduced in the U.S., and I hitched a ride with the sports medicine forefathers. For awhile now we have been looking for the next practice changing revelation in sports medicine, and the thing that we've been homing in on is biologics We thought it would come into its own in the first decade of the new millennium, but it lagged behind because it was difficult to research and to get it out to the public."

"Things are on the roll now, however, and stem cell therapy is all the rage. Here at the Andrews Institute we developed our own lab so that we can do cell counts and determine what we research is the most advantageous. I do caution my colleagues, however, about the use of stem cells getting out in front of us clinically, i.e., without having enough basic science behind it. What's happening now is that patients are clamoring for it and many doctors are just going along with their demands. This is a bit dangerous, however, because we don't know the true indications, the contraindications, what type of cells are best utilized in xyz situation, and how often it should be used. We have an increasing number of athletes heading offshore for these surgeries and we just don't know what they are doing."

"The fly in the ointment is that it's difficult to develop clinical trials because professional athletes don't want to go into a clinical trial; they don't want the placebo they want the real deal. We need to prove that it's advantageous for certain situations; we need to know how many cells survive, etc. If you try to do a study and the therapy is developed as a drug and you manipulate it then it must be controlled by the FDA. Funding is an ongoing problem. Fortunately, our institute has one stem cell therapy study on retired NFL players that is fully funded by a company."

Dual Mobility Hip Replacement Dislocation Risk "Zero" Want to reduce wear and eliminate the risk of dislocation? Try something that the Europeans have done for many years—dual mobility hip replacement. Geoffrey H. Westrich, M.D. is Research Director of the Adult Reconstruction and Joint

Replacement Service at Hospital for Special Surgery (HSS). He told *OTW*, "Dual mobility hip replacement was introduced to the U.S. several years ago and we have been using it at HSS with great success. With traditional hip replacement we have had to worry about dislocation, instability, impingement, and long-term wear on the plastic. With a dual mobility hip replacement, instead of the plastic liner being fixed to the cup and ball moves in that, the plastic liner is press fit onto the ball in the OR. The ball inside the liner is placed on the stem; then the hip is reduced and because the ball can't come out of the plastic liner the risk of dislocation with this prosthesis goes down to almost zero. These hips have eliminated dislocation in primary hip replacements… and in the revision setting our dislocation rates are always higher."

"The first study involved a number of institutions, and included almost 500 dual mobility hip replacements in primary surgery. We have yet to see any dislocations with a minimum of two year follow up. The second study involved in revisions only…over 130 cases where dual mobility was used and they only had a 3% recurrent dislocation rate."

"The major advantage to these hips is the reduction in wear characteristics. And third generation highly crosslinked plastic tested in wear simulation studies reveals little if any wear. We also have retrieval and wear studies where we see virtually no wear with this hips out to 3 million cycles. If you look at the number one reason now for revision surgery in databases is instability. It used to be wear of the plastic and loosening but because the technology is so good now fixation is not an issue."

Robert D. D'Ambrosia, M.D. Receives AAOS Diversity Award Dr. Robert D'Ambrosia has been honored with the Diversity Award from the American Academy of Orthopaedic Surgeons (AAOS). This award recognizes members of the Academy who have distinguished themselves through their outstanding commitment to making orthopedics more representative of, and accessible to, diverse patient populations.

Dr. D'Ambrosia is a professor and chair of the department of orthopedics at the University of Colorado where he helped shape the School of Medicine's Diversity Policy that increased student diversity to 30%. He embraces treating underserved patient populations to reduce the healthcare disparities they face. He also was pivotal in ensuring that the University of Colorado sports medicine faculty include female practitioners to help address the needs of female sports teams. D'Ambrosia also served as AAOS President from 1999-2000.

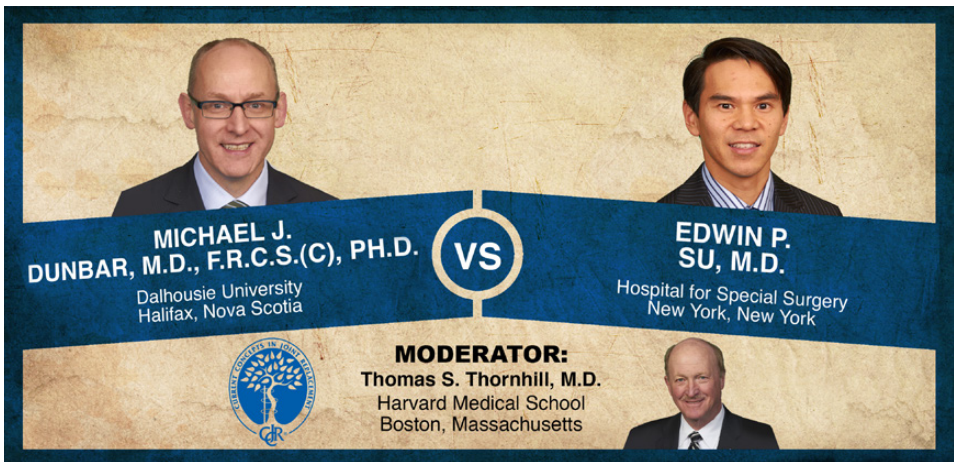
Dr. D'Ambrosia was formerly chair of orthopedics at Louisiana State University (LSU) for 27 years. While chair of the department, he trained and mentored more than 100 LSU graduates. His contributions to the LSU program are so long-lasting, a lectureship and chair have been established in his honor. ◆

Dunbar, Su Debate Surface Replacement Arthroplasty

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

"Resurfacing is more invasive, has worse outcomes, and produces metal ions and pseudotumors," says Michael Dunbar. Edwin Su differs in opinion, saying, "Surface replacement is better because you get better bone preservation, greater stability, and a higher activity level."

