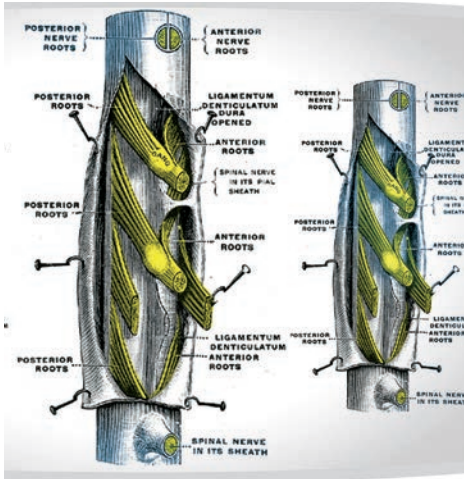
VOLUME 8, ISSUE 26 | AUGUST 14, 2012

Orthopedics This Week

week in review



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: Rumblings on Wall Street are that the Fed will launch a fresh round of bond buying to lower the U.S. unemployment rate more quickly. In other words, if there is no fiscal stimulus, look for monetary stimulus. The rally since June has benefited ortho stocks—which are still considered defensive. With both Japan and China reporting weaker-than-expected growth, this market looks fatigued.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Johnson & Johnson	25.40%	1.59%	One big reason JNJ remains at the top of the Power Rankings is its mix of high dividend yield and growth.
2	2	Smith & Nephew	21.36	5.48	SNN beat Wall Street's earnings estimate for Q2. Big stock jump this week.
3	3	Integra LifeSciences	13.36	1.80	IART also beat Wall Street's earnings expectations for Q2. U.S. spine, neuro, extremities, et al. up 13%. Decent.
4	5	Orthofix	16.23	(1.00)	What a difference a quarter makes. Total debt chopped nearly in half. Cash nearly has high as current liabilities.
5	6	Symmetry Medical	5.63	4.56	Sales mix changing faster than arms and legs in a Twister game. Direct sales up 3x, OEM down 13%.
6	7	Medtronic	28.65	1.95	China Daily says that MDT going on a Chinese buying spree. And, says local Prez Simon Li, candidates already identified.
7	4	ArthroCare	(0.80)	(2.58)	Wall Street broker Piper pushes ARTC. Says shares are cheap. Agreed. But where's the catalyst?
8	8	Zimmer	26.37	(8.76)	Zimmer crunched Genzyme (aka Sanofi) over Synvisc—which is actually a pyrrhic victory.
9	9	Stryker	23.68	(3.53)	SYK is now the 5th least expensive stock in orthopedics. Used to be a perennial premium priced company.
10	NR	Exactech	7.68	(3.79)	24% pop in extremity sales; 10% increase in hip sales. Both pulled overall sales up 7%.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	$1.52	$65	13.43%
2	Symmetry Medical	SMA	$8.79	$322	7.99%
3	Medtronic	MDT	$40.26	$41,268	5.89%
4	Smith & Nephew	SNN	$52.39	$9,408	4.57%
5	TiGenix	TIG.BR	$0.61	$56	4.51%
6	Integra LifeSciences	IART	$39.70	$1,073	4.36%
7	RTI Biologics Inc	RTIX	$3.73	$208	3.61%
8	Orthofix	OFIX	$41.86	$794	1.82%
9	TranS1	TSON	$2.65	$72	1.53%
10	Johnson & Johnson	JNJ	$68.64	$189,243	1.09%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	NuVasive	NUVA	$20.26	$881	-16.80%
2	Tornier N.V.	TRNX	$18.04	$714	-16.56%
3	Alphatec Holdings	ATEC	$1.57	$141	-10.80%
4	Conmed	CNMD	$26.59	$756	-6.08%
5	Zimmer Holdings	ZMH	$61.37	$10,721	-2.99%
6	Wright Medical	WMGI	$19.68	$780	-2.57%
7	ArthroCare	ARTC	$28.85	$800	-0.41%
8	Stryker	SYK	$53.06	$20,186	0.00%
9	CryoLife	CRY	$5.06	$139	0.40%
10	MAKO Surgical	MAKO	$14.65	$625	0.48%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$40.26	$41,268	12.13
2	Zimmer Holdings	ZMH	$61.37	$10,721	12.13
3	Johnson & Johnson	JNJ	$68.64	$189,243	13.62
4	Stryker	SYK	$53.06	$20,186	13.64
5	Orthofix	OFIX	$41.86	$794	14.29

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$19.68	$780	75.69
2	NuVasive	NUVA	$20.26	$881	61.39
3	Symmetry Medical	SMA	$8.79	$322	51.71
4	RTI Biologics Inc	RTIX	$3.73	$208	20.72
5	Exactech	EXAC	$16.71	$222	20.63

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$41.86	$794	0.93
2	ArthroCare	ARTC	$28.85	$800	1.22
3	Zimmer Holdings	ZMH	$61.37	$10,721	1.26
4	Stryker	SYK	$53.06	$20,186	1.30
5	Conmed	CNMD	$26.59	$756	1.40

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$19.68	$780	8.98
2	NuVasive	NUVA	$20.26	$881	7.73
3	Symmetry Medical	SMA	$8.79	$322	4.31
4	CryoLife	CRY	$5.06	$139	4.22
5	Smith & Nephew	SNN	$52.39	$9,408	3.72

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.57	$141	0.71
2	Symmetry Medical	SMA	$8.79	$322	0.90
3	Conmed	CNMD	$26.59	$756	1.04
4	Exactech	EXAC	$16.71	$222	1.08
5	CryoLife	CRY	$5.06	$139	1.16

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.61	$56	48.88
2	MAKO Surgical	MAKO	$14.65	$625	7.40
3	TranS1	TSON	$2.65	$72	3.77
4	Globus Medical	GMED	$13.90	$1,240	3.74
5	Johnson & Johnson	JNJ	$68.64	$189,243	2.91

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

Now That Globus Is Public

By Robin Young

Courtesy of Globus Medical Inc.

Welcome to the fish bowl. In the first eight days since putting itself up for public scrutiny Globus Medical, Inc.' value has risen 13% or $110 million. Globus, says Wall Street, is worth $1.2 billion, which makes this company the most valuable public pure spine company in the world. Here's the short list:

Company Name	Stock Symbol	Market Value in $000 (as of 8.10.12)	Trailing 12-Month Sales	Trailing 12-Month Earnings in $000 [1]
Globus Medical, Inc.	**GMED**	**$1,221,000**	**$347,916**	**$63,929**
NuVasive, Inc.	NUVA	$880,700	$589,184	$9,956
Alphatec Spine, Inc.	ATEC	$140,500	$196,452	($21,575)
TranS1, Inc.	TSON	$70,840	$17,805	($18,263)

[1] *Q1 2012 plus the last three quarters of 2011 for GMED, does not include tax expense for Q1 and Q2 2011 for NUVA, includes non-recurring expenses for Q3 and Q4 for ATEC.*
Source: RRY Publications LLC

To put more perspective on Globus' performance, here are two more data points:

- The last broad line spinal implant company to go public was Alphatec. In that company's first week as a public company, Wall Street pulled it down approximately 19% from $9.00 per share to $7.29 per share. In that underwriting, Alphatec's owners had expected to sell these shares for prices between $13-$15, but in the face of meager demand management agreed to re-price to an $11-$12 range only to have to drop *that* price to $9 per share in order to clear the market. Unfortunately, not even that number held. Today, Alphatec's stock is trading at $1.58 per share although, by virtue of increasing the number of shares outstanding 170% from 33 million in 2006 to 89 million in 2012, ATEC's market value is $140 million. Alphatec's value today is underwater 53% from the $300 million its owners had expected to receive from the public market six years ago.
- Sofamor Danek, the company that became the largest supplier of spinal implants in the 1980s and has stayed at the top ever since, sold to Medtronic, Inc. in 1998 for $3.6 billion.

When viewed against those two historic extremes of spinal implant companies, nine-year old Globus's accomplishment are particularly impressive.

What's Next?

If Globus' past is any indication, what happens next is that growth accelerates. NuVasive and Alphatec both benefited in the marketplace from the exposure of Wall Street. There is a certain glow that comes from being in the public stock

arena and surgeons do take notice. Booth traffic will pick up. Sales reps find that access improves.

We expect that there could a massive sales distributor/person recruitment effect from this IPO. The underwriting has been successful and that aura of success will attract distributors who want to jump on a bandwagon that, most people expect, will result in an acceleration of product development—either organic or by acquisition. Furthermore, if distributors get a sense that Globus could start buying other spinal implant firms, it will be better to get on board now than to have to fight for a place post-deal some day.

Furthermore, Globus has the ability to, in effect, print money in the form of publically traded stock. People who print dollar bills go to jail. But companies who print stock certificates get on the cover of *Business Week*. At $13.50 per share and with 500 million Class A common shares authorized (437 million still unissued); Globus has a theoretical $5.9 billion in dry powder.

So, while sales people in the field will see the wind pick up at the their backs, senior management, with their new financing tool, will have the capability to make product, technology or even corporate purchases at levels that could push Globus to challenge Medtronic or DePuy Synthes Spine in terms of sales force size or scope of product lines.

The other aspect which distinguishes Globus is the company's profitability.

For the first three months of this year, Globus reported $28 million in operating profit on sales of more than $97 million. Globus earns approximately 29 cents on every sales dollar. To Wall Street those kinds of numbers translate into a measure of management's operating abilities—which in their minds are eminently transferable to other companies. So if Globus goes on a shopping spree and overlays these perceived management skills on other, poorer performing spinal implant companies, Wall Street will likely cheer. In the view of Wall Street, Globus can buy sales with a premium priced security; apply its managerial expertise to squeeze new profits out of those sales and in the process drive a rising rate of earnings growth.

Fully Exposed

But of course, CEO David Paul and his team are now in the fish bowl. Until the 11th of September, he and his team have a bit of a respite during the Securities and Exchange Commission's 40 calendar day "quiet period" following an initial public offering. For now, Wall Street's chattering crowd is not allowed to make comment. After that, however, the opinions will come tumbling in from analysts, traders, hedge fund cowboys and mutual fund managers.