This week's Orthopaedic Crossfire® debate is "MOM Surface Replacement Arthroplasty: Throw That Baby Out." For the proposition is Michael J. Dunbar, M.D., F.R.C.S.(C), Ph.D. from Dalhousie University; against the proposition is Edwin P. Su, M.D. from Hospital for Special Surgery. Moderating is Thomas S. Thornhill, M.D. from Harvard Medical School in Boston.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Dunbar: "The metaphorical baby of resurfacing arthroplasty was dropped like a bomb by the stork into the UK and Australia from 2004-6 where staggering numbers of patients under 55 received such implants (46% in the UK and 29% in Australia)."

"The best argument Ed will have is that resurfacing works best in the young male. The first reason proposed is 'because the metal bearing provides an advantage to survivorship.' We can see from multiple hip replacements and multiple studies that when you compare to a total hip replacement all comers—a bit unfair—that resurfacing doesn't fare as well. But we also know from this data that we've stopped doing this surgery in women because they fare far worse than men. This has been accepted to the point where when we look at risk factors, it's now associated with older patients, smaller femoral head size, patients with developmental dysplasia, and certain implant designs."

"The experience of the UK is discouraging; the survivorship curves are worse than they are in Australia. Associated with metal-metal bearings—and particularly resurfacing—has been the generation of metal ions and the subsequent problems. In a Canadian multicenter study (Kim et al., 2011) we found that metal ions degenerated, but remained persistently elevated after two years. The concept at the time was that the ions would be generated with the wear-in period, they would then dissipate and it would be OK. That wasn't our experience. We've had excellent groups around the world—in particular Oxford University—reporting on pseudotumors associated with metal ions. They had the same experience in the Netherlands (Bisschop et al., 2013) where they reported on large numbers of pseudotumors being generated at five years with metal-metal implants."

"With the generation of metal ions in these young patients you end up in a new paradox because you have troubles that you've never had to deal with as an orthopedic surgeon. For example, we now have to deal with pain with metal-metal, and therefore we have to study metal ions. We don't know if we should get serum or urine, or if cobalt/chromium is the one to look at, and we don't know how precise a single estimate is. If they are elevated we need to move to an MRI and they're difficult to interpret and perform. And we may need to revise for pseudotumor or high ion levels. Why would you want these headaches?"

"Resurfacing is proposed for the young male also because it's perceived to be a less invasive procedure than THA. Nonsense. It's maximally invasive because these are young, strong males with big muscles. And because you have to leave the head it's difficult to get to the acetabulum. This exposure may result in odd things, such as avascularity to the femoral neck…which may result in fracturing. And it also may lead to femoral neck narrowing."

"Another argument is that we should resurface in young males because if it fails we've left the femoral canal virginal and we can then put a total hip in these patients with no problem…but that's not the case. Let's look at the data from a series of 397 cases from the Australian registry that failed and went on to total joint replacement. When they were placed back on the survivorship curves they were not on the same curve as if they had had a primary total hip replacement; they had a much worse survivorship curve."

"Another argument is that we should resurface in males because it's an intact femoral head and it results in better function. A Canadian randomized trial that won the John Charnley Award (Lavigne, 2010) looked at resurfacing versus large head metal-metal. They did gait analysis, etc., and found no difference in the outcome in terms of advantage. Yes, you have a larger head, but you also have a larger neck intact… so there is sometimes an advantage to having a THA [total hip arthroplasty] such as better ROM [range of motion] and functional outcome."

Dr. Su: "We've heard about the negative consequences of metal-metal (MOM) total hip replacements; metal-metal resurfacing is not the same thing. The types of problems are different with resurfacing versus a large diameter MOM total hip replacement. I think there is still a role for hip resurfacing in the treatment of hip arthritis."

"We all know that hip replacement is one of the most successful operations that we have to improve mobility and relieve pain. But it's not perfect, and there is a large body of experience with a generation of hip replacements that with time there will be wear and osteolysis. If you look at the Swedish registry, specifically at the results in younger patients (under 60), we see that the survival rate of a total hip replacement is poor after the tenth year. And there is about a 30-40% revision rate nearing 20 years."

"Dislocation is also a problem with total hip replacement, and dislocation as a reason for revision is increasing. I think that's because patients are more active, and we are putting these in younger

and younger patients. So the challenge is to perform a hip arthroplasty in young active patients, the group that poses the greatest challenge to implant longevity; their high activity level may lead to earlier need for revision."

"I think there are several benefits to hip resurfacing. It preserves bone and leads to greater stability. It gives better reproduction of the natural anatomy of the hip in terms of length, offset, and anteversion. It also loads the bone more physiologically and, I think, gives a greater activity level. It's indisputable that a hip resurfacing preserves femoral bone. We've done a cadaver study where we looked at the amount of bone we saved, and it was about 300% of bone saving on the femoral side with no additional bone removed from the acetabular side. It also provides a more stable joint."

"Regarding the more physiologic loading of the bone, as opposed to a hip replacement, which receives load from the top, transmits it through the stem into hoop stresses. A hip resurfacing receives load from the top and transmits it through the femoral neck…as your own hip would. My point is, 'What will happen with the continued loading of the implant?' Loading in tension may cause femoral stem fatigue fractures."