The analysts that will almost certainly be writing about Globus are:

Name	Brokerage Firm	Other Spine/Ortho Companies Covered	Total Size of Coverage Universe	Overall Earnings Accuracy and Star Rating
Bob Hopkins	Bank of America/ Merrill Lynch	NuVasive, Stryker, Zimmer, Tornier NV, Medtronic, JNJ	14	Not ranked
David Roman	Goldman Sachs	NuVasive, Stryker, Zimmer, MAKO, Medtronic	20	4 Stars
Matt Miksic	Piper Jaffray	NuVasive, Alphatec, TranS1, Stryker, Zimmer, Tornier, Wright Medical, Conmed, Integra, MAKO, Orthofix, Symmetry, ArthroCare	19	Not Ranked
Richard Newitter	Leerink Swan	NuVasive, Stryker, Zimmer, MAKO, Wright Medical	15	4 Stars
Bill Plavonic	Cannacord Genuity Adams	NuVasive, Alphatec Spine, Stryker, Zimmer, Exactech, MAKO, RTI Biologics	20	4 Stars
Matthew O'Brien	William Blair & Company	NuVasive, Stryker, Zimmer, MAKO, Bacterin, Tornier, ArthroCare, Wright Medical	13	Not Ranked
Stephen Lichtman	Oppenheimer & Co.	Stryker, Zimmer, Integra, Medtronic, Wright Medical, MAKO	13	4 Stars

Source: RRY Publications LLC

With the exception of Stephen Lichtman at Oppenheimer, all of Globus' new analysts also cover NuVasive. Again, with the exception of Lichtman, all have experience covering spinal implant companies. Of this group, Piper's Miksic covers the most spinal implant companies and will, we expect, write the most about Globus' ability to differentiate itself from other companies.

Only one of these analysts is considered a "Star" analyst for the other comparable spinal implant companies—NuVasive or Alphatec—and that is Bill Plovanic. The other star analysts for spinal implant companies are:

- Glenn Novarro with RBC Capital Markets
- Christopher Pasquale with JP Morgan
- Raj Denhoy with Jefferies & Co.
- Spencer Nam with Thinkequity
- Joanne Wuensch with BMO Capital Markets
- JT Haresco with JMP Securities
- Jeff Johnson with Robert W. Baird & Co.

Star analysts are those who've demonstrated over the course of the previous two fiscal years and four quarters to have issued the most accurate earnings estimates for the companies that they cover.

Will any of these other spinal implant company star analysts write about Globus? Absolutely. How could they not? In spine, two public companies now dominate—NuVasive and Globus.

Globus starts with seven analysts writing research reports and issuing sales and earnings forecasts. That's about one third the number that cover NuVa-

sive (23 analysts) and about the same number as follow Alphatec and twice as many as follow TranS1. Before the end of this year, we would expect that the number of analysts covering Globus will rival NuVasive.

What will these analysts say? Here's our guess:

1. More than half will put a "buy" rating on Globus' stock
2. The average one year target price will be around $19.00
3. And the key points will likely be:
   a. Higher-than-average sales growth (20% for Globus, 16% for NuVasive—off of a higher base, 1% for Alphatec).
   b. Very high comparable profit margins currently, but a growing risk that those margins will moderate in the face of overall spinal implant pricing pressure.
   c. Avenues for new growth (M&A, International expansion, new technologies)/
   d. Differences between NuVasive's direct sales approach and Globus' higher dependence on distributors.
   e. M&A discussion and the role that Globus might play in a consolidation of spinal implant industry.

Final Thoughts

As we documented a couple years ago, NuVasive has traded in a premium space virtually by itself since it came public in 2004. The orthopedic equity markets have pretty neatly divided implant and instrument suppliers into three categories in terms of valuation—under performers, average performers and one premium performer—NuVasive. Globus, we think, is different. Certainly the company has joined NuVasive in the higher valuation category. Sixteen orthopedic companies (out of 21) are less expensive than NuVasive or Globus in terms of P/E ratios or Price-to-Sales ratios or P/E to Growth Rate ratios.

But there is, we think, something else in the character of Globus Medical that may well make this company one of the most dynamic companies in orthopedics generally. Now that David Paul & Co. are public with a strong underlying security, the door is opened to some potentially interesting strategic moves. We, like most observers, are fascinated to see what might come next. ♦

Medicare Raises Ortho Reimbursement by 4.4% in 2013

By Walter Eisner

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In spite of Medicare's trustees reporting in April that the hospital trust fund will be insolvent in about 12 years, the Centers for Medicare and Medicaid Services (CMS) announced on August 1 that it will increase what the agency will pay hospitals for orthopedic related surgeries in 2013 by, on average, a whoppin' 4.4%.

The update applies to approximately 3,400 acute-care hospitals. More on the reimbursement rates for specific orthopedic and spinal procedures below.

Overall Medicare Payments Up 2.8%

Overall, CMS will increase IPPS (Inpatient Prospective Payment System) operating payment rates by 2.8%. Last year, CMS only raised the rates by 1.8%. This reflects an increase of 2.6% for the hospital market basket adjusted by a multi-factor productivity adjustment of -0.7 percentage point and an additional -0.1 percentage point in accordance with the Affordable Care Act; this is, according to the agency, increased by 1.0% for documentation and coding adjustments.

DRGs, SGR and Sequestration

Payments to surgeons for specific procedures are based on Medicare's payments to hospitals as well as direct payments for physicians' services on behalf of the patient by Medicare. This year, this complicated mix of payments takes place in a political environment governed by Medicare Severity Diagnosis Related Groups (MS-DRGs), the sustainable growth rate (SGR) and sequestration.

Each year CMS updates its pay schedule for MS-DRGs for inpatient stays in acute care hospitals under the IPPS. CMS gets a bucket of money from Congress and then begins an allocation process that weighs the "value" of one type of procedure against another. As more procedures and technologies are approved for coverage by CMS, the more the agency must spread a finite amount of money over more hospitals, care providers and patients.

Until 2008, discharges were classified into one of 538 CMS diagnosis-related groups (DRGs). In 2008, CMS replaced the 538 DRGs with 745 MS-DRGs that provide higher payments for more severely ill or injured patients and lower payments for all other cases. Since 2008, CMS has modified these MS-DRGs bringing the current total number of MS-DRGs to 751.

Physician reimbursements are based on the SGR. Without Congressional intervention, the SGR required Medicare to cut payments to physicians by more than 27% in January. The large cut is required because Congress has continually overridden smaller cuts over the years. To keep the SGR on schedule, the Congressional overrides must be made up in January.

No serious public policy observer believes that the government will cut physician reimbursements by 27% in January and a new Congress will, once again, override the mandated cuts.

On top of this looms the specter of "sequestration."

You might recall that after the midterm elections in 2010, a new class of legislators demanded that the U.S. Government not raise its debt ceiling. By refusing to approve a higher debt limit, the federal government's creditors were facing the unthinkable— a U.S. Government debt default. In order to reach a compromise between Republicans in the House, Democrats in the Senate and the White House, the people's representatives agreed that unless a "Supercommittee" came up with about $1 trillion in cuts, there would be, among others things, a 2% cut to Medicare in January 2013.

Medicare Insolvency

Medicare's trust fund's expenditures have exceeded its income each year since 2008. Despite projections that over the next 10 years the fund's expenditures will grow by an annual average of 5.3% and its income by an average 6%, the fund is expected to have enough revenue by 2024 to pay only 87% of projected costs for that year.

So given these mandated draconian cuts (which no one believes will happen) and the looming insolvency of the Medicare Trust Fund, the 4.4% increase in payments for orthopedic and spinal procedures looks remarkably generous.

Market Impact

Mizuho Securities analyst Mike Matson says the increase in rates is a small positive. In his view the increase is unlikely to have a huge impact on pricing dynamics. "Medicare reimbursement has risen by several percent per year for the past few years but pricing pressure has worsened despite these increases. "

"Reimbursement levels are just one out of a number of factors that affect prices, and we do not view the final 2013 reimbursement increases as significant enough to change the pricing trends that are being driven by weaker product cycles, an increase in the number of physicians working for hospitals and hospital cost-cutting in anticipation of healthcare reform and *sequestration*."

Spine Up 4%

During the government's fiscal year 2013, which begins October 1, spinal fusion payments will be up about 4% over 2012, with vertebral augmentation pay up by nearly 5%.

MS-DRG	Procedure	Final FY13	CAGR FY08-13	% Change vs. FY12
453	360 degree fusion (dual incision) with MCC	$61,179	**6.1%**	**(0.5%)**
454	360 degree fusion (dual incision) with CC	$45,027	4.9%	9.1%
455	360 degree fusion (dual incision) without MCC/CC	$33,898	2.0%	6.6%
	Weighted Average 360 Degree Fusion	**$43,364**	**4.1%**	**6.0%**
456	Lumbar/thoracic fusion for curvature, malignancy, or >9 levels with MCC	$54,973	8.6%	(0.5%)
457	Lumbar/thoracic fusion for curvature, malignancy, or >9 levels with CC	$37,054	4.7%	3.7%
458	Lumbar/thoracic fusion for curvature, malignancy, or >9 levels without MCC/CC	$28,577	1.4%	0.4%
	Weighted Average Complex Lumbar Fusion	**$38,299**	**5.1%**	**1.4%**
459	Lumbar/thoracic fusion with MCC	$37,758	7.6%	3.3%
460	Lumbar/thoracic fusion without MCC	$22,394	3.6%	3.1%
	Weighted Average Lumbar/Thoracic Fusion	**$23,311**	**3.9%**	**3.3%**
471	Cervical fusion with MCC	$27,182	7.8%	6.2%
472	Cervical fusion with CC	$16,192	3.9%	3.0%
473	Cervical fusion without MCC/CC	$12,273	3.2%	4.7%
	Weighted Average Cervical Fusion	**$14,374**	**4.3%**	**4.6%**
490	Back/neck procedure with MCC/CC or motion preservation device	$10,483	5.5%	3.5%
491	Back/neck procedure without MCC/CC	$5,979	2.0%	5.5%
	Weighted Average Back/Neck Procedure	**$7,510**	**4.1%**	**4.5%**
515	Vertebroplasty/kyphoplasty with MCC	$18,957	7.2%	4.1%
516	Vertebroplasty/kyphoplasty with CC	$11,401	2.9%	2.2%
517	Vertebroplasty/kyphoplasty without MCC/CC	$9,104	3.6%	3.9%
	Weighted Average Kyphoplasty/Vertebroplasty	**$11,912**	**5.7%**	**4.6%**

Source: Mike Matson, Mizuho Securities USA Inc.