"There is also better restoration of normal hip mechanics. You will see patients with high offset hips, and there is no total hip replacement—whether you template it or use a different varus extended neck offset stem—that can reproduce that high offset. There is 2012 data by Professor Haddad showing that there is a higher activity level with resurfacing. In that 10 year follow-up of a prospective, randomized study on THR [total hip replacement] versus hip resurfacing, the latter group had higher activity scores. And a survey from Dr. Barrack also found that resurfacing patients felt they had fewer limitations than THR patients."

"As Michael said, hip replacements in certain subgroups are performing well in national joint registries. If you look at the 10 year revision rate of resurfacing in males in the Australian registry, it is about 6%; in a THR in that same group it's roughly 8%."

Moderator Thornhill: "Ed, in following your MOM resurfacing patients, when do you measure levels in them, when do you get an ultrasound and/or MRI?"

Dr. Su: "I routinely measure metal levels at one, three, five years. There isn't conclusive data that we should be doing it for everyone. Anyone symptomatic will get some sort of cross sectional imaging. The levels at which I get worried will differ depending on the amount of symptoms."

Moderator Thornhill: "And Michael, you just say, 'Why worry about that? Just don't do them.'"

Dr. Dunbar: "But I end up seeing patients who have them in. We don't truly know the answers as far as what specimen should be taken and when. So I don't like being in a situation where there are elements I don't understand. THA is arguably one of the best operations out there and we've strangled it by trying to be innovative and potentially making errors along the way. I don't know when to get the ion levels. If they're symptomatic, I will…and if those are elevated I will get cross sectional imaging. Then I have difficulty interpreting the cross sectional imaging."

Moderator Thornhill: "Ed, in the past you've talked about revisiting the concept of a metal-poly now that we have better polyethylene. Are you doing this?"

Dr. Su: "I think it's being talked about. We all realize that hip resurfacing can be an attractive concept to save the bone, but the metals are its Achilles' heel. We'd love to get rid of it; with the highly cross linked poly it's a possibility, but we must be able to show good poly strength…and that it's not going to have a fatigue fracture in the dimensions that we need to make it."

Moderator Thornhill: "Michael, your thoughts on that?"

Dr. Dunbar: "Perhaps we're chasing our tail again. There is promise there, and there is probably a middle ground for some patients. But we need to say, 'Enough of the chaotic innovation. We must go slowly and methodically. And we must report problems immediately…before we have a new bearing in thousands of patients."

Moderator Thornhill: "Thank you, gentlemen." ♦

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

COMPANY

Biomet Continues Ortho Surge

Biomet, Inc. just reported a great quarter and blew up Wall Street fears that orthopedic sales would begin to slow appreciably in the first quarter of 2014.

Total reported quarter revenue of $822.5 million was up 6.6% over the previous year. On a constant currency basis, revenue climbed 7.5%.

Losses Diminish

Even better news for the company, which just announced plans for an initial public offering, reported net loss in the quarter was only $65.9 million, compared to a net loss of $304.5 million a year ago. Operating income was also up slightly. The company still carries about $5.6 billion in buyout debt added when Wall Street banks acquired the company in 2007.

Praise the Knee

But the real story was all about knee sales of $254.2 million, which climbed 8.4% on a reported basis. Spine came in 16.4% higher than the previous year's quarter, with the addition of sales from the Lanx, Inc. acquisition. Lanx sales added approximately 1.2% in sales to total company revenue.

The company's President and CEO Jeff Binder said, "Once again [we] delivered balanced constant currency sales growth across our major geographies and our major product categories."

Better Than Expected

Mike Matson, analyst at Needham & Company, LLC, noted that due to an extra selling day, the organic revenue growth on a constant currency basis slowed to 4.7% from 5.8% in the last quarter of 2013. He said that Biomet's results indicate that orthopedic market growth may have been better than expected in the first quarter despite fears of seasonality and a weather related slowdown. "Since Biomet's recon growth has been relatively well correlated to recon market growth in recent quarters, we believe that [first quarter] recon market growth may exceed our forecast and we see potential for upside to estimates at Biomet's competitors," added Matson.

Share Gainer

RBC Capital Markets, LLC's analyst Glenn Novarro noted that Biomet gained approximately 10 basis points of worldwide recon market share in 2013, and he expects that Biomet is likely to be a share gainer again this quarter. With that Biomet gain, he estimates that the worldwide recon market would be up approximately 6% year-over-year on a constant currency basis, above his previous 5% estimate.

Novarro added, "We believe underlying hip/knee demand remains strong and see better than expected Obamacare enrollment numbers as a medium-term positive for the hip/knee space."

Once again, Biomet plays the canary in the coal mine role by being the first large orthopedic company to report quarterly revenue. The canary is alive and well.

—WE (April 6, 2014)

Biomet 3Q 2014	Sales $ in million	% Change
Total Reported Sales	**822.5**	**6.6%**
Knees	254.2	8.4%
Hips	162.9	2.8%
Sports, Extremities, Trauma	169	4.7%
Spine & Bone Healing	115.9	16.4%
Dental	64.4	0.1%
Biologics and Other	56.1	5.7%

Source: Biomet, Inc.

The Great Wave off Kanagawa by Katsushika Hokusai

DJO Global: Independent Numbers Favor TENS System

DJO Global, Inc. has released an independent, estimated financial impact on Medicare patients who suffer from chronic low back pain (CLBP). The financial impact calculation estimates that using current standard of care procedures to treat approximately 1.5 million Medicare beneficiaries who have CLBP and seek medical intervention now costs approximately $1.3 billion annually. The company estimates that for an investment of slightly over $880 million, all of those patients can be supplied with a transcutaneous electrical nerve stimulation system (TENS) to take the place of other treatment options.

These figures are partly based on a recently published study in volume 36, issue 12 of *Orthopedics*, which looked at the clinical and economic impact of TENS in patients with CLBP. The study evaluated patients who were given TENS compared with a statistically matched group without TENS for one-year prior to intervention and for one-year of follow-up. Patients who were treated with TENS had significantly fewer hospital and clinic visits, used less diagnostic imaging, had fewer physical therapy visits, and required less back surgery than patients receiving other treatment modalities. Furthermore, TENS is non-invasive and non-narcotic, so it does not have the risks associated with other treatment approaches.

DJO Global indicates that this news supports its *Motion is Medicine* initiative, an effort to help patients restore motion and improve their lives by addressing four common areas: pain, alignment, strength and stability.

"Although most payors continue to pressure doctors to utilize more conservative care options, CMS [Centers for Medicare and Medicaid Services] decided in June 2012, to remove reimbursement for TENS as a treatment for chronic lower back pain," said Michael Minshall, senior director of Health Economics & Reimbursement, DJO Global, in the March 10, 2014 news release. "Medicare still has to treat and pay for those suffering from CLBP and may be overspending to achieve what is arguably poorer clinical outcomes that do not always relieve pain and discomfort."

Minshall told *OTW*, "Given the tightening healthcare budgets, surgeons have been thrilled to see that we are offering an effective conservative care option, namely, the MotionCARE Home Recovery Program. Those who suffer from degenerative disc disease and herniated disc now have a new option that can save them pain and possibly, a hospital stay."

—EH (April 1, 2014)

DJO Global, Inc.

Providence Medical Raises $6.8 Million for Cervical Fusion Launch

Providence Medical Technology, Inc. of Lafayette, California, just announced the closing of a $6.8 million Series C round of financing to advance the company's cervical fusion technology.

Providence Medical Technology, Inc.

The new funding, according to Providence CEO Jeff Smith, comes as the company is launching its DTRAX technology in the U.S. with over 15 independent distributors and over 150 sales representatives. "The acceptance of indirect decompression and fusion among surgeons who treat cervical radiculopathy has been extremely encouraging. With this investment to support execution of our business plan, we look forward to building a differentiated franchise."

Providence initiated U.S. surgeon training in November 2013 following 510(k) clearance earlier in the year of DTRAX Cervical Cage, a novel implant and delivery system for cervical fusion procedures.

Proceeds from this round are targeted to fund investment in U.S. sales, marketing, training, and clinical activities, including training additional distributors, hiring direct sales employees, and initiating prospective clinical trials.

DTRAX Spinal System

The DTRAX Spinal System is a set of single-use disposable instruments designed for use with a range of spinal implants. The system enables access to the spine through posterior surgical incisions, and preparation of the bony elements and joints. Spinal fusion with the system, according to the company, does not require removal of bone, soft tissue, or stabilizing ligaments.

In addition to the cervical cage, the company also offers DTRAX Graft, a structural allograft implanted in the cervical facets to support posterior fusion. When implanted, the graft provides an indirect decompression of the nerve roots by distracting the facets and opening the neuroforamen. They also have a sterile, single-use facet system kit containing all the tools and implants that are needed to perform a single level surgery. The system includes a proprietary, expandable, titanium implant that is used to provide indirect decompression and fusion of cervical facets.

The company previously announced that five U.S. patents have been issued in the past 12 months protecting their technologies, bringing the total number of U.S. patents issued to the company by the U.S. Patent Office to seven.

The most recent patent (U.S. Patent No. 8,623,054, "Vertebral Joint Implants and Delivery Tools," issued on January 7, 2014) describes, among other things, the company's methods and instruments for minimally invasively routing an implant into the spinal facet joint via a posterior approach.

Stanmore Medical Investments led the round through its MedVest Fund One, and was joined by Aphelion Capital and RCT Ventures.

—WE (April 2, 2014)

LEGAL

Device Recalls Double in Nine Years

The FDA says the number of recalled medical devices doubled from 604 in 2003 to 1,190 in 2012. Class I recalls, the most serious, rose from 7 in 2003 to 57 during that period.

While that overall 97% increase seems astronomical, Steve Silverman, director of the FDA medical device center's office of compliance, told The *Wall Street Journal* that the rate of recall lags industry growth.

Growing Device Market

U.S. medical device expenditures reportedly climbed by 112% from $73.7 billion in 2001 to $156.3 billion in 2010. The number of medical devices on the market grew by 25% from 2008 through 2012 alone.