Wells Fargo analyst Larry Biegelsen says companies with the most exposure to spine fusion include: NuVasive, Inc. (93% of revenue), Orthofix International NV (26%), Medtronic, Inc. (20%), Stryker Corporation (8%) and Zimmer Holdings, Inc. (5%). Medtronic, Smith & Nephew plc and Stryker all sell vertebroplasty kits.

Large Joints

Large joint payments will be up by about 4%, and trauma rates will be up by 3-4%. The final rates reflect about 0.5% to 1% increases over the proposed rates announced last spring by the agency. *(See Table Page 11)*

Biegelsen said of the companies with the most exposure in hips and knees include: Zimmer (72% of revenues), Smith & Nephew (39%), Stryker (31%) and Depuy Synthes Companies (4%).

Rate Timeline

Key orthopedic DRGs have risen slowly since 2008. *(See Line Chart Page 11)*

Quality Reporting

In addition to a rate update, CMS also addresses policy issues.

Payment rates for inpatient stays in general acute care hospitals paid under the IPPS that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program will be increased by 2.8%. Those that do not successfully participate in the IQR Program will only receive an increase of 0.8% (i.e., a 2.0 percentage point reduction).

No New Ortho Technology Add-Ons

To remove barriers to access for costly new technologies that are not yet fully reflected in the current MS-DRG payment rates, the Medicare law provides for temporary add-on payments for inpatient stays that involve the use of certain approved new technologies. CMS is approving new technology add-

MS-DRG	Procedure	Final FY13	CAGR FY08-13	% Change vs. FY12
466	Revision hip/knee with MCC	$28,916	**8.7%**	**2.9%**
467	Revision hip/knee with CC	$18,776	4.8%	2.9%
468	Revision hip/knee without MCC/CC	$15,053	2.6%	3.6%
469	Hip/knee replacement with MCC	$19,746	6.6%	1.6%
470	Hip/knee replacement without MCC	$12,099	2.5%	2.8%
	Weighted Average Hip/Knee Replacement	**$13,074**	**3.1%**	**3.3%**
461	Bilateral hip/knee replacement with MCC	$28,330	6.5%	(6.8%)
462	Bilateral hip/knee replacement without MCC	$19,485	3.1%	3.7%
	Weighted Average Bilateral Hip/Knee Replacement	**$19,927**	**3.3%**	**2.5%**
480	Femoral fracture fixation with MCC	$17,535	6.3%	1.9%
481	Femoral fracture fixation with CC	$11,170	2.3%	3.9%
482	Femoral fracture fixation without MCC/CC	$9,042	1.4%	3.6%
	Weighted Average Femoral Fracture Fixation	**$11,926**	**3.7%**	**4.2%**

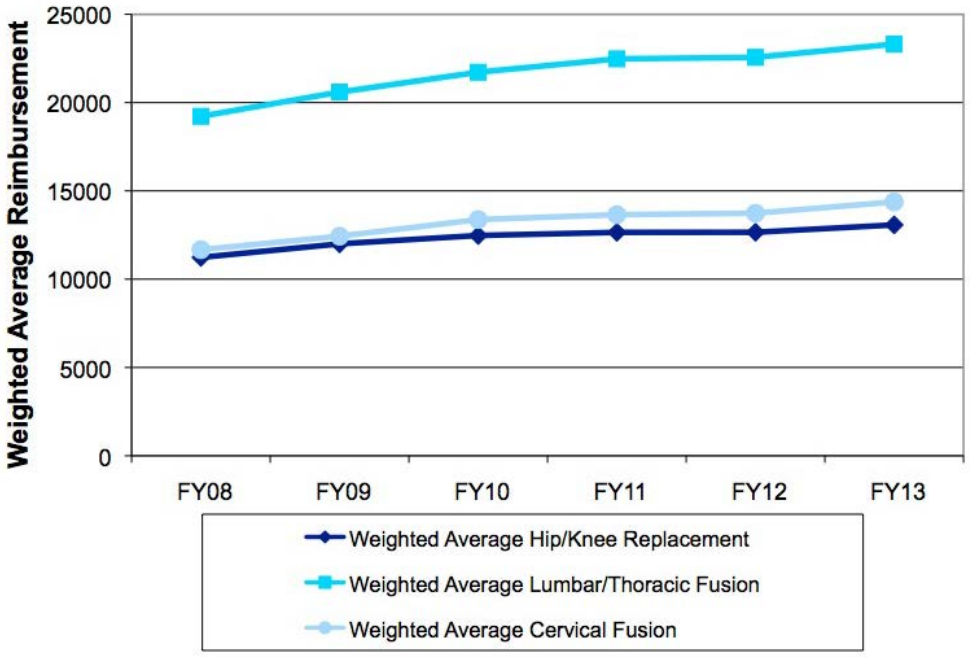
Source: Mike Matson, Mizuho Securities USA Inc.

on payments for three applications, glucarpidase (Voraxaze), fidaxomicin (DIFICIDTM), and the Zenith Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft.

Primary Care versus Specialties

A CMS fact sheet accompanying the IPPS update stated that the agency anticipates that payments to many non-primary care specialties will likely decrease under the proposed rule. As a corollary, primary care physicians would likely find that their payments would increase under the proposed rule.

The fact sheet also noted the agency estimates that payments to family care physicians would likely rise 7% and other primary care physicians would also experience a payment increase—although at a smaller 3-5% rate.



Source: Mike Matson, Mizuho Securities USA Inc.

X-Ray Services

The new IPPS payment rule expands the list of professionals that can order Medicare-covered portable X-ray services. The rule revises the conditions of coverage in order to allow non-physician practitioners and limited-license physicians to order portable X-ray services, consistent with state licensure rules.

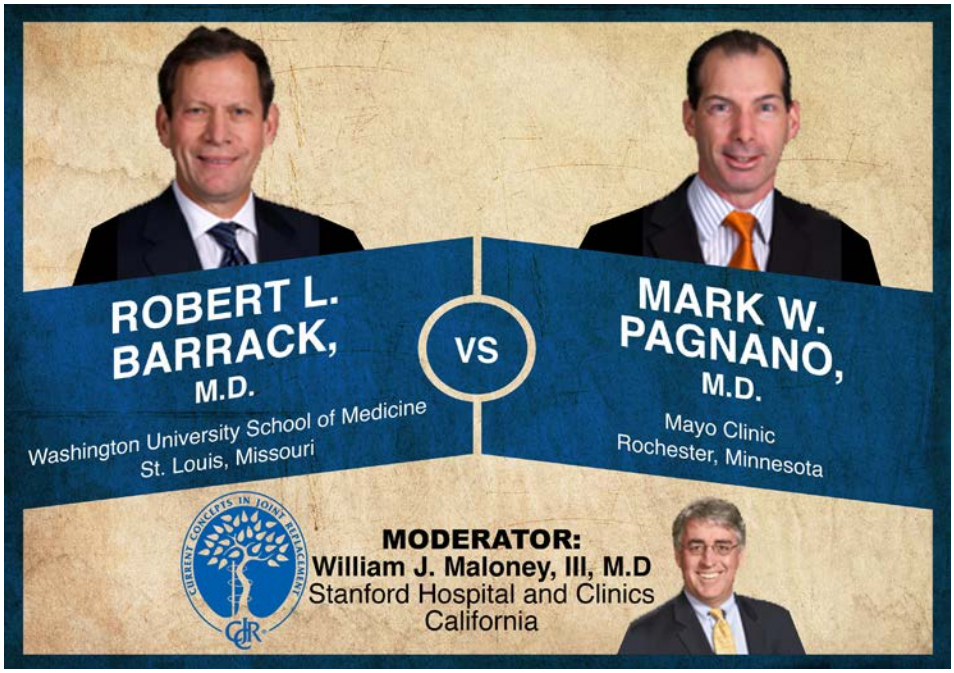
Providers may not know how Congress will fix mandated cuts in January, but for now they know what they will be paid by Medicare. ♦

Barrack vs. Pagnano: Do Patient-Specific Guides Work?

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

"Patient specific guides aren't ready for primetime," says Robert Barrack, "And being within three degrees…that probably doesn't make a difference. "Wait," counters Mark Pagnano, "In a select subgroup of surgeons these guides are ready for primetime."

This week's Orthopaedic Crossfire® debate is "Patient Specific Cutting Blocks: Of Unproven Value." For the proposition was Robert L. Barrack, M.D. from the Washington University School of Medicine in St. Louis. Against the proposition was Mark W. Pagnano, M.D. from Mayo Clinic in Rochester, Minnesota; moderating was William J. Maloney, III, M.D. from Stanford Hospital and Clinics in California.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Barrack: "I use these, and I think they have promise. But they're not there yet. Variability in component alignment…in the short term it leads to complications; in the long term it leads to earlier revision. After 15 years, I don't think navigation has had a major impact. The newer approach is patient-specific instrumentation (PSI). You get an MRI or CT, generate a model of the patient's lower limb, and produce the patient-specific instrument, which actually is a cutting guide. All approved devices in the U.S. target neutral alignment, so they're not patient-specific in that they all target the same alignment goal."

"We've done a couple of studies that were just published, one on OR efficiency, one on accuracy and elimination of outliers. We used the same cemented CR knee in all cases. It's over 200 knees, 100 in each group that are comparable, by a single surgeon."

"With this component its posterior flange wedge holes allow the technician to center the holes on the flange to have neutral rotation for all postoperative measurements. We looked at a femorotibial angle with a target of five degrees, a hip-knee-ankle axis with a target of zero degrees, and a mechanical axis so that your neutral line passes within one zone of the center of the tibia."

"The cost benefit analysis (CBA): We looked at all steps in the instrument processing; we timed every step, and we did a cost analysis of every step using our fixed hospital overhead. This is no doubt a simpler procedure. But four fewer instrument sets only translated into about $26 per case. The 12 minutes less in the OR did save about $300, but that's a total of only $326 when the guides themselves cost almost $1,000. MRIs…in this study the average dollars collected was about $1,200."