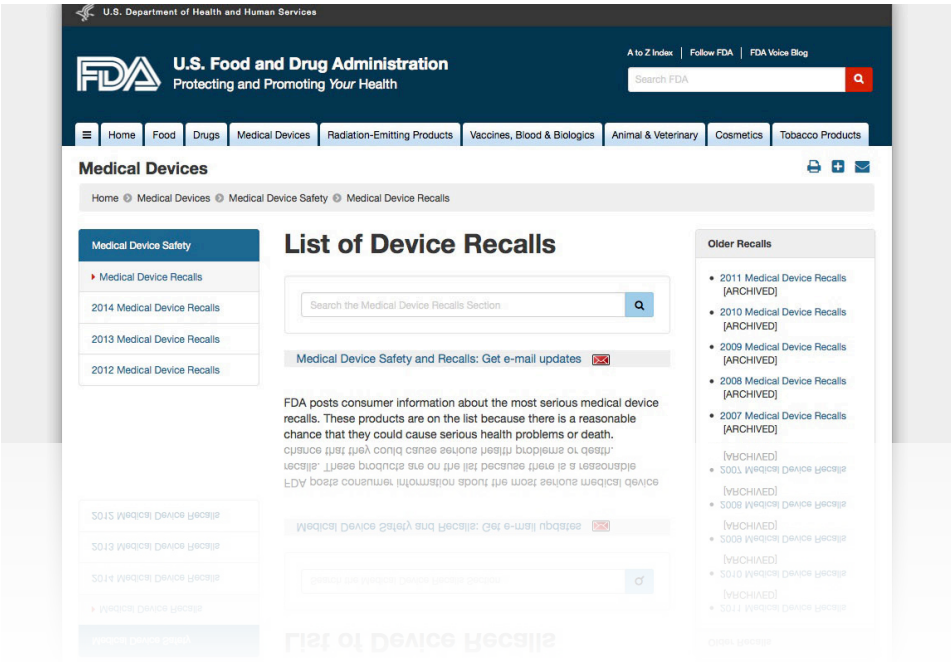
FDA Report

The FDA, in a report titled: "Medical Device Recall Report," attributes the increased number of recalls in part to improved reporting by vendors and to government and industry efforts to improve performance of devices with a history of problems, such as ventilators, infusion pumps and external defibrillators.

According to the report, device design, software and non-conforming material or component issues are the most common reasons for recalls. The FDA says that as many as 400 recalls each year might be prevented if government and vendors would work together.

Industry Segment Culprits

Two specific industry segments account for the majority of the observed increase in the number of FDA-classified recalls that occurred during the study period:



FDA

- Manufacturers of radiology devices; and
- Manufacturers that receive 21 CFR 806 observations following FDA inspections.

Procodes identify the generic category of a device for FDA and is based upon the medical device product classifications designated under 21 CFR Parts 862- 892. There are over 6,000 procodes. The most frequent device procodes for Class I recalls were:

1. FRN PUMP, INFUSION
2. MKJ AUTOMATED EXTERNAL DEFIBRILLATORS
3. CBK VENTILATOR, CONTINUOUS
4. NBW SYSTEM, TEST, BLOOD GLUCOSE, OTC
5. DYB INTRODUCER, CATHETER
6. LKK PUMP, INFUSION, IMPLANTED

Most of the Class I recalls were in the anesthesia, cardiovascular, chemistry, and general hospital specialties. The radiology, orthopedic, general hospital, and cardiovascular areas had the most Class II recalls.

Ortho Shines

The only orthopedic device that made it into the top ten of procodes recalls was:

- 96 JWH PROSTHESIS, KNEE, PATELLOFEMOROTIBIAL, SEMI-CONSTRAINED

Click here to read the entire report: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/UCM388442.pdf

—WE (April 1, 2014)

BIOLOGICS

Pluristem: Human Placental-Derived Stromal Cells Appear Promising

Pluristem Therapeutics, Inc. has announced that Dr. Scott Rodeo of Hospital for Special Surgery (HSS) has presented his research findings in a scientific poster titled, "Use of Human Placental-Derived Adherent Stromal Cells Improves Tendon Healing in a Preclinical Model of Tendon Injury."

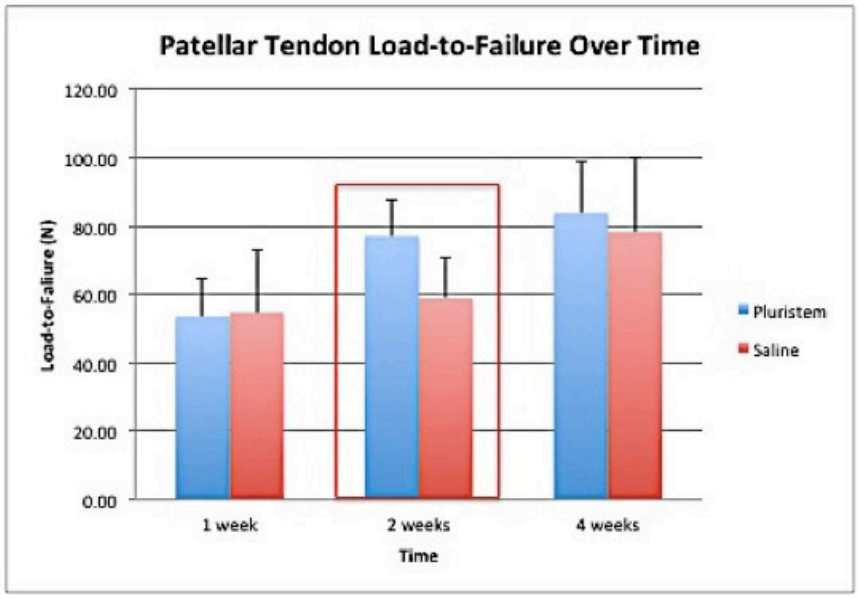
Dr. Rodeo's work has concluded that:

a) placental-expanded cell therapy appeared to have an early beneficial effect on tendon healing following collagenase injury in this preclinical model
b) since these cells are immunoprivileged and are expanded ex vivo, its potential for "off-the-shelf" use is attractive relative to existing cell-based therapies
c) additional preclinical studies are necessary to understand how these cells may affect tendon repair.

"Although our findings should be considered preliminary, adherent stromal cells derived from human placenta appear promising as a readily available cell source to aid tendon healing and regeneration," stated Dr. Rodeo in the March 12, 2014 news release. "These detailed preclinical results, as well as the favorable top-line results we announced from our Phase I/II muscle injury study in January, both validate our strategy to pursue advanced clinical studies of our PLX cells for the sports and orthopedic market," stated Pluristem CEO Zami Aberman.

Dr. Rodeo and his orthopedic research team at HSS studied the effects of Pluristem's PLacental eXpanded (PLX)-PAD cells in a preclinical model of patellar tendons that had sustained collagenase-induced injuries.

Dr. Rodeo told *OTW*, "I was surprised to learn that these cells would have



Pluristem Therapeutics, Inc. and Scott Rodeo, M.D.

an effect in our tendonosis model, as healing occurs spontaneously in small rodent models, making it difficult to improve on natural healing processes. Future work will need to optimize the dose and timing of cell application. Another avenue for future work will be to evaluate the effect of these cells in other application such as healing of a surgical tendon repair."

Asked what he was surprised to learn, Zami Aberman told *OTW*, "It was interesting to see that PLX-PAD cells have early beneficial effect on tendon healing, suggesting a better recovery from tendon injury. PLX-PAD is a real 'off the shelf' product (human cells injected to rats)."

Asked about future related work, Aberman commented, "We combined the pre-clinical data generated by Dr. Rodeo with our Phase 1/2 muscle injury study to define the best indication for our next clinical trial in the 'soft tissue' arena. Following the results of the analysis we will move into Phase 2 clinical study."

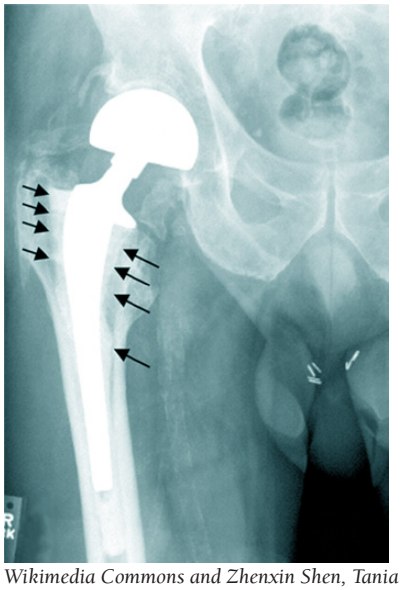
"My vision for Pluristem in 2015 is that the results from additional clinical studies will suggest that placenta derived cells are the superior cells for allogeneic cell therapy. We anticipate new clinical studies in new indication and additional out-license deals."

—*EH (April 2, 2014)*

LARGE JOINTS

HRT Cuts Revisions After Joint Surgery

People who keep track of such things in the United Kingdom estimate that doctors perform 90,000 hip replacements and 70,000 knee implant surgeries annually. Of these, at least 10% will eventually develop osteolysis post surgery. Osteolysis is an inflammatory reaction to particles of the implants in the surrounding bones.



Wikimedia Commons and Zhenxin Shen, Tania N Crotti, Kevin P McHugh, Kenichiro Matsuzaki, Ellen M Gravallese, Benjamin E Bierbaum and Steven R Goldring

When this happens, revision surgery is required. According to PR Web, a new study has discovered that hormone replacement therapy (HRT) can cut the risk of revision surgery in women by over 40%. A new led by the University of Oxford and published in the January *Annals of the Rheumatic Diseases*, analyzed data from almost 11,000 women across the UK who had received knee or hip replacement for the first time between the years 1986 and 2006.

More than 21,000 eligible women who met the criteria had not used HRT, while more than 3,500 had done so for at least six months. This provided matched samples of 2,700 HRT users and 8,100 women who had not used HRT. Researchers tracked the risk of repeat surgery in both sets of women for three years. They found that those who had taken HRT regularly for six months or more after their surgery were 38% less likely to require repeat surgery than were those who had not done so.

Those who regularly took HRT for 12 months or more after their procedure were more than 50% less likely to need further surgery during the three year monitoring period. Interestingly, the findings showed that taking HRT before surgery made no difference to the risk of implant failure. The implication of the study was clear. Those who want a better rate of success should follow their surgery with a course of hormone replacement therapy.

—BY (April 4, 2014)

Doc – When Can I Drive?

The hospital stay for hip joint replacement patients has steadily decreased from a week to a couple of days or even same-day surgery. But, the time between the hip surgery and when patients can get back in their cars and drive again has not changed—until now.

Ed Susman, writing for *Med Page Today*, reports that when doctors use minimally invasive surgical techniques their patients can safely return to driving two weeks earlier than current recommendations allow. Surgeons have long been aware that patients who undergo total hip replacements have decreased reaction time for a period following their surgery, making it unsafe for them to drive in the immediate post-operative period. Six weeks has been the standard surgeons' recommendation for waiting before resuming driving.

Geoffrey Westrich, M.D., director of research at the Hospital for Special Surgery, New York, decided to test that recommendation with a stimulator similar to those used in video games. The simulator showed that patients two and three weeks out from their hip surgery had not recovered their pre-operation driving skills. They were not safe drivers.