"One of the largest centers, the developer of this system in Columbus, Ohio, got their outliers down from 30% to about 15%. But does that make a difference? Does being within three degrees add any value? Mark Pagnano and his group demonstrated that if you're close to that there's no difference in survival among outliers."

"Is neutral access really the ideal target for all patients? Probably not. A Knee Society Award paper showed that a

third of men had constitutional varus; we've done a similar study using a new imaging technology, weight bearing 3D analysis on 200 normal knees. We showed that a third of patients are outside of this neutral mechanical axis. The real problem is that the joint line is oblique by about three degrees in a normal patient, so putting patients perpendicular to the joint line, to the mechanical axis, is changing their axis of rotation by up to eight degrees."

"When imaging allows us to truly determine a patient-specific alignment, then there is a better chance we'll be able to realize the benefits of this technology."

Dr. Pagnano: "I'd like to focus on patient-specific total knee replacement (TKR) and look in particular at CT-based solutions. As Robert alluded to, computer assisted surgery hasn't helped us in this area. Patient-specific instrumentation at least offers the opportunity to harness some of the gains of computer navigation, and take advantage of the advances in 3D reconstructive technology over the last decade."

"Perhaps we move the computer part out of the OR. By doing that we may be able to save OR time and resources, but also save some mental energy so that we can focus on the soft tissue balancing parts of knee replacement. There are patient-specific instrumentation choices from multiple vendors and multiple differences between these. They differ in the alignment goals, the imaging modality, whether you get a pin guide or an integrated cutting guide, and whether that guide is all plastic or includes a metal cutting slot. There are also differences in the degree of surgeon input into the preoperative planning process."

"CT-based data beats MRI data…it's quicker, less expensive, you get more data, and you get real time alignment information. You get more detail from a 3D model created from a CT; that's based on the physics…the image acquisition matrix for CT is twice that of an MRI."

"The surgeon involvement…I think the thought process here is 'Trust but Verify.' You want the opportunity to review, approve, change, or redesign at any stage, if necessary. I'd rather use a cutting guide than a pin guide because you get the best accuracy and efficiency. And an integrated metal slot makes sense; surgeons are used to cutting through metal, so we're going to get the most robust and accurate cuts. Blocks from any company give great contact against the bone, so why give that up and rely on two pins?"

"I think there is a role for these, and it's for two separate groups of surgeons. For the high volume joint subspecialist…and then at the other end of the spectrum, a lower volume surgeon in a lower volume hospital."

"The high volume surgeon can take that 11 minute gain in efficiency and turn that into an additional case in an operating day. That added volume is a key driver of lower cost for their institution. As for the lower volume surgeon, he may have a different OR team daily or a team that does general surgery, ENT, orthopedics. They use many vendors, so one day they're doing a DePuy knee, the next a Biomet, etc. These patients are exposed to longer operative times. In this circumstance you can save 35-50 minutes per case, based on our data."

"The cost depends on who you're talking to. As a surgeon I ask, 'Who am I responsible for?' First, to the patient, so if these guides are going to help me either save time or be a bit more accurate then it's useful. Second, my family…if I can get out of there a little quicker, that's good. And finally, the hospital and the insurer."

"The future for these instruments is going to come when we get size-specific, disposable instruments that simplify the setup and takedown; also, when the imaging technology is such that we get 3D models built from 2D plain radiographs."

Dr. Barrack: "CT and MRI are too expensive; CT has high radiation. To go forward we'll have to have lower radiation, lower cost imaging, and we'll have to prove that this has some clinical benefit. I think we can, but we got through this first generation while we really didn't have enough evidence. In the era of value-based purchasing and comparative effectiveness, we wouldn't meet those standards today."

Dr. Pagnano: "If you're in an integrated system, if the hospital is charging for the CT or the MRI they're potentially

making money. That offsets some of the cost of a subsequent instrument that you're buying."

Dr. Barrack: "We know that the technical component…it's a $1,200-$1,500 cost to somebody."

Moderator Maloney: "So Mark, let's say you and I are the payor and we're going to be doing a million total knees in the U.S. We're going to add $1,500 per case…adding $1.5 billion to knee replacement. How to justify that?"

Dr. Pagnano: "People stood up here at these podiums in the 1990s and discussed demand matching of implants to patients. That didn't go as far as we thought; we've had more and more expenditures. No question…if you take the whole system, this is adding cost. But when you say, 'For a surgeon is it adding cost, for an individual patient is it adding cost, for a health system, the answer is different depending on the point of view.'"

Moderator Maloney: "But it is adding cost."

Dr. Pagnano: "But for that surgeon who is doing 25 a year and saving about 39 minutes, that's a savings also."

Moderator Maloney: "To the surgeon personally."

Dr. Pagnano: "But it's his hospital system."

Moderator Maloney: "That's based on the fact that you're going to either be able to add another case—which most systems aren't able to do. Or you're going to fire somebody, and you don't usually have an opportunity to fire somebody because of cost savings in terms of time efficiency. Robert, what about meaningful clinical difference? In your group, it was a wash. Let's say you're getting two or three degrees more accurate—does that mean anything?"

Dr. Barrack: "No, I think the next big advance in knee surgery will be figuring out alignment. We have a huge range we're shooting for—three to eight degrees. You should be able to predict who should be at three and who should be at eight, and we have the imaging technology to be able to do that. Then we have to prove that those patients will do better."

Moderator Maloney: "Mark, we've all had a patient we've done bilateral knees on, started out with varus deformities, one we left in a little more varus than we'd like."

Dr. Pagnano: "We're still a fair distance away from being able to predict where someone should be. I think it's that the dynamic aspects of gait are what drives the ideal alignment. It's too simplistic to say that if you're born in varus you should stay in varus. That may be true if you're saying what's going to give you the lowest amount of pain postoperatively or maybe the easiest range of motion. But what we've always battled in knee replacement is saying, 'Well, that may be ideal for function, but does it have a penalty on durability?'"

Moderator Maloney: "Your data suggests that three degrees one way or the other, with newer materials, doesn't really…well we don't see bad poly wear anymore."

Dr. Pagnano: "It's one of those things where if you suddenly change the target for lots of patients then we must be aware…"

Moderator Maloney: "So what's a meaningful clinical difference? The target is neutral anatomical axis; where is it, plus or minus two, three?"

Dr. Pagnano: "The problem all along has been defining it…"
Moderator Maloney: "Short answer!"

Dr. Pagnano: "The bell shaped curve…"

Moderator Maloney: "Leo, come take him off the stage. You've got to shoot for something in the OR, what is it?"

Dr. Pagnano: "There's no question you should shoot for neutral mechanical axis."

Moderator Maloney: "You're measuring your X-rays postoperatively…what are you unhappy with?"

Dr. Pagnano: "I'm still aiming for zero, plus or minus three, but recognizing that if I hit four I can't show scientifically that that makes a clinical difference in survivorship."

Moderator Maloney: "Robert, what are you shooting for?"

Dr. Barrack: "We're all shooting for the same thing. The point is that we know that some patients belong at three degrees and some belong at eight degrees. And we're close to being able to predict that with these 3D weight bearing images."

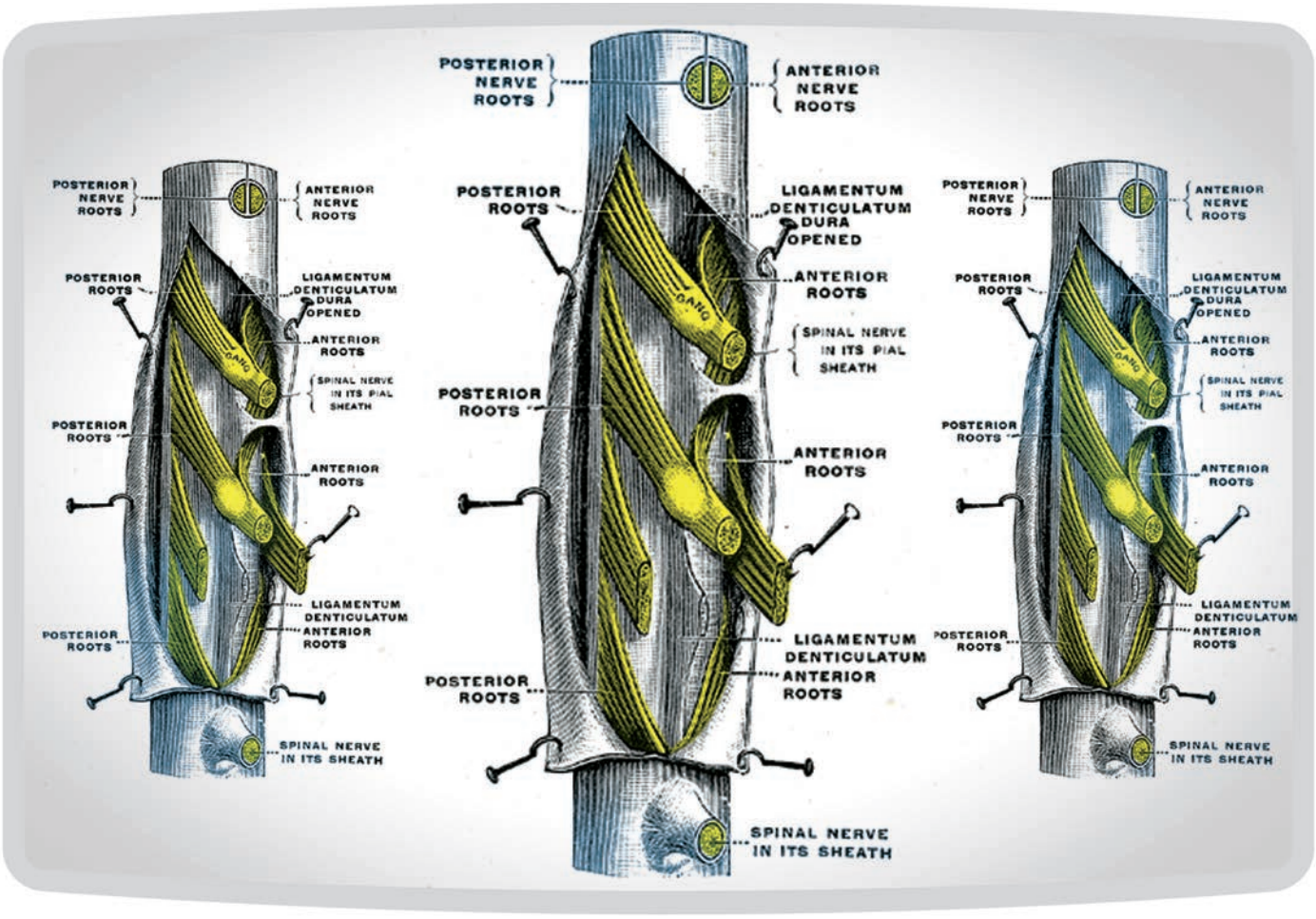
Moderator Maloney: "Robert said they're not ready for primetime. Are they?"