By four weeks following their surgery he found that 31 hip surgery patients improved their pre-operation driving reaction time from an average of 0.751 seconds to an average of 0.716 seconds by four weeks after their surgery.

Westrich then wondered if the kind of joint replacement surgery the patients experienced made a difference in their post-surgery reaction times. To find out, he and his associates enrolled 90 patients who had had hip replacement arthroplasty in a study and tested their reaction times both before and following their operations.

They divided the patients into three groups and tested them at two weeks, three weeks and four weeks following their surgery. The researchers recorded the amount of time it took for the subjects to switch from the gas pedal to the brake pedal after a stop sign appeared.

The 31 patients in the two-weeks-following-surgery group had an average reaction time of 0.862, which was more than their pre-operation time of 0.793 seconds.

The 28 patients in the three week test group had an average reaction time of 0.808 seconds after surgery compared with 0.798 seconds before surgery.

Susman quoted Westrich as saying, "We defined a return to safe driving reaction time as a return to a driving reaction time that is either the same as or better than the preoperative driving time. Observing reaction times revealed that at 2 and 3 weeks after surgery patients have not made a full recovery to their respective baseline reaction time and generally are not ready to drive."

But by four weeks, the patients not only had recovered their reaction times but had improved them. "Therefore," said the researchers," they can be cleared to drive."

—BY (April 4, 2014)

Wikimedia Commons and Lynthia Scott Eller

Canadians Cut Surgery Wait Time

Patients in Alberta, Canada with painful hips and knees are feeling good about their health service. The reason? The wait time for a joint replacement has dropped three weeks to 19.2 weeks thanks to a new Hip and Knee Replacement Program that was launched in 2010.

Wait time for surgery is not all that has changed. Over the same period, according to Markham Hislop, of the *Beacon News*, hospital stays dropped from 4.9 days for hip replacements and 4.6 days for knees to 4.1 days for both surgeries. The patient satisfaction rate went from 86% to 98% and the rate of hospital readmission following surgery, already low at 4.3%, dropped to 4.1%.

The man behind this improvement is Don Dick, M.D., Senior Medical Director of Alberta Health Services' Bone and Joint Health Strategic Clinical Network, which operates the program.

"This program has far exceeded our goals," Dick said. "It really is a win-win project. We are always focused firstly on improving care for patients but we also need to ensure we get the best value for our health care dollars and help make our system sustainable. The hip and knee replacement program does both."

Hislop noted that the reductions in the length of hospital stay have freed up about 33,000 days of hospital bed space since 2010, enabling the Alberta Health Service to perform more than 1,600 additional hip and knee surgeries with the same bed capacity.

Health Minister Fred Horne said, "As a government, we're committed to improving the performance of our health care system and today's update on hip and knee surgeries shows that we're moving in the right direction. I'm sure this is welcomed news for the many Albertans that have this type of surgery every year and are able to get back to their normal lives sooner because of this program."

—BY (April 4, 2014)

Wikimedia Commons and Rob Brewer

Doctor Does 331 Surgeries in 31 Days

The name of Manuj Wadhwa, M.D., head of the Department of Orthopaedics & Joint Replacement at Max Super Specialty Hospital, Mohali, India, has gone into the Limca Book of Records. His achievement? Performing 331 joint replacement surgeries in 31 days in March 2014. Wedhwa is a specialist in the reconstruction of adult knee, hip, elbow and shoulder joints as well as computer assisted and CT based surgery in arthroplasty.

Courtesy of Manuj Wadhwa, M.D.

Wadhwa studied at The Ranawat Adult Joint Reconstruction Fellowship at Lenox Hill Hospital, New York, with C. S. Ranawat, the surgeon of former Prime Minister, Atal Bihari Vajpayee. He also received specialty training in joint replacement at leading hospitals in Europe, the U.S. and in India.

Wadhwa recalled that when he was working abroad his parents asked him to serve the ailing population in India as they were 'our people first.' "For me, the most rewarding moments were when patients would realize that the pain in their joints is now a thing of the past and they can go back to lead a healthy life," he said.

—BY (April 4, 2014)

EXTREMITIES

ACL Surgery Can Lead to Osteoarthritis

It may seem a little unfair, but a study by Olle Mansson, M.D., of NU-Hospital Group in Uddevalla, Sweden has found that adolescents who have an anterior cruciate ligament (ACL) reconstruction are more likely to demonstrate osteoarthritic changes later in life.

"Long-term follow-ups after the surgical treatment of ACL injuries in kids are rare and this is one of the few studies that has been able to track individuals," said Mansson who is the lead author of the study.

The study, reported by *News Medical*, assessed 32 patients, aged 12 to 16 years old, at a period of 10 to 20 years after their initial ACL reconstruction using bone-patellar bone-tendon or hamstring tendon autograft.

Twenty-nine patients underwent clinical, radiographical and health-related quality of life assessments after 10 to 20 years .The results revealed significant osteoarthritic changes on the reconstructed knee (65%) compared to the non-involved knee (14%). Quality of life and other health related scores were the same or comparable to those seen in healthy controls.

Mansson agreed that early reconstruction of ACLs is often the choice for young more skeletally mature athletes to restore knee stability and prevent progressive meniscal and/or articular cartilage damage. These procedures, he noted, allow individuals to return to the playing field and continue an active lifestyle. However, Mansson said, "it is still important to evaluate long-term effects such as osteoarthritis when considering surgeries for these pediatric patients."