Dr. Pagnano: "In a select subgroup of surgeons."

Moderator Maloney: "Always hedging his bet! Thank you, guys." ♦

Please visit www.CCJR.com to register for the 2012 CCJR Winter Meeting, December 12 - 15 in Orlando, Florida.

"You may now view content from the CCJR Meetings on the CCJR Mobile™ App. Please scan the QR code to download the CCJR Mobile App to your Android or iOS mobile device, or visit www.ccjrmobile.com."



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70% Screw Misplacement, BS and Stalling From Insurers, and More

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

Screw Misplacement in 70% of Cases?!…NASS Going on the Offensive Re: Coverage…BS and Stalling From Insurers…Sumit Dewanjee, M.D. Honored With 4th Consecutive Patient's Choice Award…and more.

Screw Misplacement in 70% of Cases?! Researchers from New York have just presented their paper, "Burying One's Head in the Sand: Are We Underestimating the Significance of Pedicle Screw Misplacement?" Terry D. Amaral, M.D. is chief of pediatric orthopaedic surgery, at Montefiore Medical Center and assistant professor of surgery at Albert Einstein College of Medicine. He tells *OTW*, "We have 'come a long way, baby' as far as fixation, and there is now a push to do all of these surgeries as pedicle screw constructs. More and more we need to make sure that what we are doing is safe. The spinal cord is right next to where we are putting the screws in; we are also working near where the nerve roots exit…if you perforate that area the patient will experience weakness or even paralysis. Then in the front of the spine there are other things to be concerned about, like the aorta, the vena cava, the lungs, etc. Even world renowned surgeons are only attaining accuracy rates of 87-92%. If you have 100 patients and you've put screws in 12 vertebrae, that is 24 screws in each patient; so you're looking at 2,400 pedicles…but that is making all patients into one group. If you have 10% inaccuracy, then that means that 2 out of 20 screws could be misplaced. Amazingly, we found that as many as 70% of patients may have a screw mis-

placed. Thankfully, most screws are just misplaced by a millimeter or two out the front or are slightly off medially, so they are not doing real damage. However, 5-10% of those misplaced screws are cause for concern."

"To rectify this, we must have access to imaging devices during the procedure. We are beginning to look at intraoperative CT-scans and checking to see how accurate they are as compared to CT-scans done in a radiology suite. With intraoperative scans we can control how much radiation we are using; we are taking digital data and maximizing it with software. The software is able to interpret that digital information and give us better images. So the race is on to see which company can perfect the software. We've talked with Medtronic and they have significantly improved algorithms of translating that data so we can use a much lower dose of radiation. We are performing blinded, cadaveric studies, purposely misplacing the screws, and using an O-arm for imaging. Then we are putting the cadavers through a standard CT-scan and comparing the two. We also think that this software can be used for navigation where screw placement is done with the aid of a computer. In theory this might give us a military level accuracy. This is critical stuff…remember, if you're off by 'only' a few millimeters then you're in the aorta."

NASS Going on the Offensive Re: Coverage Chris Bono, M.D., chief of spine at Brigham and Women's Hospital, Treasurer of the North American Spine Society (NASS), and Deputy Editor of *The Spine Journal* will be presenting at the upcoming Spine Summit on August 10, 2012 in Burr Ridge, Illinois. He tells *OTW,* "We will be working on a major new effort, a coverage committee for NASS, so that we can proactively develop coverage policies and not always be *responding* to policies. We will compile a list of things we think are at risk of being cut by insurers in the future. For example, take bone graft substitutes…there have been so many brought to market without any clinical data. We will keep it generic so that it's not specific to any certain manufacturer. Then we will develop our own suggestions for moving forward. The challenges will be that for many procedures there is just not a lot of evidence and so we are having trouble building sound justification for their use. Policies are becoming so restricted that I recently had a patient with cervical myelopathy denied surgery. This is unheard of because this is a condition with no nonoperative treatment—it must be treated surgically. They are really playing games now."

Remarkable Gait Analysis Results at AOFAS Meeting David B. Thordarson, M.D. is professor of orthopaedic surgery at the University of Southern California and editor-in-chief of *Foot & Ankle International*. He found a lot to like at the recent American Orthopaedic Foot and Ankle Society meeting. Dr. Thordarson told *OTW*, "There were several standouts, including work by Tim Daniels, M.D. and the Canadian Orthopaedic Foot and Ankle Society comparing total ankle replacement to fusion. They found that when looking at gait analysis, those patients who had a replacement had a slightly better gait pattern at midterm—and they had excellent pain relief. Essentially, with a more normal gait there is less stress on the adjacent joints in the foot and that should mean less arthritis. But those replacements are going to wear out. When a hip or knee fails, it involves larger bones so you take the joint replacement out and put in a new one. In the ankle, however, if it fails there is bone loss around the prosthesis and there is often little to put a new prosthesis into. An ankle replacement should be performed at a higher threshold than knee or hip because the alternative is knee or hip fusion, both of which are horrible. The alternative to an ankle replacement is fusion…and you can still walk without a limp."

Francis Y. Lee, M.D.: Four Years of R01 Funding Columbia Orthopaedics has announced that Francis Y. Lee, M.D., Ph.D., vice chairman for research, associate professor of Orthopaedic Surgery with Tenure, chief of Musculoskeletal Oncology, director, Center for Orthopaedic Research, and Columbia University Senator has obtained his third National Institutes of Health Grant. The National Institute of Biomedical Imaging and Bioengineering has awarded a $1.44 million, four

year renewal of Dr. Lee's first R01 grant, "Mechanobiological Mechanism for Inflammatory Bone Loss." Dr. Lee completed three fellowships in Pediatric Orthopaedic Surgery, Musculoskeletal Oncology and Research. Additionally, he has been serving on NIH review panels and American Board of Orthopaedic Surgery committees.

BS and Stalling From Insurers A spine surgeon friend tells *OTW*, "Despite so much progress we are still being hammered by the insurance companies about different criteria for fusions. It's frustrating for surgeons because there is good data and there are surgeons doing bad things. We operate on a different standard than heart doctors, who in many cases only have to perform one surgery. Ideally, in orthopedics one surgery would be sufficient, but as we grow older things change. Insurers don't hold heart doctors to this standard of 'no repeat surgeries.' Insurance companies don't care; they say they didn't approve XYZ surgery because it didn't work. But patients only stay with an insurance company for an average of 18 months before they change carriers. So the insurers don't give a damn because some other carrier will be taking care of them. They tell patients, 'We will pay for anything reasonable.' They tell doctors to write up the situation; they are just stalling the patient. They say, 'There is not enough peer reviewed literature.' That is BS! Over 12 years Charité and other products have proven themselves…these are not experimental. The issue comes down to power and money. In approximately 2003 I spoke with a PR firm in Washington, D.C. and I asked, 'How much money is the insurance lobby spending?' Forty million dollars was the response. When I asked what doctors would need to spend to make a dent in their efforts, the PR people said, '$8 million.' Keep in mind that this was about ten years ago. Today we would probably need to spend $80 million to make a real difference."

Sumit Dewanjee, M.D. Wins Fourth Consecutive Patient's Choice Award Sumit Dewanjee, M.D., a Board Certified and Fellowship Trained Mesa orthopedic surgeon, has been honored with his fourth straight Patient's Choice Award. The award is based upon patient ratings, bedside manner, doctor expertise, and time spent with the patient. This honor is only conferred upon the top 5% of over 800,000 doctors across the U.S. Dr. Dewanjee is fellowship trained in sports medicine and maintains additional specialty interest in trauma. The fellowship entailed an extra year of training specifically in shoulder and knee sports surgery working with athletes on complicated cartilage, tendon, and ligament surgeries. This included cartilage transplant procedures, meniscal repairs, rotator cuff repairs, and fracture repair. He is an expert in arthroscopic surgery. ♦

company

AxiaLIF vs. ALIF: Retrospective Rtesults

How does TranS1 Inc.'s AxiaLIF (Axial Lumbar Interbody Fusion) pre-sacral interbody fusion procedure compare to ALIF (Anterior Lumbar Interbody Fusion) for effectiveness and safety?

According to the first head-to-head retrospective study, AxiaLIF demonstrated improved fusion rates over ALIF, but the difference in rates were not statistically significant.

TranS1 Inc. announced the results of the study on August 2.

Two independent spine surgeons evaluated 96 total patients, with 48 patients in each arm, at two year or greater follow up with thin slice CT scans.

Adverse Event Comparison

The combined review of both surgeons demonstrated the results. Strict radiographic criteria were employed to determine bridging bone between the vertebral bodies. Perhaps most interestingly given concerns over the AxiaLIF approach, the AxiaLIF cohort experienced no serious adverse events, compared with the ALIF cohort, which reported two serious adverse events. Ten sites contributed patients to this study.

Ken Reali, president and CEO of TranS1, stated, "This study represents an important contribution to the growing base of clinical research on pre-sacral interbody fusion. TranS1 is committed to clinical studies demonstrating the safety, efficacy and cost effectiveness of AxiaLIF."

The study represented the use of AxiaLIF 1L (L5-S1) with pedicular fixation versus ALIF (L5-S1) with pedicular fixation. Follow-up time points ranged from a minimum of two years to a maximum of six years for the AxiaLIF group and two years to nine-year follow-up for the ALIF group.

In an AxiaLIF approach, the surgeon accesses the patient's lower back through an approximately one-inch incision next to the tailbone. The center of the degenerated disc is removed, and bone growth material is inserted in its place. This material helps bone growth over time in order to fuse the spine.

Spine Institute of San Diego

With the ALIF, a traditionally open procedure, the surgeon enters through the abdomen to access the lower portion of the spine.

The study will be submitted for publication by lead author Peter G. Whang, M.D., Associate Professor of Orthopaedics and Rehabilitation at Yale University, to a peer-reviewed spine journal. Preliminary data on a subset of patients was recently presented as a poster at the International Meeting of Spine Techniques (IMAST), which was held in Istanbul, Turkey on July 19-21.

—WE (August 8, 2012)

legal

Medicare Opens Fraud War Room

Medicare has a new high-tech fraud war room. The agency opened the $3.6 million command center in a commercial office park in Baltimore at the end of July.

There are a couple dozen computer workstations arrayed in concentric semicircles in front of a giant screen that can display data and photos, and also enable face-to-face communication with investigators around the country.

Some Republican lawmakers say a $77 million investment in a new computerized fraud detection system that went into operation last year is not working very well. According to an August 1, 2012 *Associate Press* story, Senators Orrin Hatch and Tom Coburn sent a letter to Health and Human Services Secretary Kathleen Sebelius questioning spending millions more on the command center until the bugs get worked out.

"The Center Will Pay for Itself"

But Medicare fraud czar Peter Budetti, M.D., CMS Deputy Administrator and Director of the Center for Program Integrity, told reporters during a tour that the command center could be a turning point. Responding to the criticism, Budetti said, "Our expectation is that this center will pay for itself many times over."

Medicare fraud is estimated to cost more than $60 billion annually, and for years the government has been losing a game of "pay and chase," trying to recoup losses after scam artists have already cashed in.

Medicare officials say the new antifraud computer system aims to adapt tools used by credit card companies to stop theft from Medicare and Medicaid. The AP story said the system was launched with great fanfare last summer. But by Christmas, it had stopped just one suspicious payment from going out, for $7,591. Administration officials say that shouldn't be the only yardstick, and the system has made other valuable contributions.

There are three groups of staffers working in the war room. One group is responsible for developing computer models to query billing data for suspicious patterns; another is in charge of investigating data generated by the computer models, looking for mistakes as well as real fraud; and the third handles coordination with law enforcement around the country. The staffers said they expect the coordination to cut the time it takes to investigate suspected fraud schemes from months to days and weeks.

New Predictive Analytics

Budetti wrote on the CMS blog that the new command center is bringing together Medicare and Medicaid officials, as well as law enforcement partners from the HHS Office of the Inspector General, the Federal Bureau of Investigation, and CMS' anti-fraud investigators. "The Command Center will gather experts from all different areas—clinicians, data analysts, fraud investigators, and policy experts—into the same room to build and improve our sophisticated new predictive analytics that spot fraud, and to then move quickly on a lead, once potential fraud is identified. The technology also allows us to connect with field offices to track down leads in real time."

"The result is that investigations that used to take days and weeks can now be done in a matter of hours. And this new technology can help detect and prevent potential problems and payments. That can mean millions of taxpayer dollars staying out of the hands of fraudsters."

—WE (August 10, 2012)

blog.cms.gov/CMS Command Center

FDA Ortho Panel to Consider Pedicle Screw Reclassification

The FDA's Orthopaedic and Rehabilitation Devices Panel is meeting on September 21, 2012 to discuss and make recommendations about classification of posterior cervical screws.

Posterior pedicle cervical screws are currently allowed on the market through the 510(k) clearance process.

Also included are pedicle and lateral mass screws. Cervical pedicle and lateral mass screws are components of rigid, posterior spinal screw and rod systems generally intended as an adjunct to fusion for the treatment of degenerative disc disease (as defined by neck pain confirmed by radiographic studies), trauma, deformity, failed previous fusion, tumor, infection, and inflammatory disorders in the cervical spine.

There are three FDA regulatory classifications of medical devices: Class I, Class II and Class III. The classifications are assigned by the risk the medical device presents to the patient and the level of regulatory control the FDA determines is needed to legally market the device. As the classification level increases, the risk to the patient and FDA regulatory control increase.

The North American Spine Society supports the reclassification petition submitted by the Orthopedic Surgical Manufacturers' Association (OSMA) on November 22, 2011 to classify pedicle and lateral mass screws for cervical spine use from unclassified status to Class II.

To read OSMA's reclassification petition, click here http://ryortho.com/Osma_Petition.pdf

Walter Eisner

The meeting will be held at the Hilton Washington DC North, Gaithersburg, Maryland.

The public is invited to present data, information, or views, orally or in writing. Written submissions may be made to the contact person listed below on or before September 14, 2012. Oral presentations from the public will be scheduled between approximately 12:15 p.m. and 1:15 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 6, 2012.

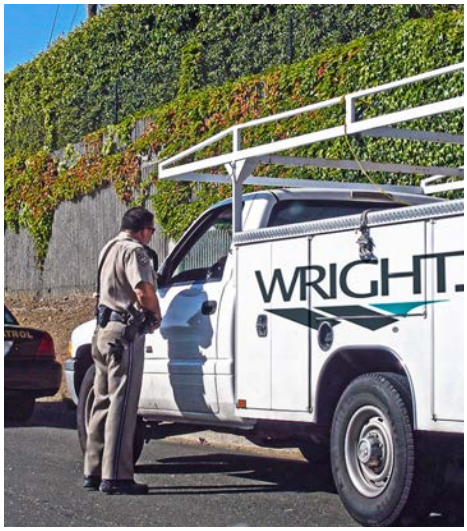
The contact person is: Sara J. Anderson, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg 66, rm. 1611, Silver Spring, Maryland 20993-0002. Her phone number is (301) 796-7047.

—WE (August 11, 2012)

New DOJ Inquiry for Wright Medical

What must Robert Palmisano, the almost new president and CEO of Wright Medical Group, Inc., be thinking?

Just as he's taken over the wheels of the Wrightmobile recovering from a serious speeding ticket (deferred prosecution agreement) that seems to be on its way to being put behind him, he's cruising down Beale Street and the sirens go off again.



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On August 3, 2012, the company disclosed in a 10-Q SEC (Securities and Exchange Commission) filing that it has received a subpoena from the U.S. Attorney's Office for the Western District of Tennessee requesting records and documentation relating to the company's Profemur series of hip replacement devices. The subpoena covers the period from January 1, 2000 to August 2, 2012. The company is in the process of collecting the responsive documents and responding to the subpoena.

No further details regarding the subpoena were disclosed.

BMO Capital Market analyst Joanne Wuensch pointed out that this was a request for information, not an allegation and does not impact the company's ability to manufacture and sell products.

Wuensch said hip sales were 33% of Wright's revenue in the six months ending June 30, 2012. Hip sales in the U.S. were only 10% of total revenue. The Profemur modular hip systems generate the majority of segment sales. Wright's overall revenues and the U.S. business have been declining at double-digit rates as the company rebuilds its recon business in the wake of new corporate compliance requirements.

In the August 3 SEC disclosure, the company also said Stryker Corporation's recall of that company's Rejuvenate Modular and ABG II modular hip stems could negatively impact sales of the Profemur system.

"Although Stryker's recalled modular hip stems differ in design and material from our Profemur modular neck hip stems, there is a risk that Stryker's recall and the resultant publicity could negatively impact sales of modular neck systems of other manufacturers, including our Profemur system, even if the issues cited by Stryker are unique to Stryker products," said the company disclosure.

One can only speculate about the nature of the U.S. Attorney's inquiry. Given that the company is under a deferred prosecution agreement related to relationships with surgeon customers, the inquiry seems likely to be about other matters.

—WE (August 7, 2012)

Zimmer Kills Genzyme's Synvisc Patent

Warsaw-based Zimmer Holdings, Inc. and Boston-based Genzyme Corp. have been in a Boston federal court for the last year fighting over the patent for hyaluronic acid injection treatments for arthritic knees.

On August 3, 2012, a jury ruled in Zimmer's favor.

Dueling FDA Approvals

Genzyme's Synvisc was approved by the FDA in August 1997 and Synvisc-One was approved in February 2009. Zimmer's Gel-One, manufactured by Tokyo-based Seikagaku was approved by the FDA in March 2011. Both products, according to the FDA, are hyaluronate hydrogels produced from chicken combs, in a phosphate-buffered saline solution.

Gel-One is designed as a single injection treatment to reduce pain associated with osteoarthritis of the knee for up to 13 weeks. Synvisc-One is designed as a single intra-articular injection option to reduce pain associated with osteoarthritis of the knee for up to 26 weeks.

Until Gel-One, Genzyme's Synvisc-One was the only single-injection treatment approved by the FDA.

Within a month of Zimmer's March 2011 FDA approval, Genzyme filed a patent infringement suit against Zimmer in Boston. On December 30, 2011, U.S. District Judge Douglas Woodlock issued an order to prevent Zimmer from selling its product at a price less than $547.60 or giving out free samples and undercutting the price of Synvisc-One.

Zimmer Victory

The jury trial ended in a victory for Zimmer as the jury found that Zimmer's Gel-One does not infringe Genzyme's U.S. patent number 7,931,030: "Regiments for Intra-Articular Viscosupplementation" by Francois Bailleul and assigned to Genzyme, Inc. The patent was filed in December 2005 and was granted in April 2011

It gets worse for Genzyme. The jury also ruled that the patent is invalid because it covered obvious variations of earlier work. After the jury verdict, the judge vacated his December order.

Sales of Synvisc and Synvisc-One have been good for Genzyme's parent, Paris-based Sanofi. According to a Bloomberg report, the product had sales of $228 million the first half of the year, up 8.9% over the year-earlier period.