—BY (April 4, 2014)

Wikimedia Commons and Pasm

REIMBURSEMENT

New CPT Code for 2-Level Cervical Disc Replacement

The American Medical Association (AMA) CPT Editorial Panel has added a new Category I CPT code for two-level cervical total disc arthroplasty. The code will go into effect January 1, 2015.

The Current Procedural Terminology (CPT) code set is a medical code set maintained by the AMA. The code set describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes.

American Medical Association

CPT coding is similar to ICD-9 and ICD-10 coding, except that it identifies the services rendered rather than the diagnosis on the claim.

Category I CPT codes are assigned to procedures that are deemed to be within the scope of medical practice across the U.S. In general, such codes report services whose effectiveness is well supported in the medical literature and whose constituent parts have received clearance from the FDA.

The AMA Relative Value System Update Committee (RUC) will now develop value recommendations for the code. Once the RUC has approved the value recommendations, they will be forwarded to the Centers for Medicare and Medicaid Services (CMS) for consideration in the 2015 Medicare physician fee schedule.

William Watters III, M.D., the president of the North American Spine Society, wrote his members on March 3, 2014 to say that after a review of the proposal from NASS regarding a new code, the AMA CPT Editorial Panel added the code and revised the existing Category III CPT code to describe disc arthroplasty performed at three or more levels.

"These changes will allow for accurate reporting of additional levels and will preserve the ability to obtain a Category I code for three or more level arthroplasty in the future as more literature becomes available," Watters stated in the letter.

—WE (April 2, 2014)

Doctors Held SGR Hostage: Year 11

Call it political Münchausen syndrome by proxy.

Molly Cooke, M.D., FACP, president of the American College of Physicians (ACP) said Congress was holding healthcare for seniors, military families, and disabled persons on Medicare and TriCare "hostage."

For the seventeenth time in 11 years, Congress has acted at the last minute to save the patient made sick by their own required 24% cuts to Medicare payments to physicians called for by the Medicare Sustainable Growth Rate (SGR) funding formula. This time the temporary cure includes year-long delays to the cuts, the implementation of the ICD-10 medical coding set and the so-called 2-midnights rule. The new law also includes an 18-month hiatus for RACs (Recovery Audit Programs).

Physicians will see a 0.5% increase in payments during the next year.

The hostages will now be held until April Fool's Day in 2015. Ironic.

Physicians Upset

Physicians are particularly upset this time because an affordable permanent fix had been agreed to by a bipartisan group of congressional leaders. With midterm elections at hand and the next presidential campaign on the horizon, neither political party will have any incentive to act boldly on any issue.

The American Medical Association's President Ardis Dee Hoven, M.D., said the association, "is deeply disappointed by the Senate's decision to enact a 17th patch to fix the flawed formula. Congress has spent more taxpayer money on temporary patches than it would cost to solve the problem for good."

RRY Publications LLC

AdvaMed Applauds

While physicians were upset, AdvaMedDx, a division of AdvaMed, the device industry trade association, was downright giddy, applauding the legislation because it included diagnostic payment reforms.

The House took a voice vote on the bill on Thursday, with no debate and no record of how votes were cast. The Senate, over the objections of most physician organizations, passed the bill on March 31, 2014. The Senate voted 64-35 to delay the cuts. Fifteen Republicans voted with Democrats in favor of the delay while six Democrats voted against it.

None of this came as a surprise as Republican support in the House for SGR repeal began to crumble over where the $122 billion to pay for the fix would come from. They insisted Democrats in the Senate and President Obama delay implementation of Obamacare for five years and use those funds to pay physicians.

ICD-10 Delay

Sharon F. Canner, senior director of Public Policy at the College of Healthcare Information Management Executives said the ICD-10 delay was put in the bill as a sop to specialty physicians' groups who were upset that the chance for a permanent fix had been wasted. "It was something they were unhappy with and so they came to the leadership and asked them to pull this," Canner says.

The ICD-10 deadline had already been pushed back one year to 2014, and CMS (Centers of Medicare and Medicaid Services) has estimated that the cost of delaying it another year could range from $1 billion to $6 billion.

Hospitals Cheer, Watchdogs Howl

The hospitals cheered the delay of the 2-midnights rule until March 31, 2015.

The suspension of the RAC program was criticized by the taxpayer watchdog organization, the Council for Citizens Against Government Waste. The council said CMS had already suspended recovery audit contractor post-payment reviews for the past six months. A year-long extension of the suspension of the program would cost taxpayers billions of dollars in undetected overcharges to hospitals and other providers.

According to CMS, spending on Medicare totaled about $580 billion in 2012 for 49 million beneficiaries. Spending is projected to reach $1.123 trillion in 2022.

—*WE (April 1, 2014)*

Orthopedics This Week | RRY Publications LLC

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

WRITERS

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

Walter Eisner
Senior Writer
walter@ryortho.com

Biloine W. Young
Senior Writer
bgwy@msn.com

ADVERTISING

Tom Bishow
Vice President of Sales
tom@ryortho.com

PRODUCTION

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Email, Web, & Conference Coordinator
jayme@ryortho.com

Dana Bader
Graphic Designer
dana@ryortho.com

---

116 Ivywood Lane • Wayne, PA 19087
TOLL FREE: 1-888-749-2153
www.ryortho.com