—WE (August 11, 2012)

Synvisc-One/Gel-One

biologics

PRP Treatment for Cartilage Tears

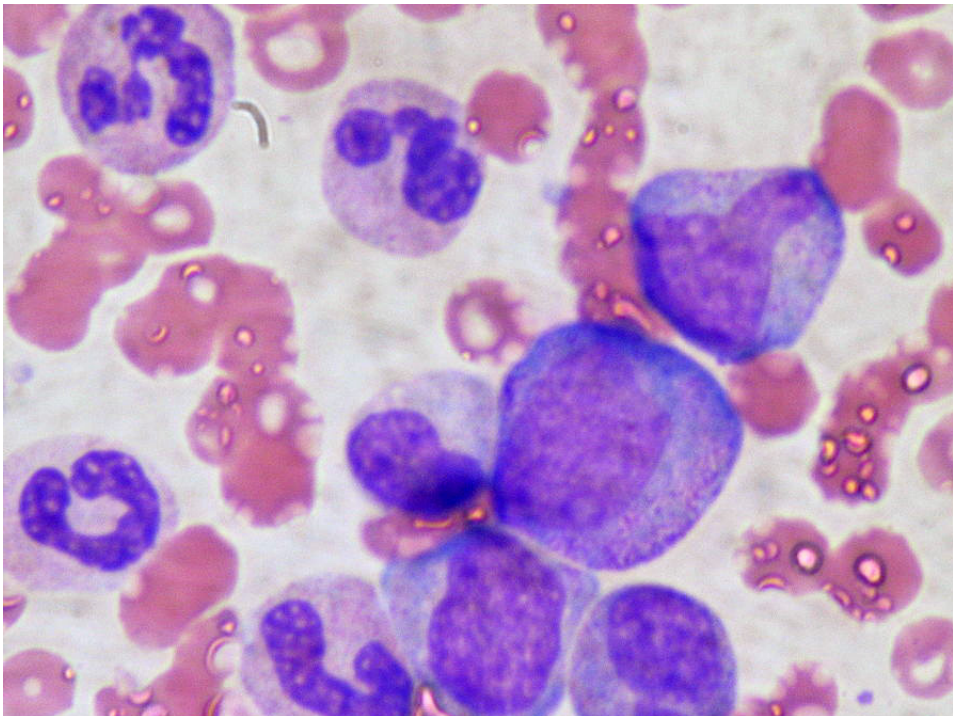
Additional therapeutic uses for platelet rich plasma (PRP) have come from research conducted in Bologna, Italy. PRP can be a safe and effective treatment for cartilage tears in athletes according to a study led by Elizaveta Kon, M.D. director of the Nano-Biotechnology Laboratory at the Rizzoli Orthopaedic Institute, Bologna.

"Using PRP therapy to repair cartilage is still relatively experimental, but studies like this show it's not only safe but also offers a significant improvement in function and quality of life for patients," said Kon in the July 14 news release. "None of the patients treated experienced complications like infection, deep vein thrombosis or fever," she said.

For the study, researchers treated 180 patients for chronic pain or swelling of the knee with either PRP therapy or viscosupplementation, which is a more common hyaluronic acid-based treatment for cartilage damage. A total of 109 patients, who had an average age of 56, stayed with the study for a final evaluation. Both treatment groups demonstrated significant improvement based on higher post-treatment IKDC scores, which measure pain and basic function in follow-up interviews.

"As athletic participation has grown," Kon noted, "new problems like cartilage lesions or tears continue to emerge. Finding the right approach to treatment is difficult, but PRP has emerged as a viable option according to our research." Kon added that long-term follow-ups for PRP treatments are needed to further evaluate the overall effectiveness of the therapy for future patients.

—BY (August 9, 2012)



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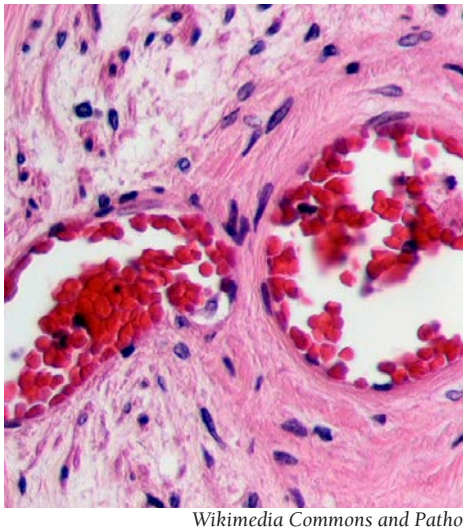
Stem Cells Treat Critical Limb Ischemia

Medistem, Inc., of San Diego, California, and the Chinese Conglomerate Shanghai Jia Fu Medical Apparatus, Inc. have successfully used Medistem's universal donor stem cell product in two patients with critical limb ischemia. The stem cell product, called Medistem's Endometrial Regenerative Cell (ERC), is derived from the endometrium—the lining of the uterus. The two patients who were treated, reportedly without any adverse effects, are part of a 15 patient study.



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Thomas Ichim, CEO of Medistem, explained in the July 13 news release, "The ERC is unique amongst clinical grade stem cells in that the cell is derived from the endometrium. Every month new blood vessels are formed in the endometrium which subsequently are sloughed off during menstruation. We believe the ERC plays a critical role in forming new blood vessels. Since the biological role of the ERC is to produce new blood vessels, it is our desire to use these cells to produce new blood vessels in the legs of patients with critical limb ischemia."

Critical limb ischemia is an advanced form of peripheral artery disease that causes approximately 150-200,000 amputations per year in the USA, according to Dr. Michael Murphy of Indiana University, who is the principle investigator for Medistem's FDA cleared clinical study on critical limb ischemia.

"Due to the high incidence of diabetes in the Chinese population, critical limb ischemia is a significant cause of suffering in our country," said Wei Zhang, CEO of Shanghai Jia Fu Medical Apparatus Inc. "We are optimistic that the lessons we have learned from successfully commercializing DC-CIK can be applied to the first universal donor stem cell that is extracted from the endometrium." Medistem and Shanghai Jia Fu intend to develop the ERC product in China through a series of clinical trials with the goal of eventually obtaining marketing approval.

—BY (August 8, 2012)

large joints

MIS Value in THR, TKR Questioned

Do the advantages of minimally invasive total hip replacement (THR) or total knee replacement (TKR) surgeries outweigh the higher complication rates reported? That is the question that investigators asked in a study designed to determine whether minimally invasive surgery (MIS) enhances recovery after total hip or knee replacement. John M. Lloyd, FRCS, of Bournemouth, United Kingdom, presented the study findings at the 13th EFORT Congress in May 2012, in Berlin, Germany.

The investigators defined MIS surgery as incisions less than 10 cm in the hip and less than 14 cm in the knee. They then searched the literature using MEDLINE and PubMed databases, including case series, randomized controlled trials and systematic reviews, to determine the outcomes when MIS was used in THR or TKR.

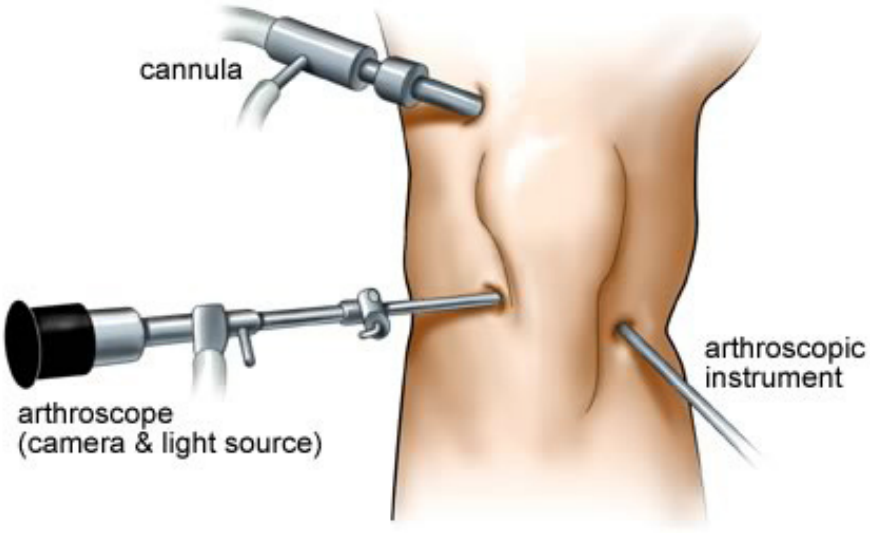
They found that improvement in recovery with MIS for THR and TKR was multi-factorial and, when combined with improved anesthetic and rapid rehabilitation pathways, the procedures result in enhanced recovery, Lloyd said. However, he noted that only a small amount of data indicated that MIS alone made a significant difference.

"If we look at length of stay, there were very few randomized controlled trials investigating this but it was very clear from the evidence available that there are benefits for unicompartmental knee replacement (UKR)," Lloyd said in the July 12 news release. "However, if we hone down to total knee replacement, there does not appear to be any clear advantage."

The study found that complication rates of MIS associated with low- to medium-volume surgeons were unacceptably high when compared to more traditional approaches. "Purely in isolation, [MIS] does not appear to reduce the length of hospital stay," Lloyd said. "And there do appear to be higher complication rates. I think only time will tell whether these small benefits are at the expense of long-term implant survival."

"[MIS] offers marginal benefits in total hip and knee replacement recovery. For the average user, I think any benefit would clearly be overshadowed by an unacceptably high complication rate," he said. "We therefore conclude, with the exception of [UKR], it [MIS] should not be part of a fast track hip and knee pathway."

—BY (August 9, 2012)



Courtesy of tour2india4health

Hernias Connected To Hip Disorder

Could there be a connection between a common type of athletic hip disorder and the risk of a sports hernia? According researchers in the orthopedics department at the University of Virginia, the answer is "yes."

Sports hernias, a tear of the oblique abdominal muscles, are a common cause of groin pain in athletes but little has been known about why they occur. The Virginia study suggests that a condition called femoral acetabular impingement (FAI)—essentially friction between the hip ball and socket—may be a contributing factor.

Researchers reviewed the records of 43 patients who underwent surgery to repair sports hernias between 1999 and 2011. Of those patients, 37 (86%) showed evidence of some form of femoral acetabular impingement on MRI, CT scans or X-rays.

"Our study illustrated that those patients with FAI tend to have a change in hip biomechanics, which, in turn, leads to increased stress across the groin," study lead author Kostas Economopoulos, M.D. said in a July 13 news release. "With these stresses, a sports hernia is more likely to occur."

He added, "We hope our study encourages physicians who see sports hernia and chronic groin pain in athletes to further investigate the possibility of FAI, and, in turn, can recommend better treatment options for this puzzling condition." The study was presented at the annual meeting of the American Orthopaedic Society for Sports Medicine in Baltimore.

—BY (August 9, 2012)

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extremities

Obesity Ups Ankle Fracture Severity

Lose weight and save your ankles. According to Lynda Williams, writing July 13 in *News Medical*, obese patients experience more severe ankle fractures than do individuals with a healthy body mass index (BMI). Her report focused on study findings, published in the *Journal of Foot and Ankle Surgery,* which reported that patients with a BMI of 30 kg/m2 or above were almost twice as likely to have a Weber C fracture as they were to experience the less critical type A or B fractures.

Patients with Weber C fractures are routinely recommended for surgery and their fracture usually disrupts the tibiofibular syndesmosis, causing instability, explained Christy King of the Kaiser San Francisco Bay Area Foot and Ankle Residency Program. Patients who experience a Weber A fracture do not require

Wikimedia Commons and Bill Branson, National Cancer Institute

surgery unless there is a medial injury, and patients with type B fractures are operated on only if there are also complex bimalleolar, trimalleolar, or bimalleolar equivalent fractures.

In their study, the researchers reviewed radiographs from 280 patients, 180 of whom were female. The women had an average age of 52 years. Half (51.4%) the patients had a BMI of 30 kg/m2. Of these, 21% had Weber A fractures, 59% had B fractures, and 20% had C fractures. Obese patients accounted for 46% of Weber A, 50% of Weber B fractures, and 61% of Weber C fractures.

In multivariate analysis, the odds ratio for Weber C versus A and B fractures was 1.78 for obese patients. The likelihood of Weber C fractures was not influenced, however, by patients' osteoporosis, tobacco use, or bone mineral density. The researchers did note that overweight or obese patients generally experience a more complicated recovery than do those with a healthy weight. They believe that it is important that patients be aware of the potential risks of obesity, including the possibility of experiencing a more severe ankle fracture.

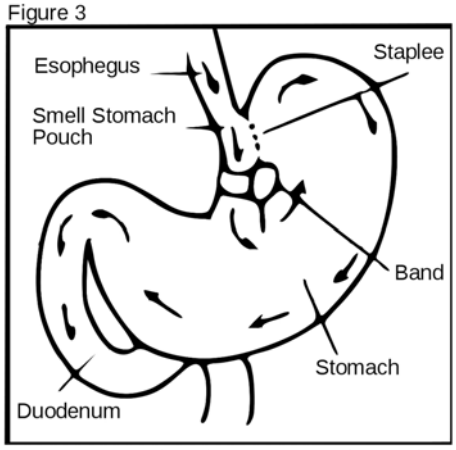
—BY (August 9, 2012)

trauma

Bariatric Patients: Elevated Fracture Risk?

A study just published in the *British Medical Journal* has found that obese patients who undergo bariatric surgery are not at an increased risk of broken bones in the first few years after the operation. However, the international research team did find a possibility of an increase in fracture risk after three to five years.

Figure 3



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Scientists from at the Medical Research Council Lifecourse Epidemiology Unit (MRC LEU) at the University of Southampton, along with colleagues at the University of Utrecht, Netherlands, and the Medicines and Healthcare products Regulatory Agency in London, compared the fracture rates of people who had had bariatric surgery between 1987 and 2010, with people who had not had the surgery but were matched by age, sex, body mass index, practice, and calendar year.

Studies have shown that weight loss can lead to a reduction of bone density and specifically studies have suggested that bone density is lost after bariatric surgery; however no previous work has been able to investigate whether such changes might result in an increased risk of fracture relative to a control population.

Results showed that compared to the control group, the overall risk of fracture was not significantly increased in bariatric surgery patients in the first

few years post-operation, but there was a slight trend towards an increased fracture risk after three to five years. The researchers also found a slight tendency for fracture risk to increase with greater post-operative decrease in body mass index.

Dr. Nicholas Harvey, Senior Lecturer at the MRC LEU at the University of Southampton commented in the August 6, 2012 news release, "Obesity is an increasing public health problem worldwide, which affects between 15 and 20 per cent of Europeans; it has been recognised that surgical treatment is the most effective route to weight loss for many with morbid obesity. Overall, for the first few post-operative years, these results are reassuring for patients undergoing bariatric surgery, but do not exclude a more protracted adverse influence on skeletal health."

—EH (August 7, 2012)

spine

Spinal Elements Launches Unique Titanium Coated PEEK Implant

Spinal Elements, Inc. is launching its Lucent Ti-Bond line of PEEK interbody implants that have been coated with a porous plasma-sprayed titanium coating. Company officials say that the titanium coating creates an ideal environment for bone healing during fusion.

Spinal Element's Ti-Bond coating consists of random, unconnected titanium pores that are biomechanically adhered to the superior and inferior surfaces of its PEEK-OPTIMAinterbody implants through a plasma vacuum spray process. This process results in an ideal bone-opposing surface while allowing for direct visualization of the fusion mass through the radiolucent PEEK material, according to company officials.

They note that plasma-sprayed titanium porous surface coatings have been used on orthopedic patients for over 30 years with positive long-term clinical outcomes. Officials believe that the Ti-Bond coating, with its strong bond, will create the ultimate union between PEEK and titanium.

Spinal surgeon Scott Kitchel, M.D., with the NeuroSpine Institute in Eugene, Oregon, said in the August 1 news release, "This is an exciting new technology for application in the spine. It's easy to envision this becoming the new standard for interbody fusion implants."

Jason Blain, president and co-founder of Spinal Elements, says that Spinal Elements is the first company to introduce this technology for posterior lumbar and transforaminal interbody fusion devices into the marketplace. He added, "With the launch of our new Ti-Bond product, the spinal device market is taking a great step forward. This launch is one of an extensive line-up of product introductions we will be executing over the next 12 months. The company will be introducing its first allograft product in October."

Spinal Elements, located in Carlsbad, California, was founded in 2003 by Todd Andres and Jason Blain. The original name of the firm was Quantum Orthopedics, Inc. In 2004, the company received its first product clearance for Lucent and Crystal and became one of the world's largest users of PEEK in medical applications. The company name changed to Spinal Elements, Inc. in 2006 to reflect its focus on spine. Later that year it commercialized the world's first polymer stand-alone cervical implant, Mosaic.

—BY (August 10, 2012)

Courtesy of Spinal Elements, Inc.

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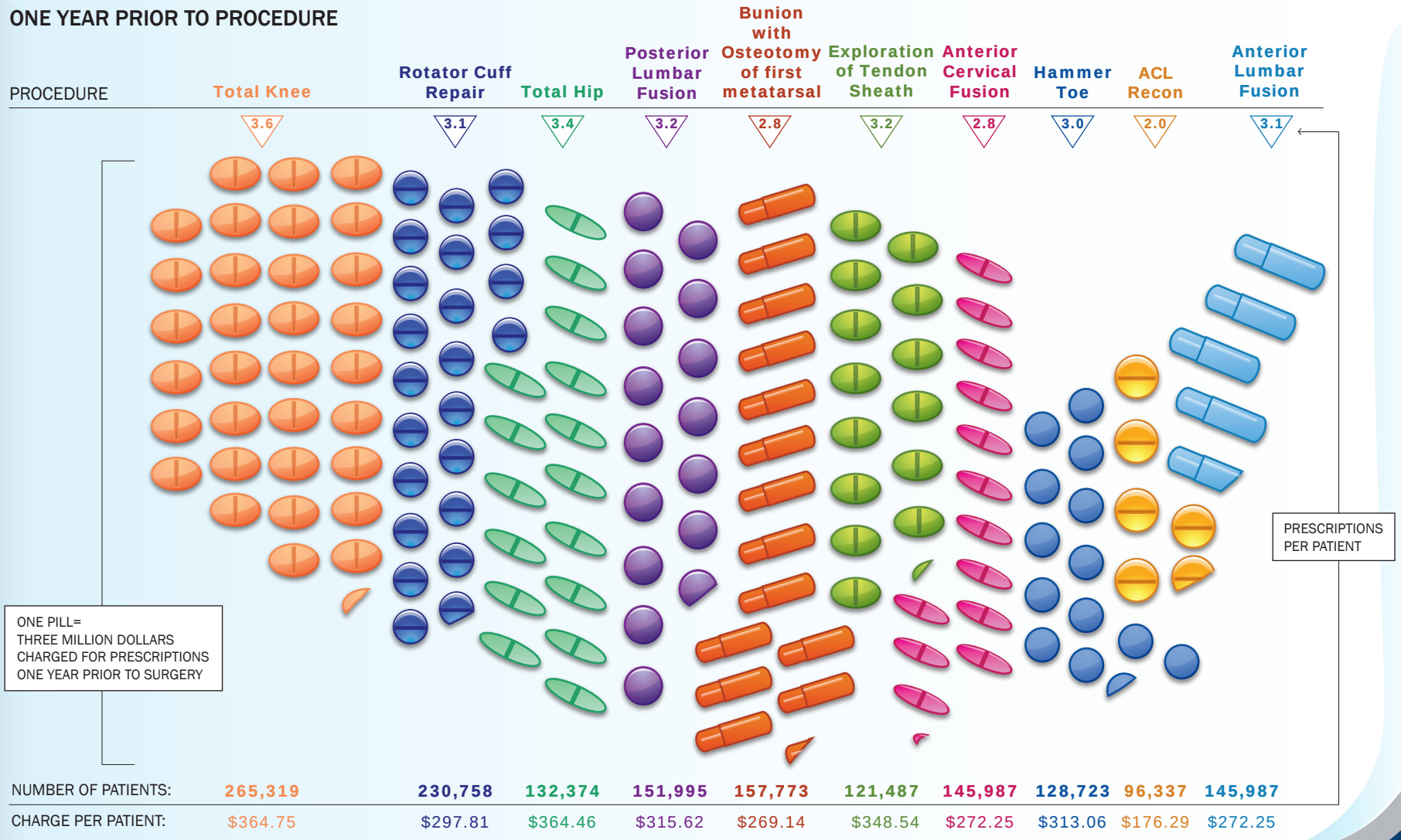

	Total Knee	Rotator Cuff Repair	Total Hip	Posterior Lumbar Fusion	Bunion with Osteotomy of first metatarsal	Exploration of Tendon Sheath	Anterior Cervical Fusion	Hammer Toe	ACL Recon	Anterior Lumbar Fusion
NUMBER OF PATIENTS:	265,319	230,758	132,374	151,995	157,773	121,487	145,987	128,723	96,337	145,987
CHARGE PER PATIENT:	$364.75	$297.81	$364.46	$315.62	$269.14	$348.54	$272.25	$313.06	$176.29	$272.25

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